INDIVIOR R&D DAY

New York City, USA - December 9th, 2016

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction

INDIVIOR
Focus on you.

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Statements about an investigational product in development are for discussion and planning purposes only.

INDIVIOR R&D DAY DECEMBER 9TH, 2016

OUTLINE OF THE DAY

Christian Heidbreder, Ph.D., Chief Scientific Officer

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INDIVIOR R&D DAY: AGENDA & OUTLINE

Time (EST)	Topic	Presenter
7:30 AM - 8:00 AM		Coffee – Get Together
8:00 AM - 9:00 AM	**Outline of the day** - Welcome & Agenda **R&D Strategic Drivers** - Architecture; People; Strategic Pipeline; Processes	**Christian Heidbreder**, *Chief Scientific Officer*
9:00 AM - 10:30 AM	**RBP-6000: Once Monthly Buprenorphine**	
	- Vision for RBP-6000: Part I	**Glenn Tyson**, *VP Global Therapy Areas*
	- Clinical Development	**Susan Learned**, *SVP Global Clinical Development*
	- RBP-6000 through the lens of a clinician	**Barbara Haight,** *Medicine Development Leader* & **Brent Boyett**, *Boyett Health Services, Hamilton, AL*
	- Vision for RBP-6000: Part II	**Glenn Tyson**, *VP Global Therapy Areas*
10:30 AM - 10:45 AM		Break
10:45 AM - 12:00 PM	**RBP-7000: Once Monthly Risperidone**	
	- Schizophrenia through the lens of a psychiatrist	**Anne Andorn**, *Head, Late Stage Clinical Development*
	- Clinical Development	**Susan Learned**, *SVP Global Clinical Development* & **Jay Graham**, *Medicine Development Leader*
	- Vision for RBP-7000	**Glenn Tyson**, *VP Global Therapy Areas*
12:00 PM - 12:20 PM	**Strengthening our global leadership in treatment of addiction**	**Shaun Thaxter**, *Chief Executive Officer*
12:20 PM - 1:00 PM		Q&A

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R&D STRATEGIC DRIVERS

Christian Heidbreder, Ph.D., Chief Scientific Officer

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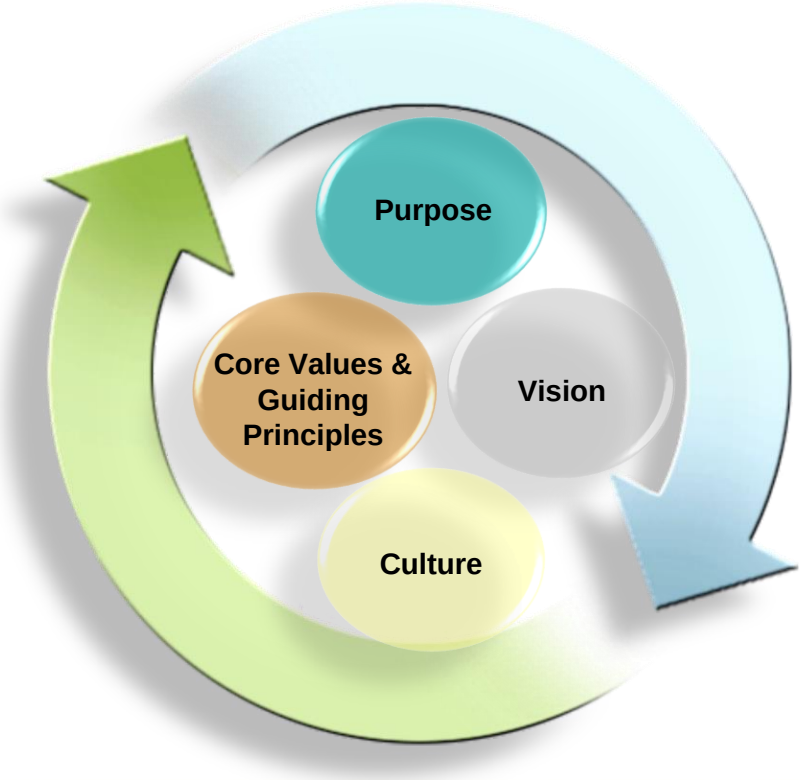
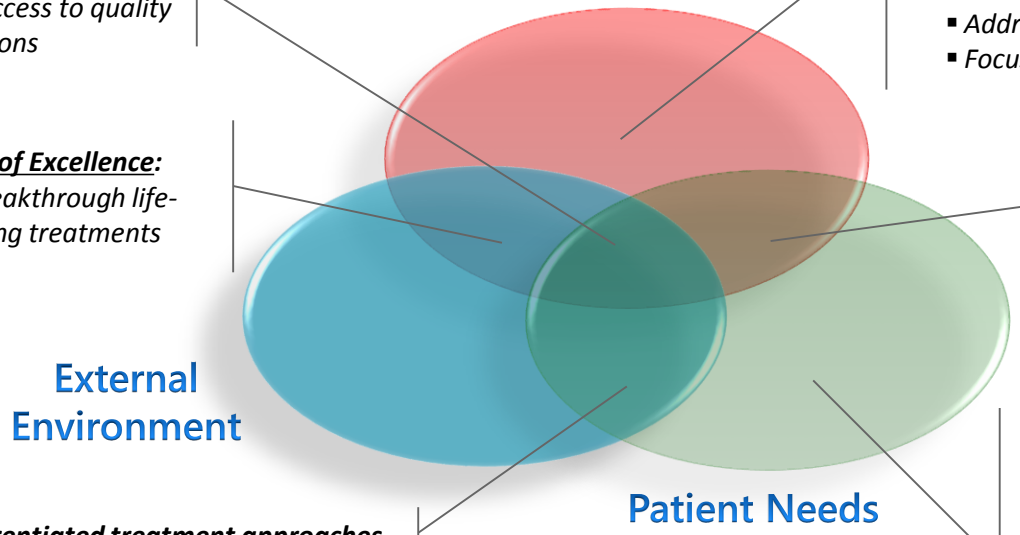
INDIVIOR CORE VALUES & GUIDING PRINCIPLES



- *Focus on patient needs to drive decisions*
- *Seek the wisdom of the team*
- *Believe that people's actions are well intended*
- *Care enough to coach*
- *See it, own it, make it happen*
- *Demonstrate honesty and integrity at all times*

A Vision to Enable Indivior's Future



Indivior's Current Position:
- *Expand access to treatment in opioid use disorder*
- *Open access to rescue medications*
- *Address unmet needs in alcohol use disorder*
- *Address unmet needs in stimulant use disorder*
- *Focus on psychiatric co-morbidities of addiction*

Leadership:
- *Set and lead access to quality treatment options*

R&D Center of Excellence:
- *Pioneer breakthrough life-transforming treatments*

Core values:
- *Unmatched patient focus*
- *Treatment leadership*
- *Increase patient access to care*
- *Seeking the wisdom of KOLs and patient advocacy groups*

Indivior's Future Position
- *Expand core capabilities into new geographies*
- *Expand access to treatment in alcohol use disorder and stimulant use disorder*
- *Address unmet needs in cannabis use disorder*
- *Focus on co-morbidities of addiction*
- *Explore new opportunities*

Create differentiated treatment approaches
- *Stream of sustained innovations*
- *Contribute to help shape public policies*

R&D Strategic Drivers 2016

R&D Strategic Drivers 2016: ARCHITECTURE

Building a new R&D Centre of Excellence in Hull, UK
Our Vision back in December 2015

Source: Boulting Environmental Services (BES), Manchester, UK

Delivering on Our Vision: December 2016

- New building (5,000m^2/54,000Ft^2) to be handed over to Indivior within Q2-2017.
- On track for completion by end of Q4-2017.

R&D Strategic Drivers 2016: PEOPLE

EXPERIENCED & TALENTED TEAM

Presenting today

Christian Heidbreder
Chief Scientific Officer

Susan Learned
SVP Clinical Development

Graham Cairns
Sr Director CMC

Eddie Li
SVP Regulatory Affairs

Ju Yang
VP R&D China

Dan Hutcheson
R&D Liaison Officer

Bill Dewey
Director R&D Training

Barbara Haight
Medicine Dvlpt Leader

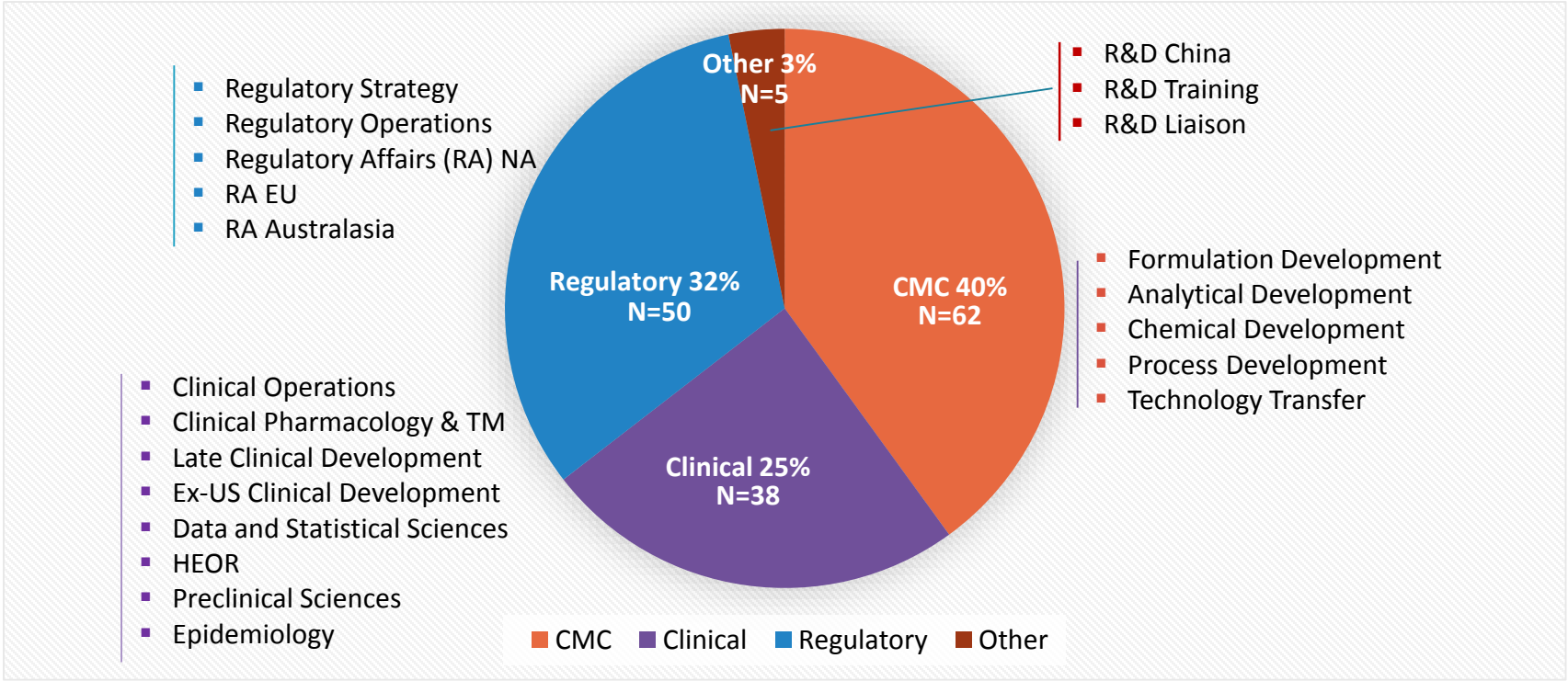
Anne Andorn
Head Late Stage Clin Dvlpt

Jay Graham
Medicine Dvlpt Leader

Vijay Nadipelli
Director HEOR

Glenn Tyson
VP Global Therapy Areas

CURRENT R&D ORGANIZATION (N=155 IN DECEMBER 2016)



R&D Strategic Drivers 2016: PORTFOLIO

Opioid Use Disorder

Product	Geography	Milestone
SUBOXONE® Tablet		**Additional Dosage Strengths 12mg/3 mg and 16 mg/4 mg:** sNDS submitted to Health Canada (HC) Dec 6th, 2016.
		**NDA preparation:** Plan to submit NDA to CFDA by end of Q4-2016
RBP-6000 in ATRIGEL®		▪ **Phase 3 efficacy and safety trial (RB-US-13-0001):** Positive top line results Aug 17th. ▪ **Phase 3 long-term safety trial (RB-US-13-0003):** Database lock achieved Oct 31st. ▪ **Extension study (INDV-6000-301):** First Patient dosed in Aug 2016. ▪ **REmission from Chronic Opioid Use: Studying EnVironmental and socioEconomic factors on Recovery (RECOVER®) study:** Logo USPTO-approved registered TM in Jul 2016; >400 subjects achieving baseline survey; Baseline interim analysis report in Q4-2016. ▪ **Regulatory:** Fast Track Designation May 23rd; REMS meeting Sep 28th; Pre-NDA meeting Dec 14th; NDA submission (*pending outcome of pre-NDA meeting*): Q2-2017.
		**Meeting with Regulatory Agencies Q4-2016:** TGA; HC; ANSM; MHRA; MPA; BfArM

NDS: New Drug Submission; NDA: New Drug Application; TGA: Therapeutic Goods Administration; HC: Health Canada; ANSM: Agence Nationale de Sécurité du Médicament et des Produits de Santé; MHRA: Medicines and Healthcare products Regulatory Agency; MPA: Medical Products Agency; BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte.

PSYCHIATRIC CO-MORBIDITIES

Product	Geography	Milestone
RBP-7000 in ATRIGEL®		▪ **Phase 3 efficacy and safety trial (RB-US-09-0010):** ✓ Positive top line results released May 5th, 2015. ▪ **Phase 3 long-term safety extension trial (RB-US-13-0005):** ✓ Database Lock achieved Oct 21st, 2016. ▪ **US Health Economics & Outcomes Research (HEOR) studies:** ✓ Analysis of HEOR endpoints in Phase III RB-US-09-0010 and RB-US-13-0005 with budget Impact Model & AMCP dossier. ▪ **Pre-NDA meeting held August 4th, 2016:** ✓ FDA agreement with proposed stability testing timelines & NDA submission strategy (Target: Q4-2017).

Alcohol Use Disorder

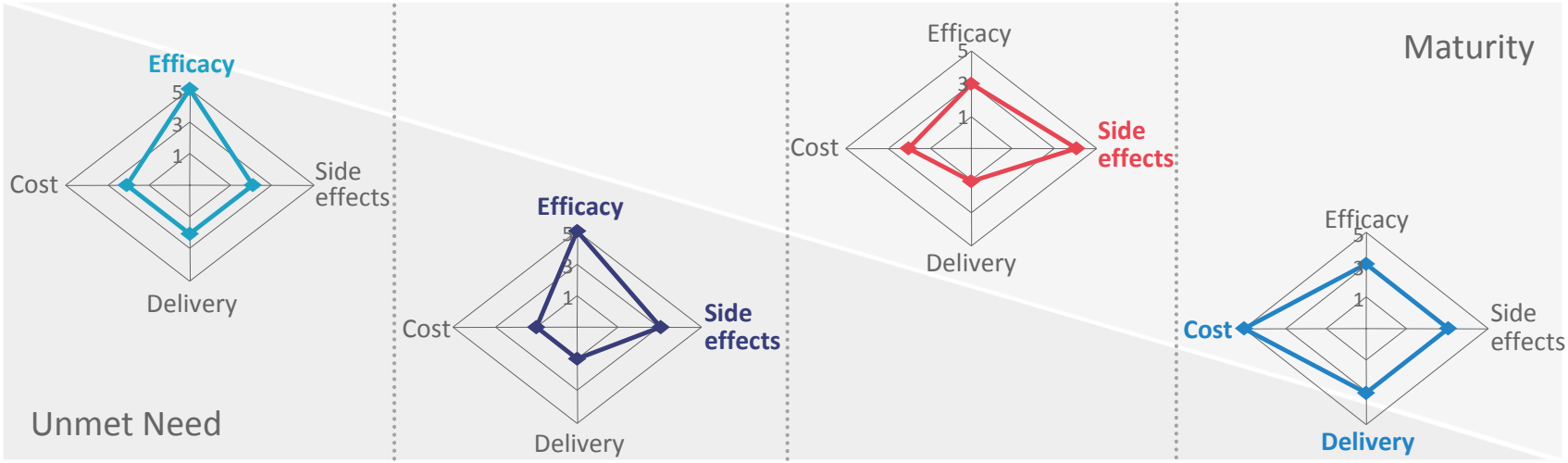
Product	Geography	Milestone
Arbaclofen Placarbil		▪ **RB-US-14-0001:** Final Clinical Study Report Jun 29th, 2016. ▪ Arbaclofen Placarbil appears to be safe & well tolerated up to a dose of 240mg in controlled abstinence setting. *However:* ▪ Significant inter-individual variability in pharmacokinetics profile as doses increased. ▪ *In vitro* and potential *in vivo* alcohol interactions require: — new formulation development. — additional clinical studies (regional absorption and alcohol interaction) to mediate safety risk prior to further outpatient studies in AUD patients.

Rescue Medications for Drug Overdose/Intoxication

Product	Geography	Milestone
Intranasal Naloxone for Opioid Overdose		▪ **Temporary Authorization for Use (ATU):** Approved by French ANSM on Nov 5th, 2015. ▪ ANSM approved **ATU launch** on Jul 26th, 2016 with NALSCUE® launch in France on Jul 27th, 2016. ▪ **MAA** submitted Nov 28th, 2016.
RBP-8000: Cocaine Esterase for Cocaine Intoxication		▪ **Breakthrough Therapy Designation:** Granted Oct 17th, 2014. ▪ **Second Type B meeting with the FDA:** Mar 16th, 2016. ▪ Per agreement with FDA, work has continued with the development of a lyophilized product and first test batch has been manufactured in October 2016.

ANSM: Agence Nationale de Sécurité du Médicament et des Produits de Santé; MAA: Marketing Authorisation Application

Early Stage Asset Development



Stimulant Use Disorder (SUD)

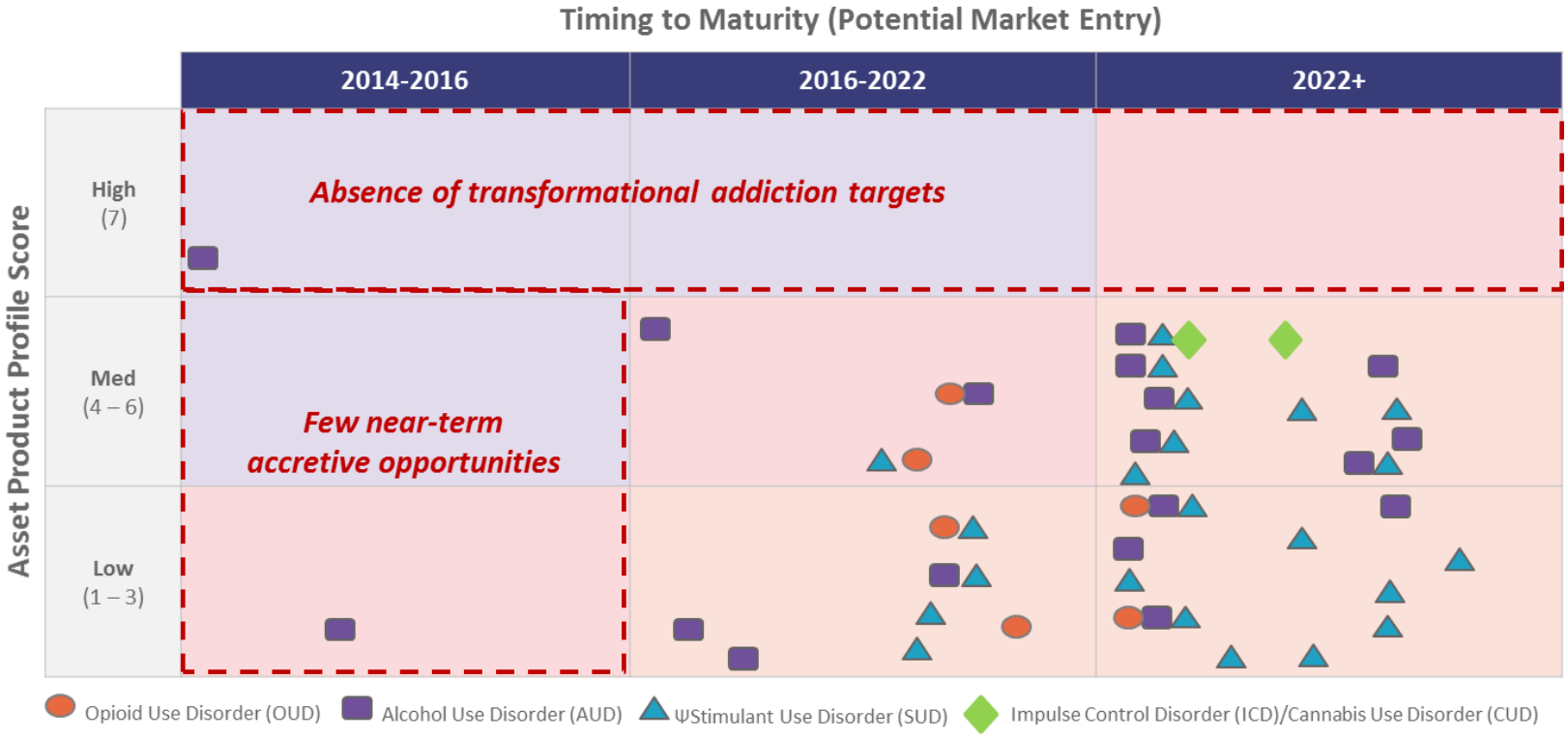
Impulse Control Disorder (ICD)

Cannabis Use Disorder (CUD)

Alcohol Use Disorder (AUD)

Opioid Use Disorder (OUD)

Early Stage Asset Development Opportunity Mapping



R&D Strategic Drivers 2016: PROCESSES

Effective Decision Making Processes

Science & Policy Committee

Composition: Subset of Board Members with scientific background & expertise

Responsibility: Reviews all scientific matters related to R&D and pipeline progress

R&D Leadership Committee

Composition: R&D Function Heads

Responsibility: Manages all matters related to pipeline progression and makes recommendations to Portfolio Review Committee

Portfolio Review Committee

Composition: Key stakeholders beyond R&D

Responsibility: Makes recommendations to the Executive Committee and Board on R&D strategy, priorities and all major pipeline-related decisions

INDIVIOR R&D DAY DECEMBER 9TH, 2016

RBP-6000: ONCE MONTHLY BUPRENORPHINE

Glenn Tyson, VP Global Therapy Areas, Indivior Inc.
Susan Learned, SVP Global Clinical Development, Indivior Inc.
Barbara Haight, Medicine Development Leader, Indivior Inc.
Brent Boyett, Boyett Health Services, Hamilton, AL.

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RBP-6000: Vision for the Treatment of Opioid Use Disorder

Glenn Tyson
Vice-President, Global Therapy Areas, Indivior Inc.

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>3 people in the US die of opioid overdose

every hour of every day[1]

Images like this one from the shocking Ohio overdose story in September are becoming all too common

[1]*Center for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, Mortality File. (2015). Number and Age-Adjusted Rates of Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 2000–2014. Data related to death from the year 2014.*
Picture source: http://globalnews.ca/news/2932561/shocking-photos-of-ohio-overdose-victims-problematic-say-addiction-experts/

THE DAILY RATE OF OVERDOSE DEATHS IN THE US IS THE EQUIVALENT OF AN 80-PASSENGER PLANE CRASHING EVERY DAY WITH NO SURVIVORS[1]

[1]*Center for Disease Control and Prevention, National Center for Health Statistics, National Vital Statistics System, Mortality File. (2015). Number and Age-Adjusted Rates of Drug-poisoning Deaths Involving Opioid Analgesics and Heroin: United States, 2000–2014.*
Picture source: http://www.civilaviation.eu/Embraer/EMB-170.htm

RBP-6000 GOALS

Improving treatment access

>2.5m

patients diagnosed with OUD in the US[1]

<50%

of diagnosed patients receive any BMAT[2]

Improving treatment retention

52%

of BMAT patients leave treatment within 2 months[2]

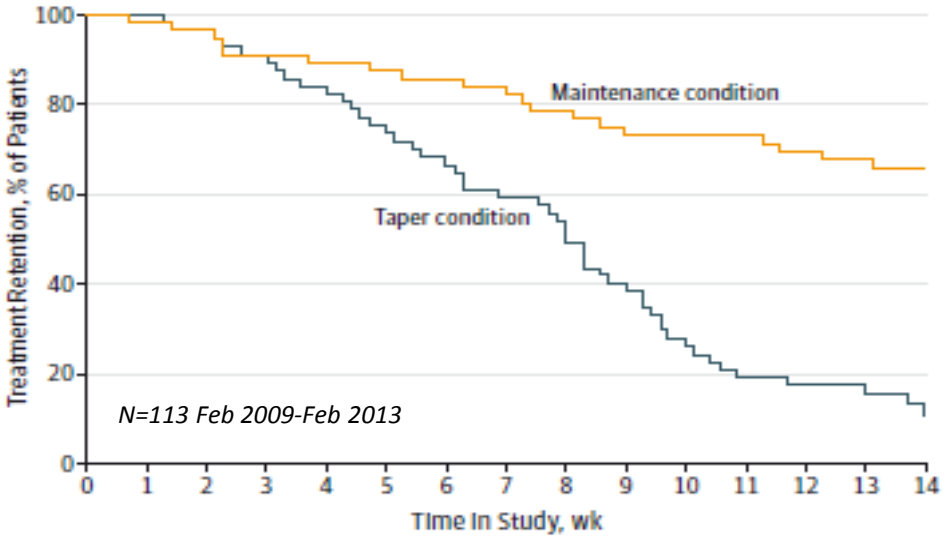
69%

of patients who leave treatment are asked to leave by their physician as assessed in quantitative market research[3]

[1]SAMHSA, Results from the 2014 National Survey on Drug Use and Health. Rockville, MD: Substance Abuse and Mental Health Services Administration,
[2]NSDUH survey 2014 and INDV analytics, [3]INDV quantitative market research, 2015, n=123
MAT: Medication-Assisted Treatment; BMAT: Buprenorphine Medication-Assisted Treatment

A Study Shows Long-term maintenance leads to greater treatment retention and better outcomes

Treatment Retention and Mean Buprenorphine Dosage for Patients With Prescription Opioid Dependence[1]



Study Design

- **Maintenance arm:** subjects were induced and stabilized at 16 mg, then maintained there for duration
- **Taper arm:** patients were inducted, stabilized at 16 mg for 4 weeks, then tapered by 2 mg decrease every 3 days for 3 weeks

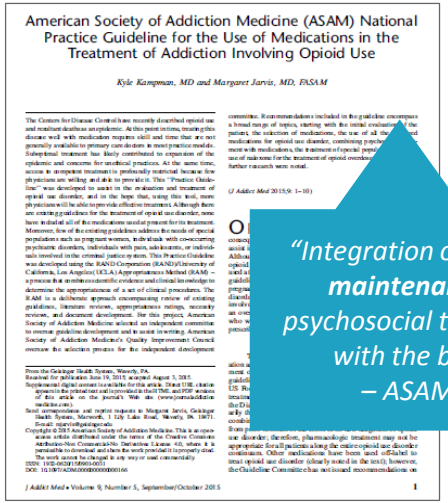
Results

- Buprenorphine short term treatment/taper resulted in poorer retention in treatment
- 28% of patients in the taper arm required re-initiation of buprenorphine therapy due to relapse after the taper

[1]*Fiellin DA, Schottenfeld RS, Cutter CJ, Moore BA, Barry DT, O'Connor PG. Primary care-based buprenorphine taper vs maintenance therapy for prescription opioid dependence: a randomized clinical trial. JAMA Intern Med. 2014 Dec;174(12):1947-54. DOI: http://dx.doi.org/10.1001/jamainternmed.2014.5302*

ASAM GUIDELINES OUTLINE OPTIMAL TREATMENT

Studies show long-term maintenance proven to lead to better outcomes



American Society of Addiction Medicine (ASAM) National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use

Kyle Kampman, MD and Margaret Jarvis, MD, FASAM

*"Integration of pharmacotherapy via **maintenance** treatments with psychosocial treatment…is associated with the best clinical results."*
– ASAM Guidelines 2015

Market research suggests only 43% of physicians treating OUD patients know and incorporate these guidelines[2]

American Society of Addiction Medicine (ASAM) and the World Health Organization (WHO), consider Medication-Assisted Treatment [MAT, maintenance] **an evidence-based best practice** for treating opioid use disorder (OUD).[1]

*"Although MAT [maintenance] has significant evidence to support it as an effective treatment, it remains **highly underutilized.**"*[3]

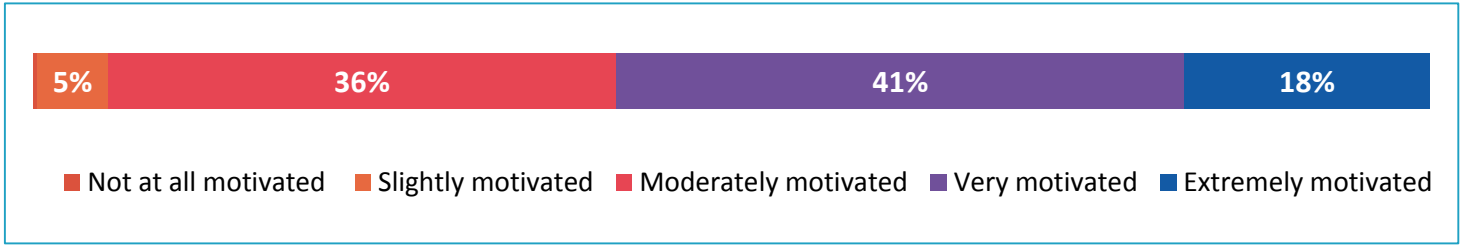
- Health and Human Services Secretary Sylvia M. Burwell

[1]*SAMHSA Advisory, Winter 2016 • Volume 15 • Issue 1 American Society of Addiction Medicine*
[2]*INDV quantitative market research, 2016, n=150*
[3]*DHHS, Opioid Abuse in the U.S. and HHS Actions to Address Opioid-Drug Related Overdoses and Deaths, March 26, 2015*

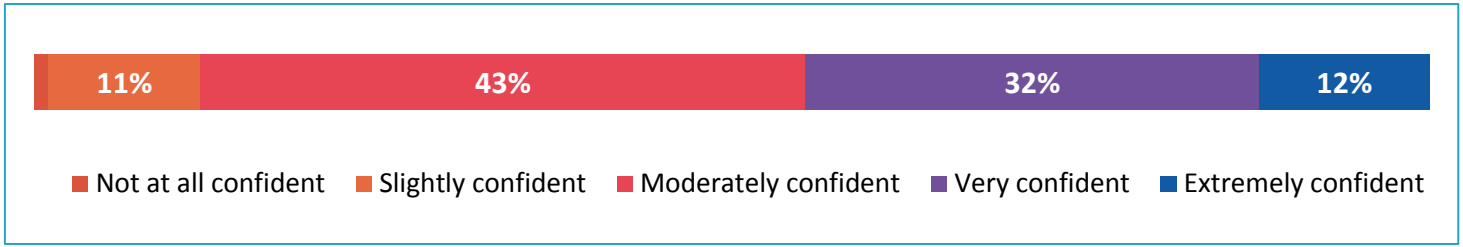
PHYSICIANS IN MARKET RESEARCH ARE MOTIVATED & CONFIDENT THEY CAN ACHIEVE SUCCESS

But a disconnect still exists between waivered physicians and patient perceptions of success[1]

PHYSICIAN MOTIVATION



PHYSICIAN CONFIDENCE



ONGOING USE OF ILLICIT OPIOIDS

- Only 1 in 8 (12%) physicians perceive that the patient described is still using illicit opioids
- But, nearly half (41%) of patients receiving BMAT claim to use illicit opioids

[1]*INDV quantitative market research, July 2016, n=376*
BMAT: Buprenorphine Medication-Assisted Treatment

On How to Address Current Unmet Medical Needs?

- Sustained plasma levels of buprenorphine that translate into high μ-opioid receptor occupancy to suppress withdrawal symptoms **and** block the subjective and objective effects of opioid agonists.
- Once-monthly buprenorphine delivery that is consistent across the **entire** 1-month period.
- Reduce risk of diversion and misuse.
- Enhance compliance/adherence to treatment.
- Monthly decisions (12/year) rather than daily decisions (365/year).

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RBP-6000: CLINICAL DEVELOPMENT

Susan Learned, M.D., Pharm.D., Ph.D.
Senior Vice-President, Global Clinical Development, Indivior Inc.

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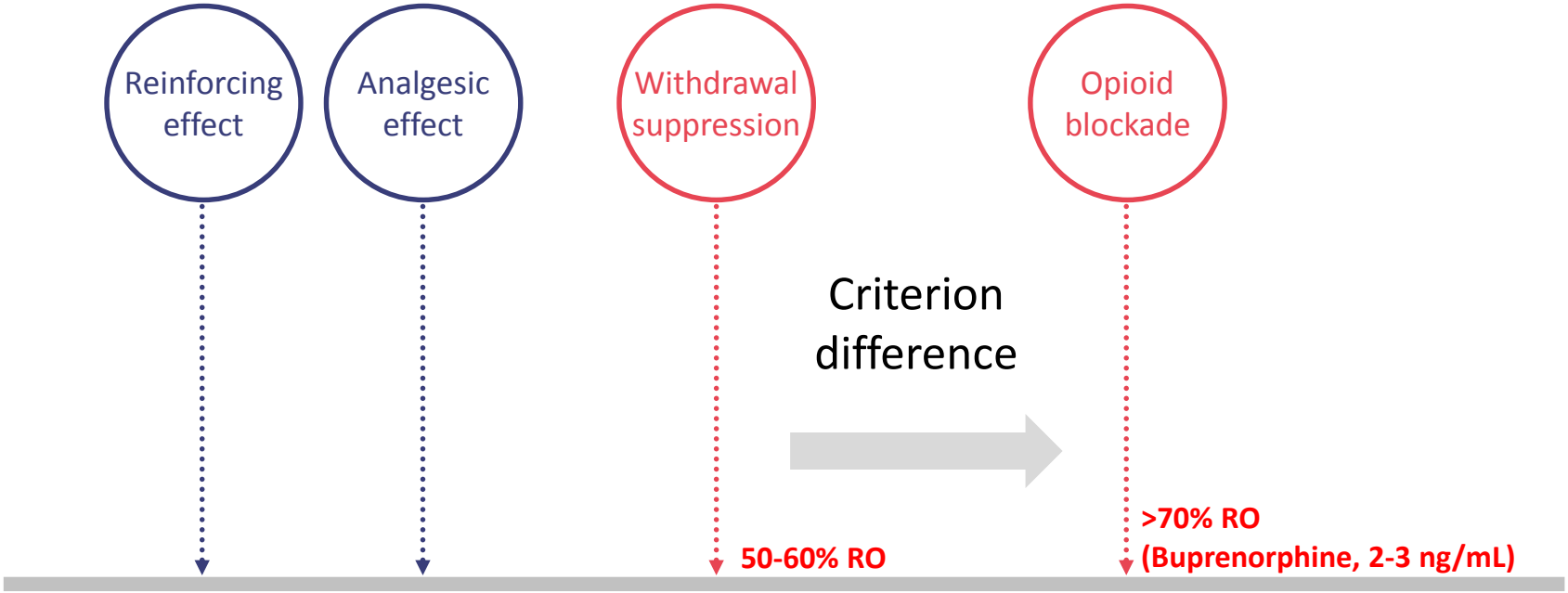
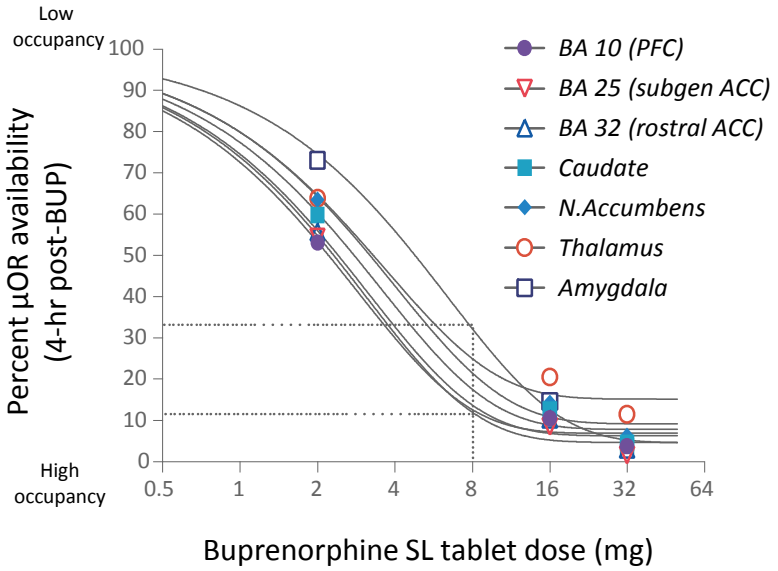
Theoretical ordering of μ-Opioid Receptor requirements
From withdrawal suppression to blockade of opioid subjective effects

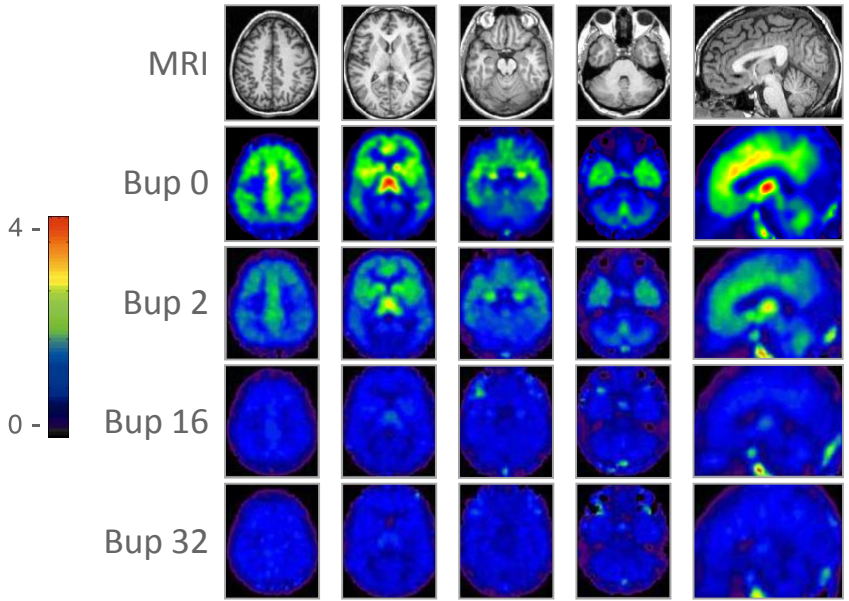


Greenwald MK, Comer SD, Fiellin DA (2014) Buprenorphine maintenance and mu-opioid receptor availability in the treatment of opioid use disorder: implications for clinical use and policy. Drug and Alcohol Dependence 144: 1-11. DOI: http://dx.doi.org/10.1016/j.drugalcdep.2014.07.035

Buprenorphine Dose-Effect on μ-Opioid Receptor Availability

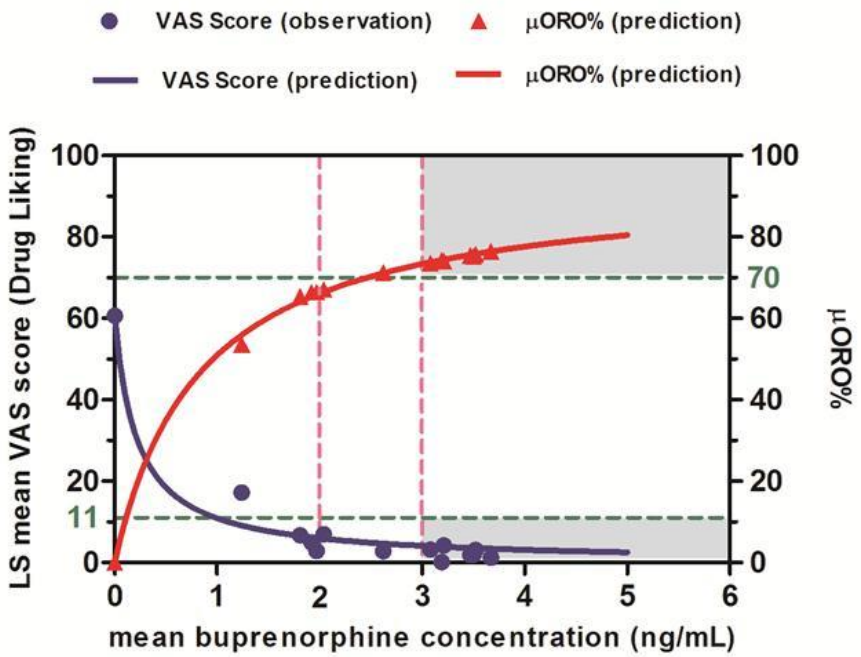


Greenwald MK, Comer SD, Fiellin DA (2014) Buprenorphine maintenance and mu-opioid receptor availability in the treatment of opioid use disorder: implications for clinical use and policy. Drug and Alcohol Dependence 144: 1-11. DOI: http://dx.doi.org/10.1016/j.drugalcdep.2014.07.035



Greenwald MK, Johanson CE, Moody DE, Woods JH, Kilbourn MR, Koeppe RA, Schuster CR, Zubieta JK (2003) Effects of Buprenorphine Maintenance Dose on Mu-Opioid Receptor Availability, Plasma Concentrations, and Antagonist Blockade in Heroin-Dependent Volunteers Neuropsychopharmacology 28: 2000-2009. DOI: http://dx.doi.org/10.1038/sj.npp.1300251

PK/PD/RO Relationship & Blockade of Opioid Subjective Effects with RBP-6000

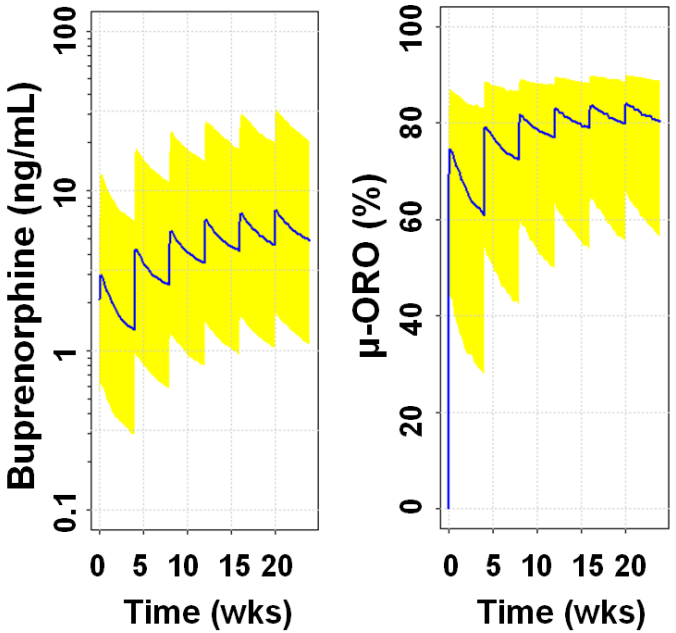


- An average buprenorphine plasma level of 2-3 ng/mL is expected to produce ~70% μ-opioid receptor occupancy
- The "opioid blockade" hypothesis was tested clinically
- The outcome of the "opioid blockade" study was used to support the design of the pivotal Phase 3 trial

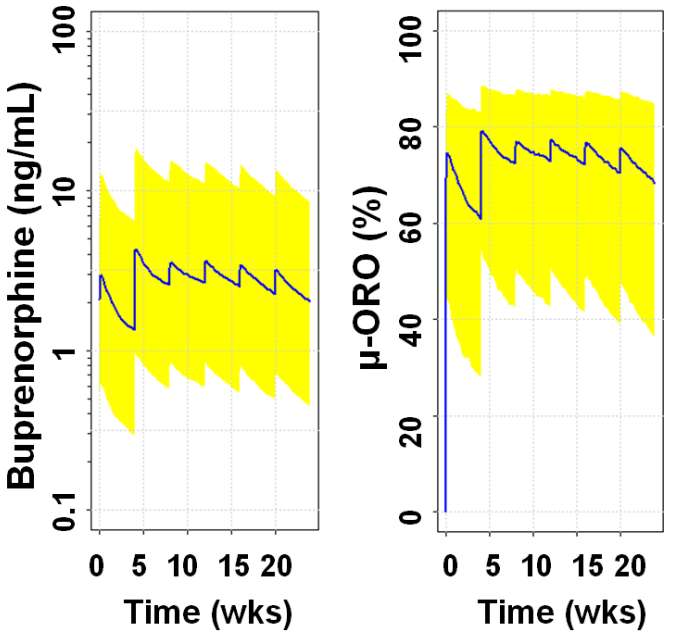
Source: Data on file and also data included in following: Nasser AF, Greenwald MK, Vince B, Fudala PJ, Twumasi-Ankrah P, Liu Y, Jones JP III, Heidbreder C (2016) J Clin Psychopharmacol, 36(1):18-26. http://dx.doi.org/10.1097/JCP.0000000000000434; Laffont CM, Gomeni R, Heidbreder C, Jones JP 3rd, Nasser AF (2016) J Clin Pharmacol, 56(7):806-815. http://dx.doi.org/10.1002/jcph.665

Modeled PK/PD/RO to define Phase 3 RBP-6000 Dosing Regimens

Dose regimen #1: 6 x 300 mg



Dose regimen #2: 2 x 300 mg + 4 x 100 mg



RBP-6000: Phase 3 study (RB-US-13-0001)
Comparative Inclusion/Exclusion Criteria

RBP-6000

Key Inclusion:

- Moderate-severe OUD
- Seeking treatment for OUD
- No MAT for OUD within 90 days

Key Exclusion:

- Other current diagnosis requiring opioids
- Other SUD (other than: mild cocaine or cannabis SUD if UDS negative at screening; mild alcohol UD, caffeine or nicotine UD)
- Recent history of suicidality
- Significant medical problems

CAM2038*

Key Inclusion:

- Moderate-severe OUD
- Seeking treatment for OUD
- No MAT for OUD within 60 days

Key Exclusion:

- Current diagnosis of pain requiring opioids
- Other Moderate-Severe SUD (other than opioids, caffeine or nicotine)
- Recent history of suicidality
- Significant medical problems

PROBUPHINE*

Key Inclusion:

- Clinically stable OUD: Treated with sublingual (SL) Buprenorphine X 6 months and abstinent on stable doses of SL Buprenorphine ≤ 8mg/day X 3 months

Key Exclusion:

- Current diagnosis of pain requiring opioids
- Other SUD (other than opioids or nicotine)
- Significant medical problems

OUD: Opioid Use Disorder; SUD: Substance Use Disorder; MAT: Medication-Assisted Treatment

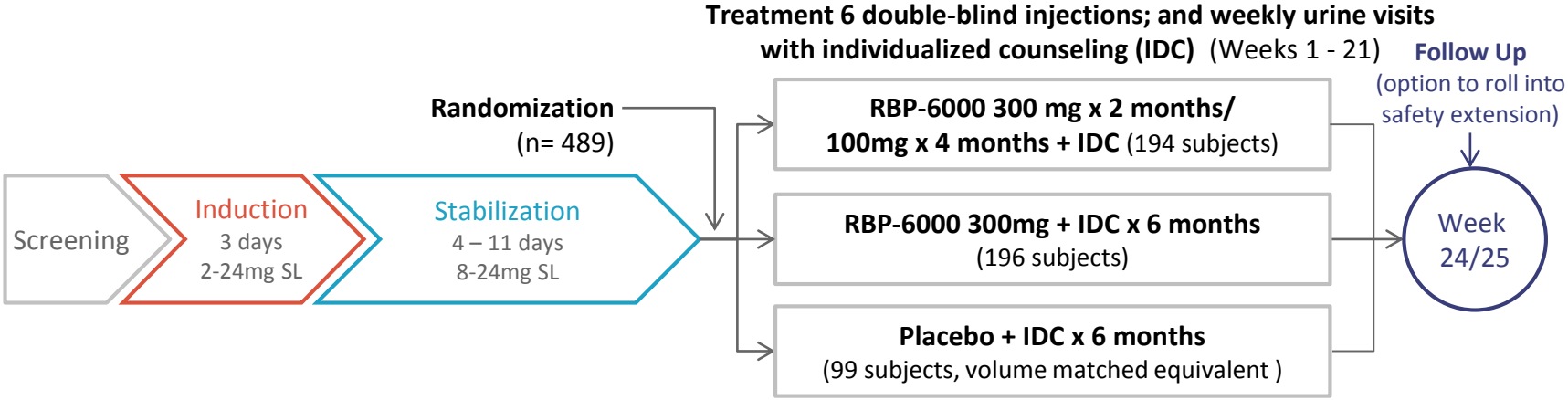
** Source: www.ClinicalTrials.gov*

RBP-6000: Comparative Primary & Secondary Endpoints[1]

	Key differentiators
Primary endpoints	Superiority to placebo is a higher efficacy bar for RBP-6000 trial
Definition of primary endpoint	RBP-6000 trials set higher bar for primary efficacy endpoints: 1) More rigid definitions of no illicit opioid use 2) RBP-6000 abstinence endpoint was regulatory authority agreed
Definition of Responder	▪ RBP-6000 higher order responder rate definition
FDA Definition of Responder	▪ The primary endpoint for RBP-6000 was the regulatory-agreed primary endpoint of the study, with dosing designed to achieve opioid blockade
Craving and withdrawal measures	▪ Clear measures for craving for treatment-duration ▪ Prescribed supplemental treatment not allowable
Prospective HEOR	HEOR endpoints embedded into pivotal Phase 3 trials and dedicated RECOVER® study

[1] *Based on Phase 3 trial RB-US-13-0001 vs. ClinicalTrials.gov information on CAM2038 and Probuphine*

RBP-6000: PHASE 3 STUDY (RB-US-13-0001) DESIGN



Randomized, double-blind, placebo-controlled study

Primary endpoint:
The CDF (Cumulative Distribution Function) of the percentage of urine samples negative for opioids combined with self-reports negative for illicit opioid use collected from Week 5 through Week 24.

Key Secondary Endpoint:
Treatment success, defined as any subject with ≥80% of urine samples negative for opioids combined with self-reports negative for illicit opioid use between Week 5-24.

RB-US-13-0001: Subject Demographics

	RBP-6000 300mg/100mg + IDC %	RBP-6000 300mg/300mg + IDC %	Placebo + IDC %
Mean Age (years)	40	39	39
Male	66	67	65
Race			
White	68	71	78
Black or African American	29	28	20
American Indian or Alaska Native	2	<1	1
Multiple	1	<1	1
Ethnicity			
Hispanic or Latino	6	9	10

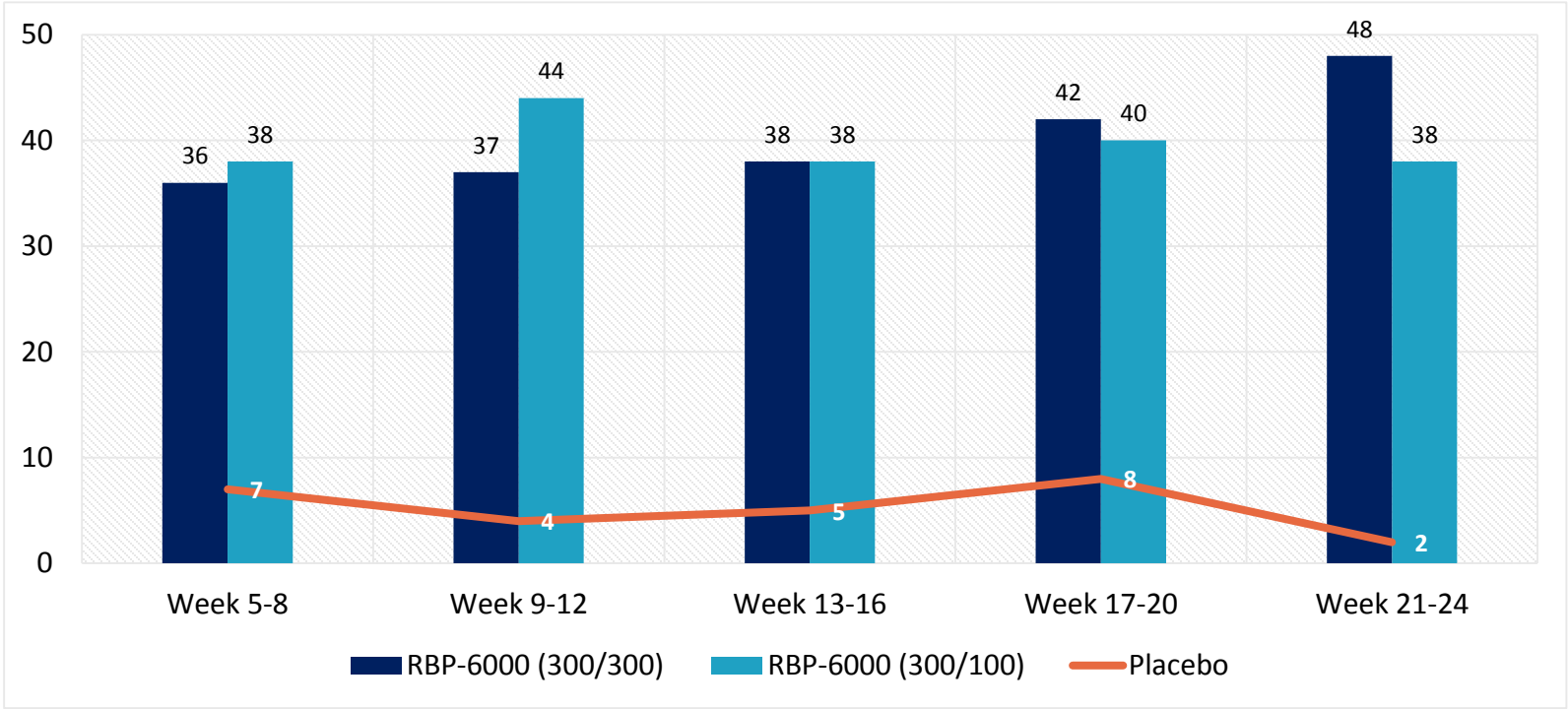
Topline results Phase 3 study (RB-US-13-0001); IDC: Individualized Counseling

RB-US-13-0001: Baseline Clinical Characteristics

	RBP-6000 300mg/100mg + IDC %	RBP-6000 300mg/300mg + IDC %	Placebo + IDC %
Substance Use At Screening			
Non-injectable opioid user	71	69	58
Injectable opioid user	43	41	51
Tobacco	92	92	93
Alcohol	78	79	81
Caffeine	92	92	95
Drug Use History			
Cannabinoids	55	47	53
Cocaine	47	40	42
Amph/Methamph	25	15	19
Psychiatric Disorders History			
Depression	14	11	13
Anxiety	9	10	10
Medical History			
Hepatitis C	16	12	10

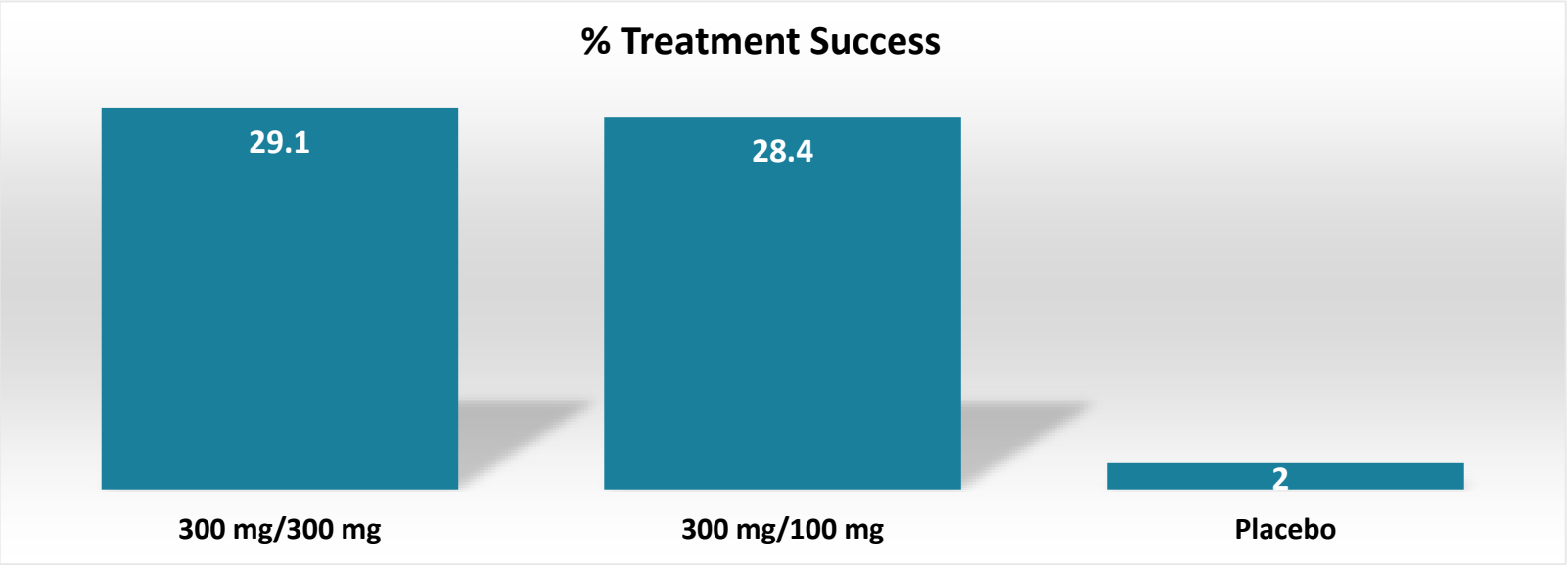
Topline results Phase 3 study (RB-US-13-0001); IDC: Individualized Counseling

RBP-6000 IN BOTH DOSING REGIMENS SIGNIFICANTLY SUPERIOR TO PLACEBO (*P<0.0001*) ON THE PRIMARY ENDPOINT (ABSTINENCE RATE WEEKS 5-24)



Topline results Phase 3 study (RB-US-13-0001)

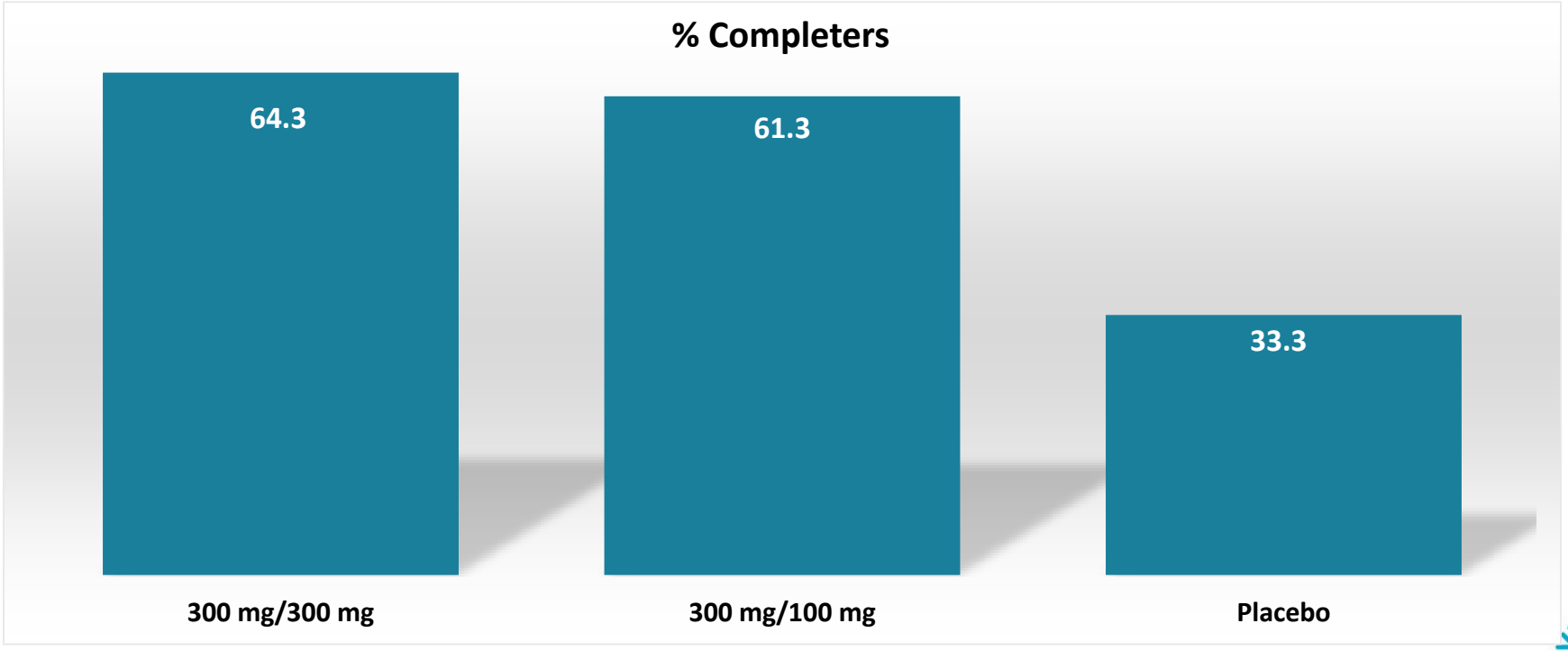
RBP-6000 IN BOTH DOSING REGIMENS STATISTICALLY SUPERIOR TO PLACEBO *(P<0.0001)* ON THE KEY SECONDARY ENDPOINT OF TREATMENT SUCCESS*



** Defined as ≥80% of urine samples negative for opioids combined with self-reports negative for illicit opioid use (Weeks 5-24)*

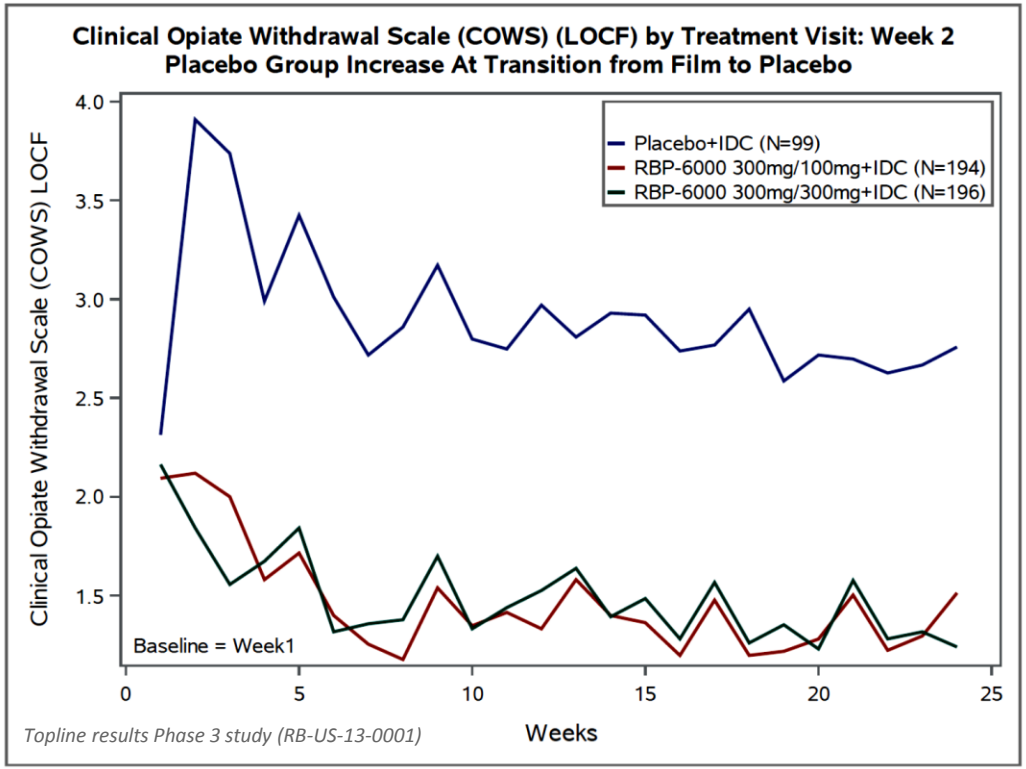
Topline results Phase 3 study (RB-US-13-0001)

Significantly more RBP-6000 Subjects in both groups completed the Study Compared with Placebo (*P<0.0001*)



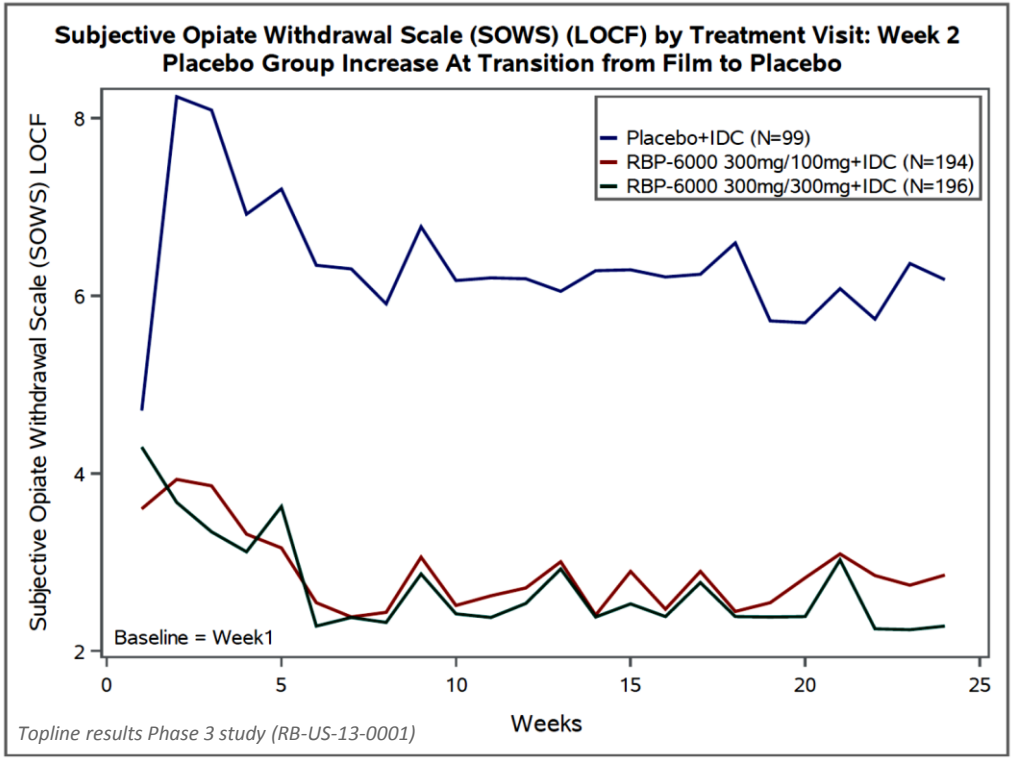
Topline results Phase 3 study (RB-US-13-0001)

Clinical Opiate Withdrawal Scale (COWS)



- RBP-6000 reduced withdrawal symptoms relative to baseline as measured by the investigator.
- Placebo group experienced an increase in withdrawal symptoms *vs.* baseline despite more than twice the rate of illicit opiate use in Placebo subjects as early as week 2.

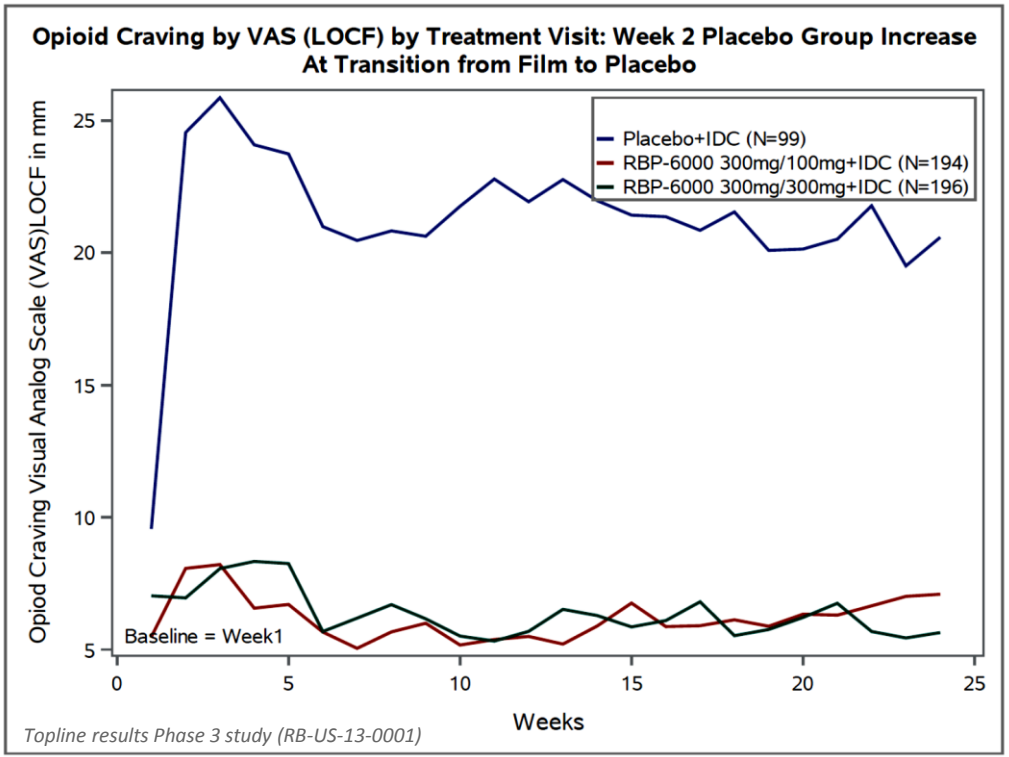
Subjective Opiate Withdrawal Scale (SOWS)



Topline results Phase 3 study (RB-US-13-0001)

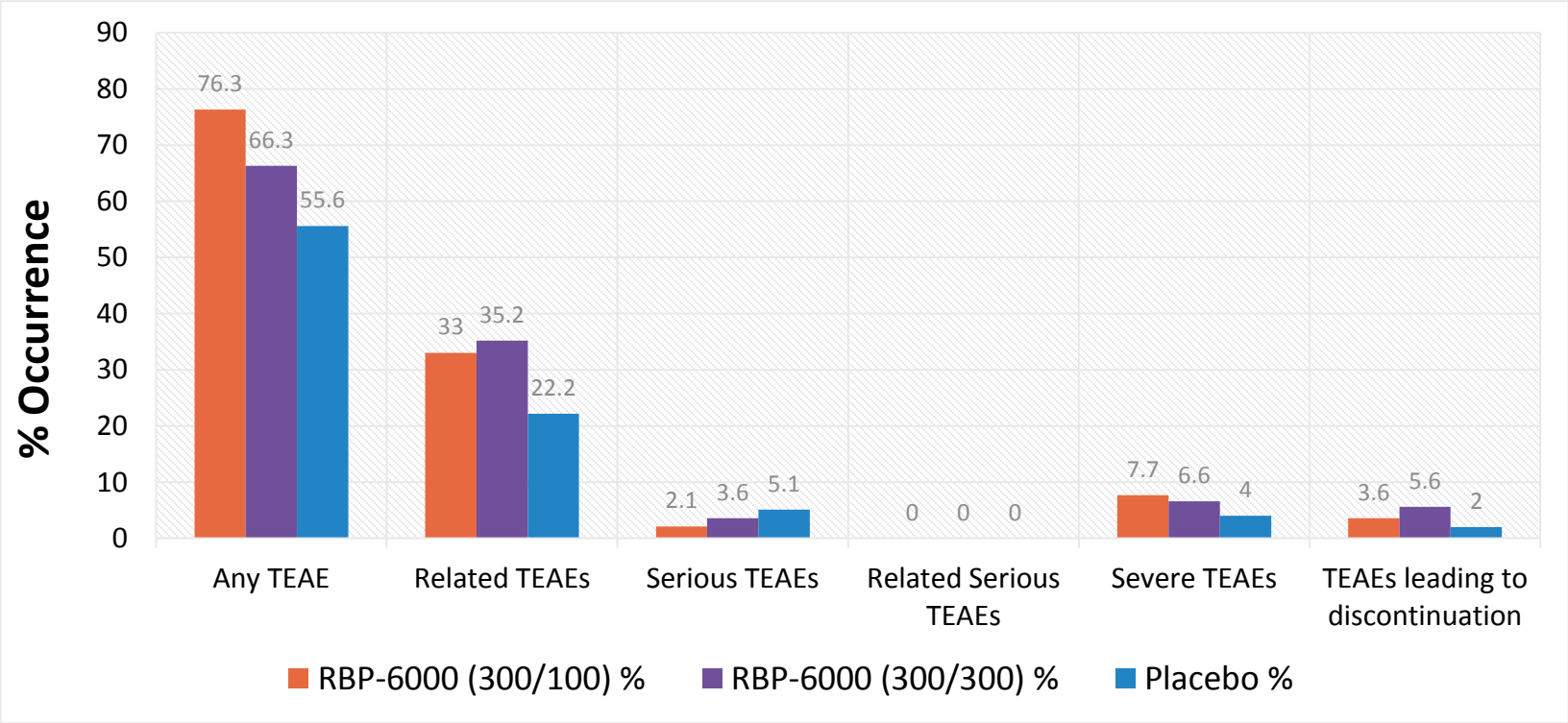
- RBP-6000 reduced withdrawal symptoms relative to baseline as rated by the subject.
- Placebo group experienced an increase in withdrawal symptoms *vs.* baseline despite more than twice the rate of illicit opiate use among Placebo subjects as early as week 2.

Opioid Craving by VAS



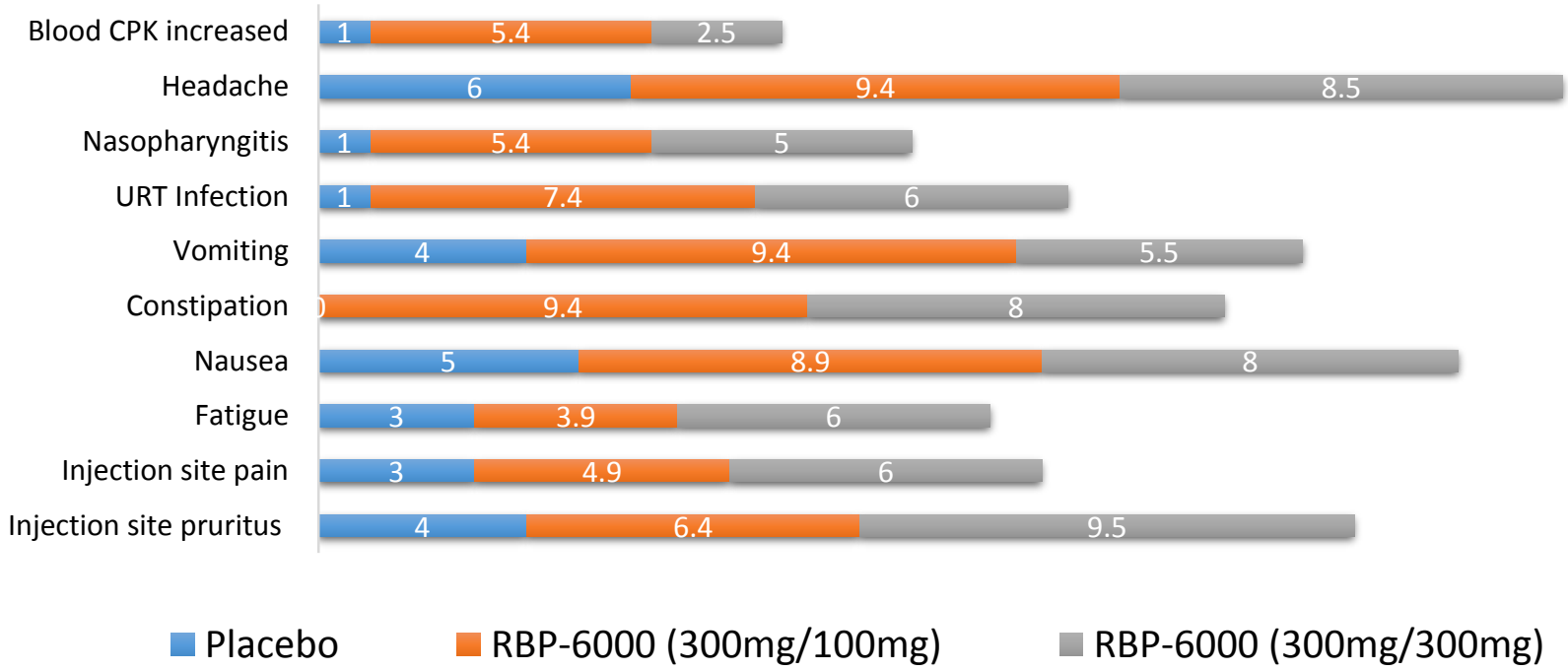
Increase in craving in the Placebo group, relative to baseline and compared with active groups, despite more than twice the rate of illicit opiate use among Placebo subjects as early as week 2.

Safety Results - No new or unexpected safety findings Generally Well Tolerated



Topline results Phase 3 study (RB-US-13-0001); TEAE's: Treatment Emergent Adverse Events

SAFETY RESULTS - TEAES OCCURRING IN ≥ 5% IN ANY TREATMENT GROUP AND MORE FREQUENTLY IN RBP-6000 GROUP THAN IN PLACEBO GROUP



Topline results Phase 3 study (RB-US-13-0001); TEAE's: Treatment Emergent Adverse Events

RBP-6000 Value Dossier Contents

- Disease Overview & Epidemiology
- Burden of Disease
- Treatment Patterns, Costs & Unmet Needs
- Clinical Evidence
- Economic Evidence
- Humanistic /Quality of Life/ Patient Reported Outcomes Evidence
- Product Value Proposition (Evidence-based)
- References & Appendices

Retrospective HEOR Research

Prospective HEOR Research

AMCP: Academy of Managed Care Pharmacy

RETROSPECTIVE HEOR STUDIES: MARKETSCAN® & AETNA HEALTHCARE CLAIMS

Characteristics and Treatment Patterns of OUD Patients
How is relapse measured in claims data?
What are the dosing patterns of patients on BMAT?
What are the determinants of BMAT adherence?
What are the concomitant meds used before & after BMAT?
What are the effects of BMAT dosing and adherence on relapse and healthcare utilization and costs?
What are the incidence and costs of relapse?

OUD: Opioid Use Disorder; BMAT: Buprenorphine Medication-Assisted Treatment

PROSPECTIVE HEOR STUDIES

RB-US-13-0001 Efficacy Trial Analysis

Quality of life
Treatment satisfaction
Resource use
Employment status & health insurance

Targeted HEOR Trial Analysis of 0001/ 0003

Comparison of outcomes in 0001/0003 by: Retention; Opioid use, withdrawal, cravings

RB-US-13-0003 Long-Term Safety Trial Analysis

Quality of life
Treatment satisfaction
Impact of opioid dependence on daily living

RECOVER® Study

THE RECOVER STUDY™

Characterize the periods of abstinence over a 12-month observational window, such as # days abstinent, time to relapse, # relapses, and time to return to abstinence after relapse -- Economic impact of compliance such as adherence & persistence to MAT

MAT: Medication-Assisted Treatment

RBP-6000: Planned Phase 3 & HEOR Data Rollout

Conferences	Date	Presentation
CPDD	June 2017	Phase 3 Efficacy & Safety Phase 3 HEOR
ACoP	October 2017	Phase 3 Exposure/Response
AATOD	March 2018	Phase 3 Efficacy Safety Phase 3 HEOR
ASCPT	March 2018	Phase 3 Exposure/Response
ASAM	April 2018	Phase 3 Long-term Safety

Peer-Reviewed Publications	Target Submission Date
Phase 3 Efficacy & Safety	3Q2017
Phase 3 HEOR	3Q2017
Phase 3 Exposure/Response	1Q2018
Phase 3 Long-term Safety	1Q2018

***CPDD**: College on Problems of Drug Dependence; **ACoP**: American Conference on Pharmacometrics; **AATOD**: American Association for the Treatment of Opioid Dependence; **ASCPT**: American Society for Clinical Pharmacology and Therapeutics; **ASAM**: American Society of Addiction Medicine*

INDIVIOR R&D DAY

RBP-6000 THROUGH THE LENS OF A CLINICIAN

Brent Boyett, D.M.D., D.O.
Boyett Health Services, Hamilton, AL

Barbara Haight, Pharm.D.
Medicine Development Leader, Indivior Inc.

INDIVIOR

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction

Dr. Brent Boyett, D.M.D., D.O.

- Trained and practices both Family Medicine and Family Dentistry (Diplomat of the *American Academy of Family Practice* & the *American Dental Society of Anesthesiology*).
  - ✓ Completed his undergraduate education at Birmingham-Southern College then graduated from the University of Alabama at Birmingham in 1994 with a D.M.D. degree.
  - ✓ Went on to medical school at the University of Health Sciences College of Osteopathic Medicine and graduated in 1998.
  - ✓ Started a three-year Family Medicine Residency (internal medicine, anesthesia and oral surgery) with the University of Mississippi in Tupelo, which he completed in 2001.
- Board certified in addiction through the *American Board of Addiction Medicine (ABAM).*
  - ✓ Implemented an addiction program for the treatment of opioid dependence in 2009.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RBP-6000: Vision for the Treatment of Opioid Use Disorder

Glenn Tyson
Vice-President, Global Therapy Areas, Indivior Inc.

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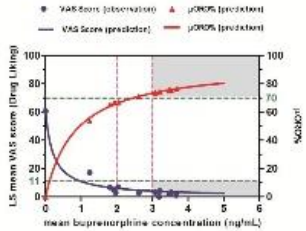
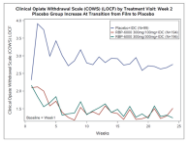
Educating Physicians on PK/PD/RO Relationship to Efficacy & Safety Variables is a Key Launch Objective for RBP-6000

Clearly articulate RBP-6000 PK/PD/RO relationship to efficacy & safety

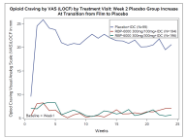
Sustained Opioid Blockade
(> 70% RO; > 3 ng/mL)



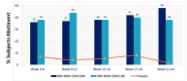
Withdrawal Suppression



Craving Suppression

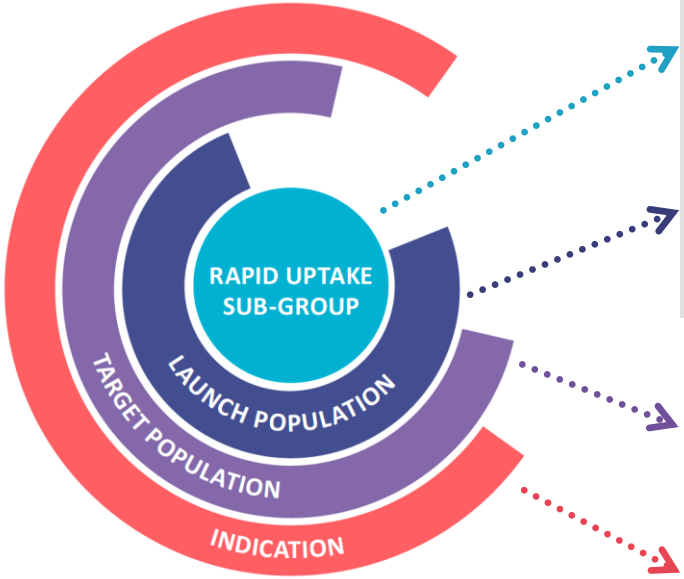


Sustained Abstinence



Physicians connect these attributes with patient success in recovery

RBP-6000 Potential Patient Build



POPULATION DESCRIPTION	MOST COMPELLING DIFFERENTIATOR RELEVANT TO THIS POPULATION
Core segment of patients with moderate to severe OUD with multiple relapses	Delivers once-monthly buprenorphine with stable plasma concentrations of buprenorphine
Patients new to OUD treatment and naïve to BMAT, and OUD patients relapsing but not currently on MAT	Therapeutically-relevant plasma concentrations of buprenorphine for entire dosing interval, reduces withdrawal, craving, and protects against illicit use
Defined OUD patient population with multiple relapses and/or adherence challenges, i.e. patients in need of treatment	Delivers Long-Acting Injectable (LAI) benefits that may include better long-term outcomes, help prevent relapse, lower risk of misuse and diversion
Total OUD potential patient population	Provides potentially transformative treatment to patients who are struggling in the grip of addiction

Dynamic Market

MAT: Medication-Assisted Treatment; BMAT: Buprenorphine Medication-Assisted Treatment
Any statements about RBP-6000 are for discussion and planning purposes only.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INDIVIOR R&D DAY DECEMBER 9TH, 2016

RBP-7000: ONCE MONTHLY RISPERIDONE

Anne Andorn, *Head Late Stage Clinical Development*
Glenn Tyson, *VP Global Therapy Areas*
Susan Learned, *SVP Global Clinical Development*
Jay Graham, *Medicine Development Leader*

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INDIVIOR R&D DAY

Schizophrenia through the lens of a Psychiatrist

Anne Andorn, M.D.
Head Late Stage Clinical Development, Indivior Inc.

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INTRODUCTION

- Schizophrenia is a devastating chronic relapsing illness characterized by[1]
  - ✓ Adolescent onset
  - ✓ Abnormalities of perception, thought, volition, cognition
- Affecting around 5 million people world-wide[1]
- Due to complex genetic/environmental interaction as yet unidentified[1]
- A top 10 cause of disability (and health care cost) in Western world[1]
- No known cure but effective treatments to control symptoms are available[1]

Long acting treatments have been shown to reduce disability[2]

[1] *Janoutová J et al. (2016) Epidemiology and risk factors of schizophrenia. Neuro Endocrinol Lett, 37(1):1-8; Owen MJ et al. (2016) Schizophrenia. Lancet, 388(10039):86-97.*
[2] *Achilla E, McCrone P (2013) The Cost Effectiveness of Long-Acting/Extended-Release Antipsychotics for the Treatment of Schizophrenia. A Systematic Review of Economic Evaluations. Appl Health Econ Health Policy, 11:95–106*

What are the Symptoms of Schizophrenia?

Positive Symptoms

- Multiple defects in perception (hallucinations, delusions)
- Defects in reality testing, loss of tight reality based associations
- Abnormal ideation (paranoia, grandiosity, bizarre ideation)

Negative Symptoms

- Loss of ability to engage socially (flat affect or diminished emotional expression, amotivational, anhedonic [inability to derive pleasure])

Cognitive Defects

Leading to impairment of executive function and other functions

- impaired insight
- impaired abstraction/planning ahead
- rapid cognitive disintegration *(dementia praecox)*

Tandon R, Gaebel W, Barch DM, Bustillo J, Gur RE, Heckers S, Malaspina D, Owen MJ, Schultz S, Tsuang M, Van Os J, Carpenter W. Definition and description of schizophrenia in the DSM-5. Schizophr Res. 2013 Oct;150(1):3-10. DOI: http://dx.doi.org/10.1016/j.schres.2013.05.028

Case Vignette

- Ph.D. from prestigious university, male aged 29
- Gradual onset of suspiciousness developing into frank paranoia
- Became agitated and convinced his team was out to harm him
- Hallucinating but denying both auditory and visual hallucinations
- Did not recognize his abnormal behavior
- Only first generation antipsychotics (e.g. haloperidol) were available at the time
- Rapidly lost cognitive function even though paranoia resolved to a manageable level
- Severe Extrapyramidal Syndrome (EPS) which could not be well managed

The Second Generation Of Antipsychotics (SGAs)

Clozapine

- Significant effect on negative symptoms

Risperidone

- Janssen molecule risperidone then shown to benefit negative symptoms
- Clinicians talk about it as a typical atypical because predominantly dopamine antagonist

SGAs

- For the most part SGAs affect many neurotransmitter systems with differing potencies

Citrome L. A systematic review of meta-analyses of the efficacy of oral atypical antipsychotics for the treatment of adult patients with schizophrenia. Expert Opin Pharmacother. 2012 Aug;13(11):1545-73. DOI: : http://dx.doi.org/10.1517/14656566.2011.626769

Case Vignettes

- 24-year old male college student with 2-year history of social withdrawal, delusions, and auditory hallucinations, with prominent negative symptoms
- First generation antipsychotics had no effect on negative symptoms which were disabling – no motivation, no insight into illness, no social engagement, blunted affect
- Started an investigational second generation antipsychotic and within weeks recognized he had something wrong, after months went back to school, completed an MA, and had insight into his persistent difficulty with social cues and sought group treatment for that
- *Another patient* with similar trajectory in the same clinical trial stopped the medication because of fear of a side effect and reverted to disability level which left him unable to care for himself and disabled son

Non-Compliance Remains a Significant Challenge

- Adverse Events
- Not curative – auditory hallucinations just not as clear - more annoying
- Impaired insight into illness is a major cause of non-compliance
- Anosognosia (deficit of self-awareness)
- Lack of motivation to address disease – and lack of motivation is a symptom
- Behavior improves enough for family/friends so they stop monitoring

It takes a care team

Source: Robinson D. First-episode schizophrenia. CNS Spectrum 2010;15 (Suppl 6): 4-7; Doshi JA, Pettit AR, Stoddard JJ, Zummo J, Marcus SC. Concurrent Oral Antipsychotic Drug Use Among Schizophrenia Patients Initiated on Long-Acting Injectable Antipsychotics Post-Hospital Discharge. J Clin Psychopharmacol. 2015 Aug;35(4):442-6. DOI: http://dx.doi.org/10.1097/JCP.0000000000000353

COMPLIANCE & SCHIZOPHRENIA

Compliance with Medication

- Hospital stays are reduced (recidivism decreases)
- Disability is reduced and functional ability is improved

Non-Compliance with Medication

- Recidivism is high – 3-5 hospitalizations
- Disability increases – longer psychosis
- Primary cause of relapse

Source: Robinson D. First-episode schizophrenia. CNS Spectrum 2010;15 (Suppl 6): 4-7; Doshi JA, Pettit AR, Stoddard JJ, Zummo J, Marcus SC. Concurrent Oral Antipsychotic Drug Use Among Schizophrenia Patients Initiated on Long-Acting Injectable Antipsychotics Post-Hospital Discharge. J Clin Psychopharmacol. 2015 Aug;35(4):442-6. DOI: http://dx.doi.org/10.1097/JCP.0000000000000353

Long Acting Antipsychotics (LAI) Help With Compliance But There are Currently Clinical Limitations

We believe that the following characteristics are potential differentiating attributes for future LAIs[1]:

- Rapid onset
- Extended treatment duration
- Manageable tolerability
- No oral co-medication
- Measurable quality of life benefits

[1] *Based on prescribing Information for RISPERDAL® CONSTA®, INVEGA SUSTENNA®, and ARISTADA®, Section 2 Dosage and Administration*

INDIVIOR R&D DAY

RBP-7000: CLINICAL DEVELOPMENT

Susan Learned, M.D., Pharm.D., Ph.D.
Senior Vice-President, Global Clinical Development, Indivior Inc.

Jay Graham, Pharm.D.
Medicine Development Leader, Indivior Inc.

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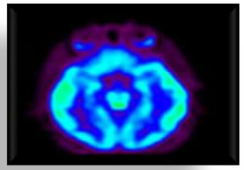
Clinical Development: Phase 1 And Phase 2A

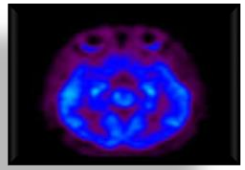
Phase	Title	Description	Population
Phase 1	RB-US-09-0007	First-in-man, OL study to assess the safety, tolerability & PK of a single dose (60 mg)	Clinically stable schizophrenics (N=11)
Phase 1	RB-US-09-0008	Single ascending dose (SAD), open-label study to assess the safety, tolerability, and PK of RBP-7000 (60 mg, 90 mg, 120 mg)	Clinically stable schizophrenics (N=43)
Phase 2A	RB-US-09-0009	Multiple ascending dose (MAD), open-label study to assess the safety, tolerability, PK and switchability of 60 mg, 90 mg and 120 mg RBP-7000	Clinically stable schizophrenics (N=45)
Phase 3	RB-US-09-0010	Randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of RBP-7000 (90 mg, 120 mg)	Subjects with acute schizophrenia (N=354)
Phase 3	RB-US-13-0005	Open-label, long-term safety and tolerability study of RBP-7000 in the treatment of subjects with schizophrenia	Clinically stable schizophrenics (N=500)

PK/PD Model: Dopamine (DA) D_2 Receptor Occupancy

- Data from Gefvert et al. (2005), where 13 schizophrenic patients received injections of Risperdal Consta (25, 50 or 75 mg) every 2 weeks
- Brain DA D_2 receptor occupancy assessed with [^{11}C]Raclopride under steady-state conditions for active moiety plasma concentrations

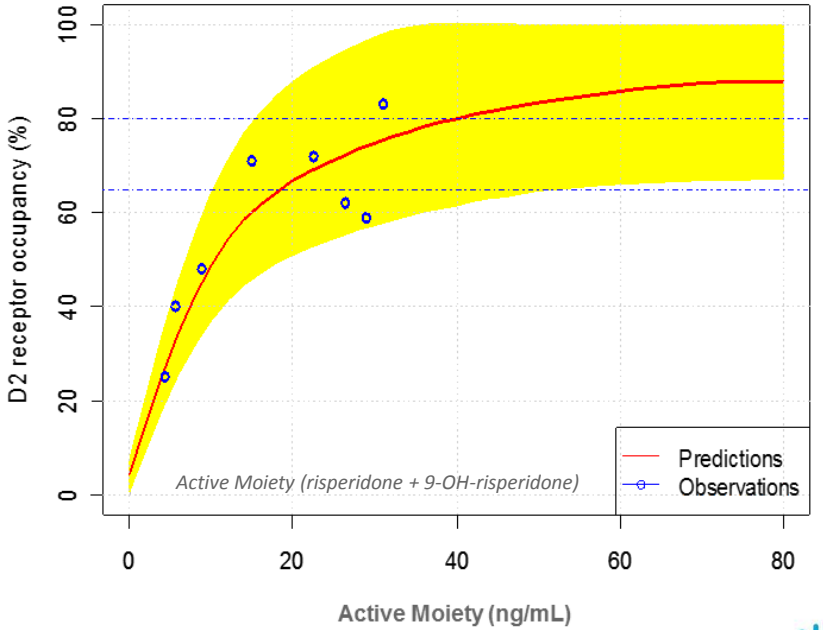


Free state



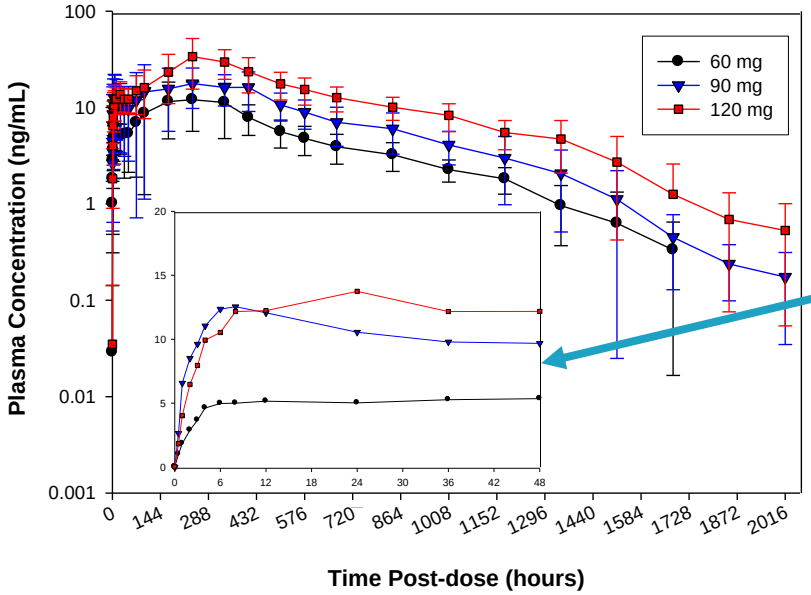
Risperidone state

Model Predictions & 95% Confidence Intervals



Gefvert O, Eriksson B, Persson P, Helldin L, Björner A, Mannaert E, Remmerie B, Eerdekens M, Nyberg S. Pharmacokinetics and D2 receptor occupancy of long-acting injectable risperidone (Risperdal Consta) in patients with schizophrenia. Int J Neuropsychopharmacol. 2005 Mar;8(1):27-36. DOI: http://dx.doi.org/10.1017/S1461145704004924

RB-US-09-0008:
Single Ascending Dose Population PK Model

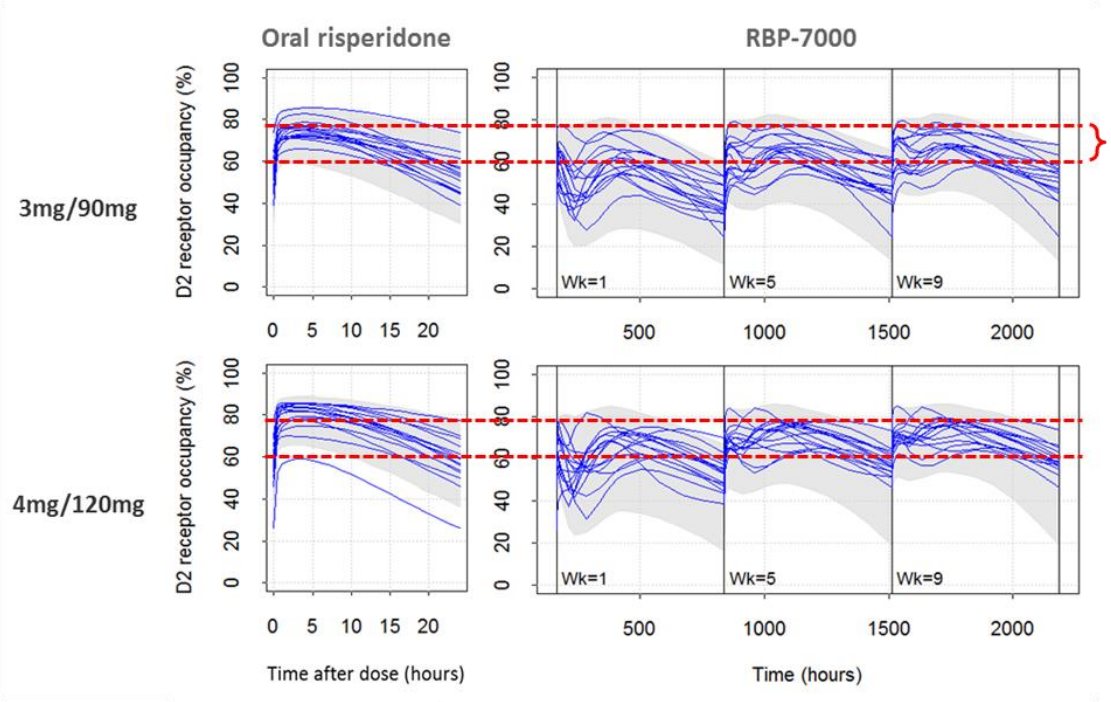


Plot of Mean (± SD) Plasma Concentration versus Time on a Semi-Log Scale
(Insert: Initial Burst Phase [~ 48 hours] on a Linear Scale)
Total Active Moiety (risperidone + 9-OH-risperidone)

RBP-7000 provides therapeutically-relevant plasma concentrations of risperidone immediately after the first injection

Source: Gomeni R, Heidbreder C, Fudala PJ, Nasser AF. A model-based approach to characterize the population pharmacokinetics and the relationship between the pharmacokinetic and safety profiles of RBP-7000, a new, long-acting, sustained-released formulation of risperidone. J Clin Pharmacol. 2013 Oct;53(10):1010-9. DOI: http://dx.doi.org/10.1002/jcph.141

Predicted Receptor Occupancy (RO) in Phase 2a Multiple Dose Study



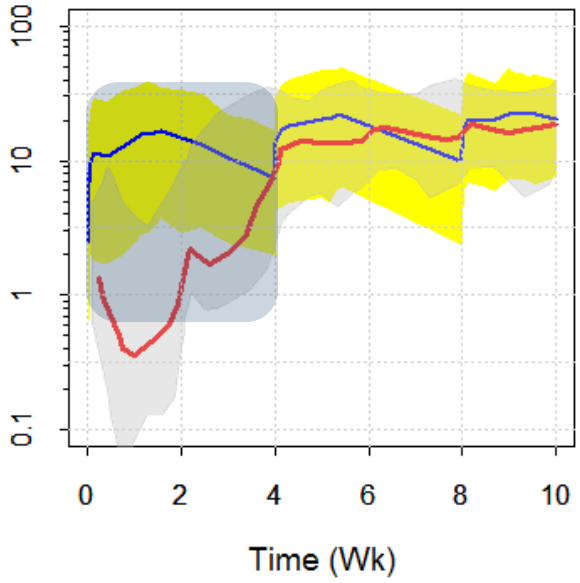
Target therapeutic window
(> Efficacy; < Extrapyramidal Syndrome)

- 9 of 15 subjects exceeded 80% DA D_2 RO under oral risperidone 4 mg
- 2 of 15 subjects exceeded 80% DA D_2 RO under RBP-7000 120 mg

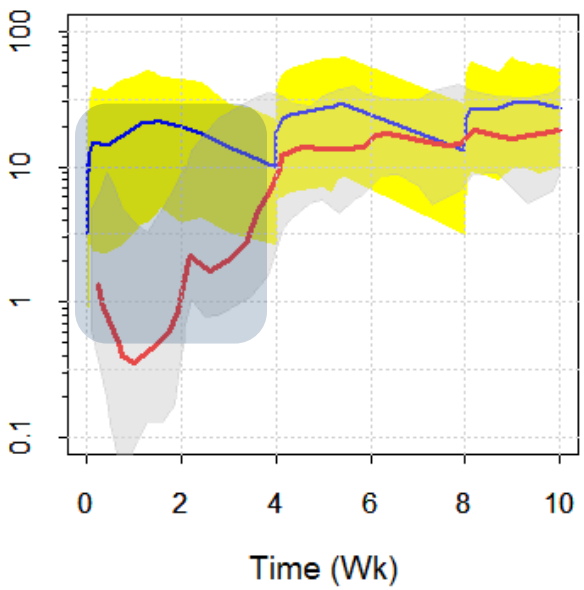
Source: Laffont CM, Gomeni R, Zheng B, Heidbreder C, Fudala PJ, Nasser AF. Population pharmacokinetics and prediction of dopamine D2 receptor occupancy after multiple doses of RBP-7000, a new sustained-release formulation of risperidone, in schizophrenia patients on stable oral risperidone treatment. Clin Pharmacokinet. 2014 Jun;53(6):533-43. DOI: http://dx.doi.org/10.1007/s40262-014-0132-7

Active Moiety Exposure: Comparing RBP-7000 vs. Risperdal Consta® (RLAI) 25mg

RBP-7000 90mg vs. RLAI 25 mg



RBP-7000 120mg vs. RLAI 25 mg

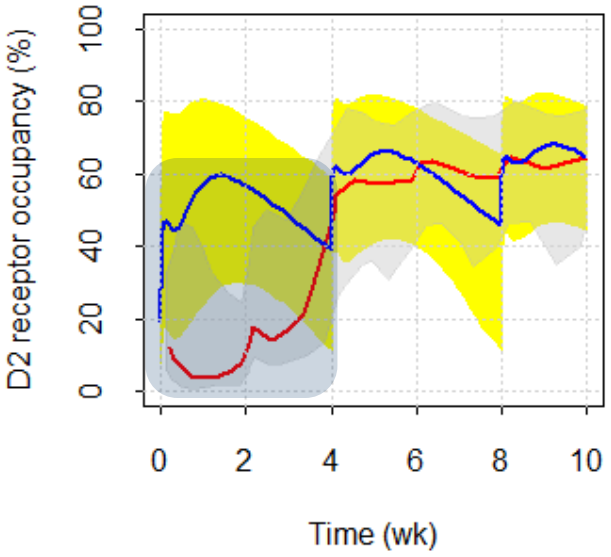


- *The **blue line** represents the median predicted active moiety concentrations, the yellow region represent the 5th and 95th percentiles predicted for the active moiety after the SC RBP-7000 injections*
- *The **red line** represents the median predicted active moiety concentrations, the gray region represents the 5th and 95th percentiles predicted for the active moiety after RLAI*

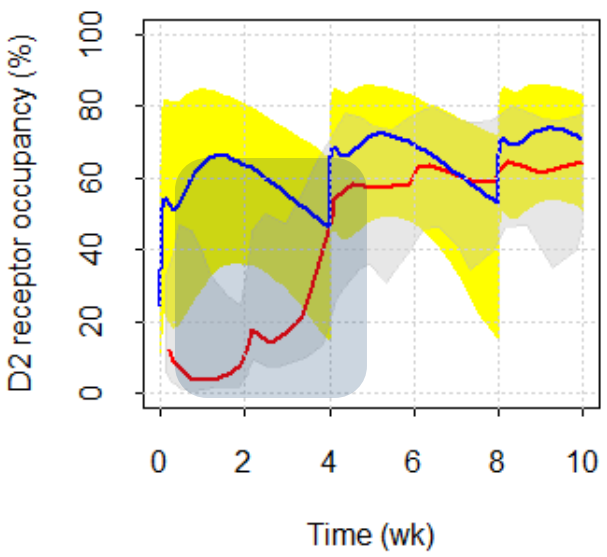
Source: Laffont CM, Gomeni R, Zheng B, Heidbreder C, Fudala PJ, Nasser AF. Population pharmacokinetic modeling and simulation to guide dose selection for RBP-7000, a new sustained-release formulation of risperidone. J Clin Pharmacol. 2015 Jan;55(1):93-103. DOI: http://dx.doi.org/10.1002/jcph.366; Samtani MN, Gopal S, Gassmann-Mayer C, Alphs L, Palumbo JM. Dosing and switching strategies for paliperidone palmitate: based on population pharmacokinetic modelling and clinical trial data. CNS Drugs. 2011 Oct 1;25(10):829-45. DOI: http://dx.doi.org/10.2165/11591690-000000000-00000

Predicted DA D_2 Receptor Occupancy: Comparing RBP-7000 vs. Risperdal Consta® (RLAI) 25mg

RBP-7000 90mg vs. RLAI 25 mg



RBP-7000 120mg vs. RLAI 25 mg



- *The **blue line** represents the median predicted D2 receptor occupancy, the yellow region represents the 5th and 95th percentiles predicted for D2 receptor occupancy after the SC RBP-7000 injections*
- *The **red line** represents the median predicted D2 receptor occupancy, the gray region represents the 5th and 95th percentiles predicted for D2 receptor occupancy after RLAI*

Source: Laffont CM, Gomeni R, Zheng B, Heidbreder C, Fudala PJ, Nasser AF. Population pharmacokinetic modeling and simulation to guide dose selection for RBP-7000, a new sustained-release formulation of risperidone. J Clin Pharmacol. 2015 Jan;55(1):93-103. DOI: http://dx.doi.org/10.1002/jcph.366; Samtani MN, Gopal S, Gassmann-Mayer C, Alphs L, Palumbo JM. Dosing and switching strategies for paliperidone palmitate: based on population pharmacokinetic modelling and clinical trial data. CNS Drugs. 2011 Oct 1;25(10):829-45. DOI: http://dx.doi.org/10.2165/11591690-000000000-00000

Conclusions Phase 1 & Phase 2A

- The PK/PD modeling strategy was successful in supporting dose selection for Phase 2A and Phase 3
- Biomarker (DA D_2 RO) increased the probability of targeting the right therapeutic window in confirmatory Phase 3 trials
- Modeling & simulation accelerated decision making by bringing together PK, biomarker, and other PD data from various sources (internal data & peer-reviewed literature)

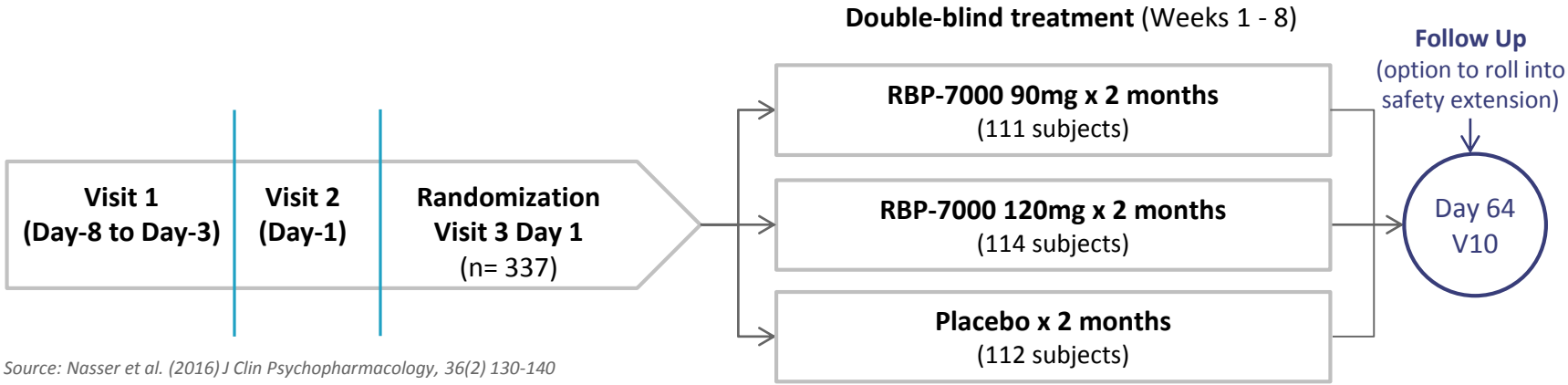
Clinical Development: Pivotal Phase 3

Phase	Title	Description	Population
Phase 1	RB-US-09-0007	First-in-man, OL study to assess the safety, tolerability & PK of a single dose (60 mg)	Clinically stable schizophrenics (N=11)
Phase 1	RB-US-09-0008	Single ascending dose (SAD), open-label study to assess the safety, tolerability, and PK of RBP-7000 (60 mg, 90 mg, 120 mg)	Clinically stable schizophrenics (N=43)
Phase 2A	RB-US-09-0009	Multiple ascending dose (MAD), open-label study to assess the safety, tolerability, PK and switchability of 60 mg, 90 mg and 120 mg RBP-7000	Clinically stable schizophrenics (N=45)
Phase 3	RB-US-09-0010	Randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of RBP-7000 (90 mg, 120 mg)	Subjects with acute schizophrenia (N=354)
Phase 3	RB-US-13-0005	Open-label, long-term safety and tolerability study of RBP-7000 in the treatment of subjects with schizophrenia	Clinically stable schizophrenics (N=500)

RB-US-09-0010:
Objectives of Phase III Efficacy & Safety Trial

- Randomized, double-blind, Placebo (PBO)-controlled, multicenter trial to evaluate the efficacy, safety and tolerability of RBP-7000 (90 mg and 120 mg) in subjects with acute schizophrenia over 8 weeks.
  - **Primary objective**: Assess the efficacy of RBP-7000 compared with PBO using the change from baseline to end of treatment in total *Positive and Negative Syndrome Scale* (PANSS) score and *Clinical Global Impression Severity of Illness* (CGI-S) scale.
  - **Secondary objective**: Establish a PK/PD/RO model.
  - **Tertiary objective**: Assess health-related quality of life, subjective well-being, subject satisfaction with medication, and subject and caregiver medication preference.

RB-US-09-0010:
Design of Phase 3 Efficacy & Safety Trial



Source: Nasser et al. (2016) J Clin Psychopharmacology, 36(2) 130-140

Entry Criteria:

- Each subject who met entry criteria at Visit 1 was placed in an in-patient facility
- Positive and Negative Syndrome Scale (PANSS) total score between 80 and 120 at Visit 1, and a score of > 4 on at least two of the following 4 items: hallucinatory behavior, delusions, conceptual disorganization, or suspiciousness/persecution.

Diagnosis:

- Diagnosis of acute exacerbation of schizophrenia and PANSS total score were confirmed by an experienced State, Assessability, Face, Ecological, and Rule (SAFER) rater of Massachusetts General Hospital's (MGH) Clinical Trials Network & Institute (CTNI).
- Subjects were excluded if improvement in their PANSS total score was ≥ 20% between the initial screening visit (Visit 1) and first injection (Visit 3; Day 1)
- At Visit 3, subjects were randomized to one of the three treatment arms: RBP-7000 (90 mg), RBP-7000 (120 mg) or placebo

RB-US-09-0010: Subject Demographics

Characteristic	Placebo (n=112)		90 mg RBP-7000 (n=111)		120 mg RBP-7000 (n=114)	
	n	%	n	%	n	%
Gender						
Male	81	72.3	93	83.8	84	73.7
Female	31	27.7	18	16.2	30	26.3
Race						
White	25	22.3	28	25.2	30	26.3
Black	84	75.0	79	71.2	80	70.2
Asian	1	0.9	1	0.9	3	2.6
Native Hawaiian or Pacific Islander	1	0.9	1	0.9	1	0.9
Other	1	0.9	2	1.8	0	0
Ethnicity						
Hispanic/Latino	10	8.9	7	6.3	9	7.9
Not Hispanic or Latino	101	90.2	104	93.7	104	91.2
Unknown	1	0.9	0	0	1	0.9

Source: Nasser AF, Henderson DC, Fava M, Fudala PJ, Twumasi-Ankrah P, Kouassi A, Heidbreder C (2016) J Clin Psychopharmacology, 36(2):130-140.
http://dx.doi.org/10.1097/JCP.0000000000000479

RB-US-09-0010: Baseline Clinical Characteristics

Characteristic	Placebo (n=112)		90 mg RBP-7000 (n=111)		120 mg RBP-7000 (n=114)	
	Mean	SD	Mean	SD	Mean	SD
Age at First Schizophrenia Diagnosis (years)	26.6	9.25	25.5	8.21	26.9	8.48
PANSS						
Total Score	94.1	8.89	95.5	9.23	94.9	8.09
Positive symptom subscale	25.4	3.31	26.0	3.36	25.9	3.42
Negative symptom subscale	22.6	3.79	23.5	3.68	22.6	3.96
General psychopathology subscale	46.2	5.49	45.9	5.94	46.5	5.15
CGI-S	4.8	0.59	4.8	0.58	4.8	0.48
C-SSRS						
Suicidal ideation and behavior	0	0	1	0.9	3	2.6
Suicidal ideation score	*	*	1	0.9	2.7	0.58
Suicidal intensity rating	10.9	2.10	3	4.73	12	10.3
SAS	0.3	0.70	0.4	0.79	0.4	0.94
AIMS	0.1	0.43	0.2	0.57	0.1	0.52
BARS	0.2	0.62	0.2	0.56	0.1	0.51

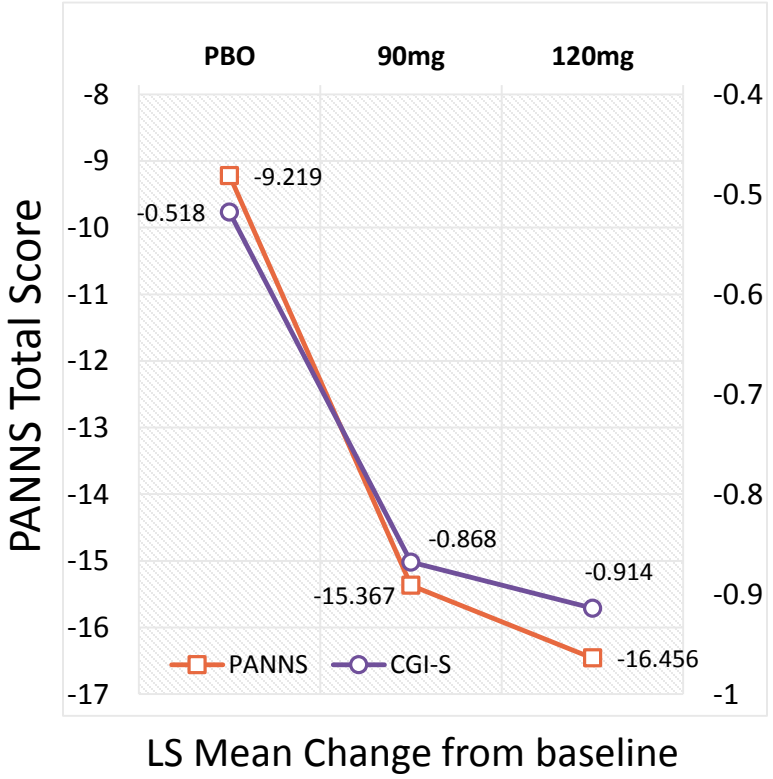
AIMS, Abnormal Involuntary Movement Scale; BARS, Barnes Akathisia Rating Scale; SAS, Simpson-Angus Scale; SD: standard deviation

Source: Nasser AF, Henderson DC, Fava M, Fudala PJ, Twumasi-Ankrah P, Kouassi A, Heidbreder C (2016) J Clin Psychopharmacology, 36(2):130-140.
http://dx.doi.org/10.1097/JCP.0000000000000479

RB-US-09-0010: Efficacy & Safety Study Results

Endpoints	Treatment	LS Means	Difference vs. Placebo (95% CI)	P-value
Primary: PANSS Score	90 mg (N=111)	-15.367	-6.15 (-9.98; -2.31)	0.0004
	120 mg (N=114)	-16.456	-7.24 (-11.05; -3.43)	<0.0001
	Placebo (N=112)	-9.219		
Secondary: CGI-S Scale	90 mg (N=111)	-0.868	-0.35 (-0.56; -0.14)	0.0002
	120 mg (N=114)	-0.914	-0.39 (-0.60; -0.19)	<0.0001
	Placebo (N=112)	-0.518		

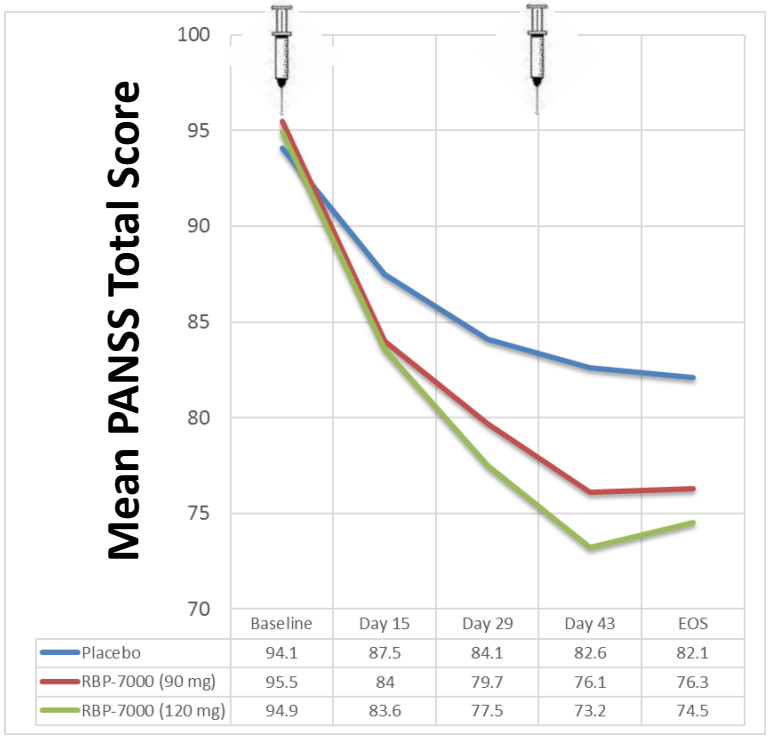
	90 mg (N = 115)	120 mg (N = 117)	Placebo (N = 118)
Subjects With 1+ TEAE	81 (70.4%)	91 (77.8%)	81 (68.8%)
Subjects With 1+ Serious TEAE	0 (0.0%)	1 (0.9%) - Chest Pain	1 (0.8%) - GI



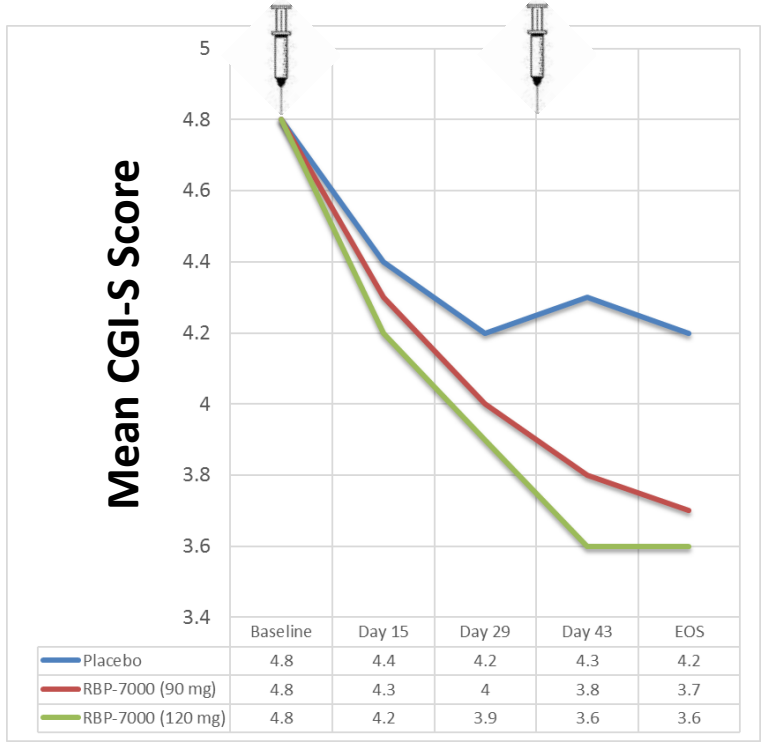
TEAE: Treatment Emergent Adverse Events

Nasser AF, Henderson DC, Fava M, Fudala PJ, Twumasi-Ankrah P, Kouassi A, Heidbreder C (2016) J Clin Psychopharmacology, 36(2):130-140. http://dx.doi.org/10.1097/JCP.0000000000000479

RB-US-09-0010: Efficacy & Safety Study Results



	Baseline	Day 15	Day 29	Day 43	EOS
Placebo	94.1	87.5	84.1	82.6	82.1
RBP-7000 (90 mg)	95.5	84	79.7	76.1	76.3
RBP-7000 (120 mg)	94.9	83.6	77.5	73.2	74.5



	Baseline	Day 15	Day 29	Day 43	EOS
Placebo	4.8	4.4	4.2	4.3	4.2
RBP-7000 (90 mg)	4.8	4.3	4	3.8	3.7
RBP-7000 (120 mg)	4.8	4.2	3.9	3.6	3.6

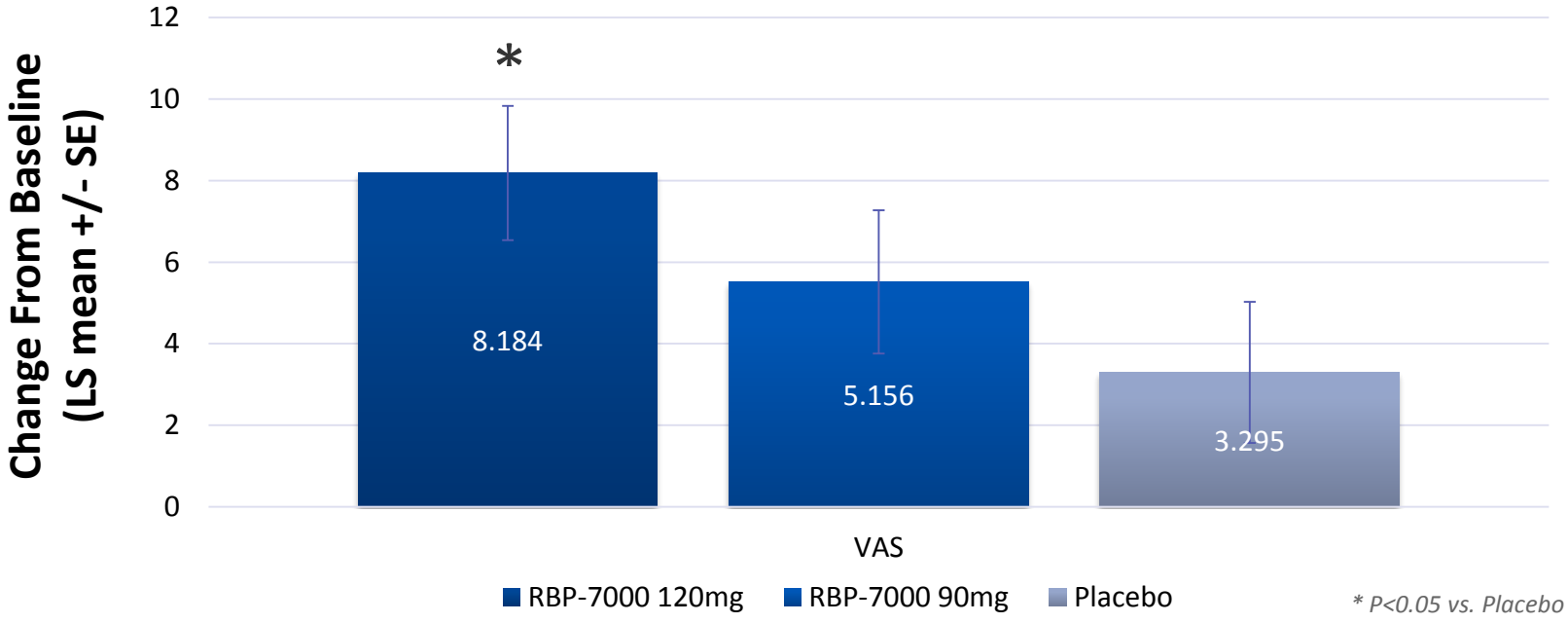
Data on file - Baseline was the last measurement on or before the date of randomization

RB-US-09-0010: HEOR Endpoints & Measures

Subjective well-being	**SWN-S** Under Neuroleptic Scale: Mental functioning; Self-control; Physical functioning; Emotional regulation; Social integration; Total score
Health-related quality of life	**EuroQol EQ-5D-5L:** Mobility; Self-care; Usual activities; Pain/discomfort; Anxiety/depression
Patient and caregiver preference	**Preference of Medicine Questionnaire (POM):** Subjects' preference for the current antipsychotic compared with their most recent pre-study antipsychotic
Patient satisfaction	**Medication Satisfaction Questionnaire (MSQ):** Satisfaction with patients antipsychotic medication

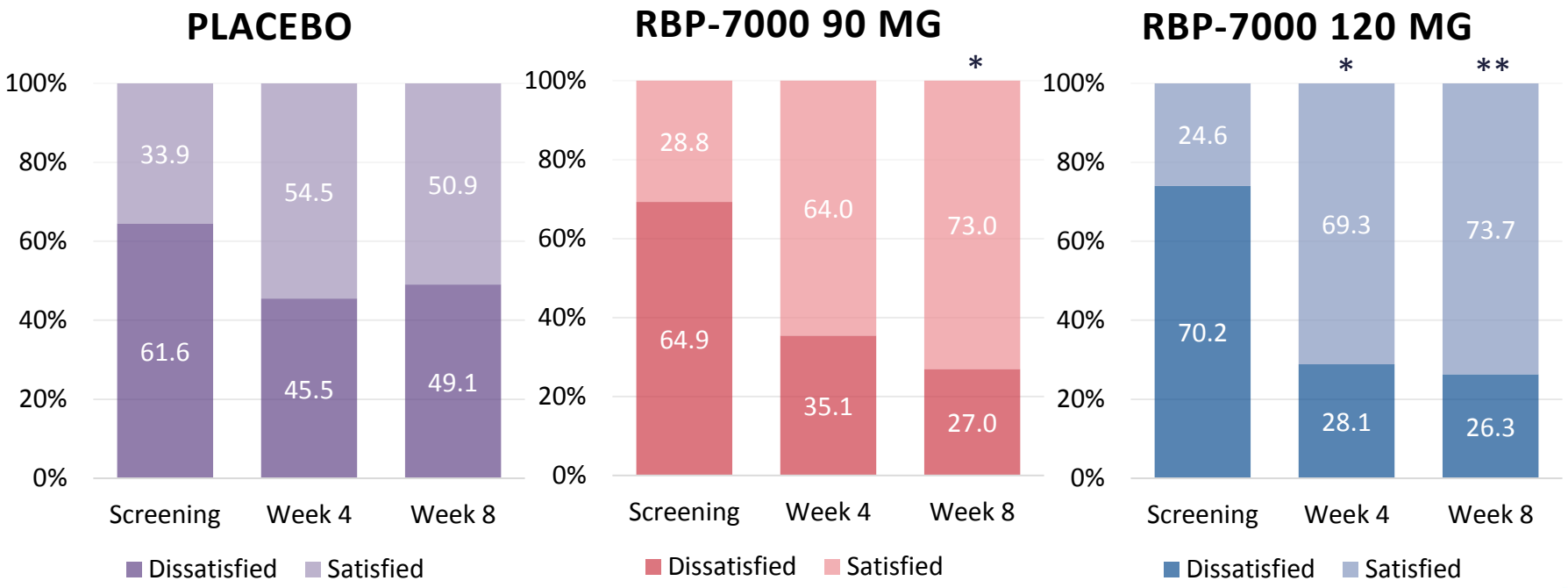
Isitt JJ, Nadipelli VR, Kouassi A, Fava M, Heidbreder C (2016) Schizophr Res, 174(1-3):126-131. http://dx.doi.org/10.1016/j.schres.2016.03.020

RB-US-09-0010: Quality of Life (EQ-5D-5L Scores)



Isitt JJ, Nadipelli VR, Kouassi A, Fava M, Heidbreder C (2016) Schizophr Res, 174(1-3):126-131. http://dx.doi.org/10.1016/j.schres.2016.03.020

RB-US-09-0010: Medication Satisfaction



** P<0.05; ** P<0.01 vs. Placebo*

Isitt JJ, Nadipelli VR, Kouassi A, Fava M, Heidbreder C (2016) Schizophr Res, 174(1-3):126-131. http://dx.doi.org/10.1016/j.schres.2016.03.020

RB-US-13-0005: Ongoing Phase 3 Long-Term Safety Trial

- Open label, long-term safety and tolerability study of RBP-7000 for the treatment of subjects with schizophrenia
  - **Primary objective:** Assess the long-term safety and tolerability of RBP-7000 (90 mg, 120 mg).
  - **Secondary objective:** Continue collecting clinical outcome data with RBP-7000 (90 mg, 120 mg) using the PANSS and CGI-S scales.
  - **Tertiary objective:** Continue collecting health economics and subject-reported outcome data with RBP-7000.

PHASE 3 & HEOR DATA SUMMARY: RBP-7000

- Once a month dosing
- Rapid onset of action
- No loading dose with initiation of treatment
- No supplemental dosing during treatment
- Demonstrated clinical efficacy & safety in schizophrenia
- Overall well tolerated
- Measurable quality of life and medication satisfaction benefits

INDIVIOR R&D DAY

RBP-7000: Vision for the Treatment of Schizophrenia

Glenn Tyson
Vice-President, Global Therapy Areas, Indivior Inc.

INDIVIOR

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction

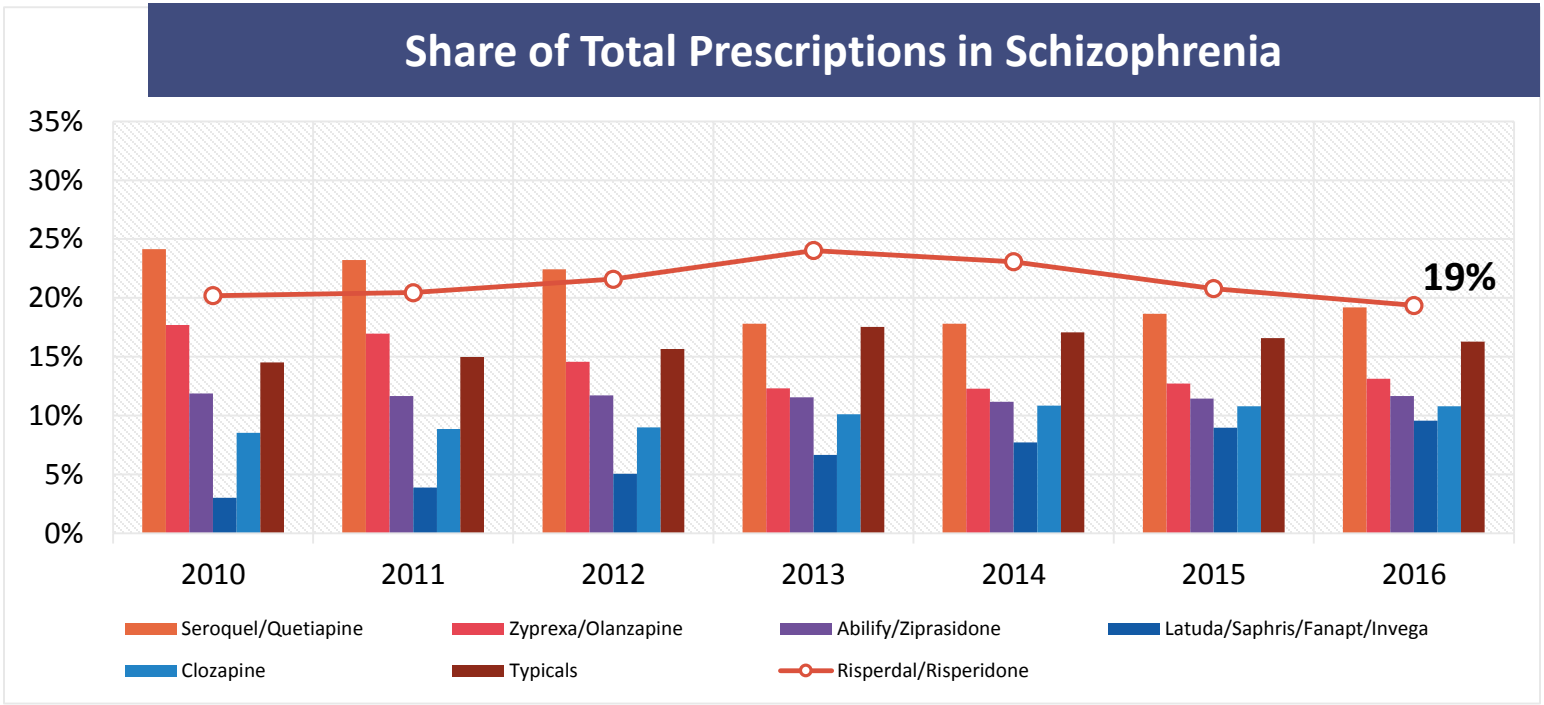
MARKET RESEARCH REFLECTS PHYSICIAN PERCEPTIONS OF RBP-7000

Physicians see RBP-7000 as having the potential to increase compliance

1. **Well known molecule,** in addition to having a **better dosing** regimen
2. Perceived as **convenient**. Its dosing schedule and lack of concomitant oral dosing may lead to better compliance, especially in those who are struggling
3. Perceived as providing **more stability and reliability** for patients with schizophrenia, due to its better dosing schedule and convenience

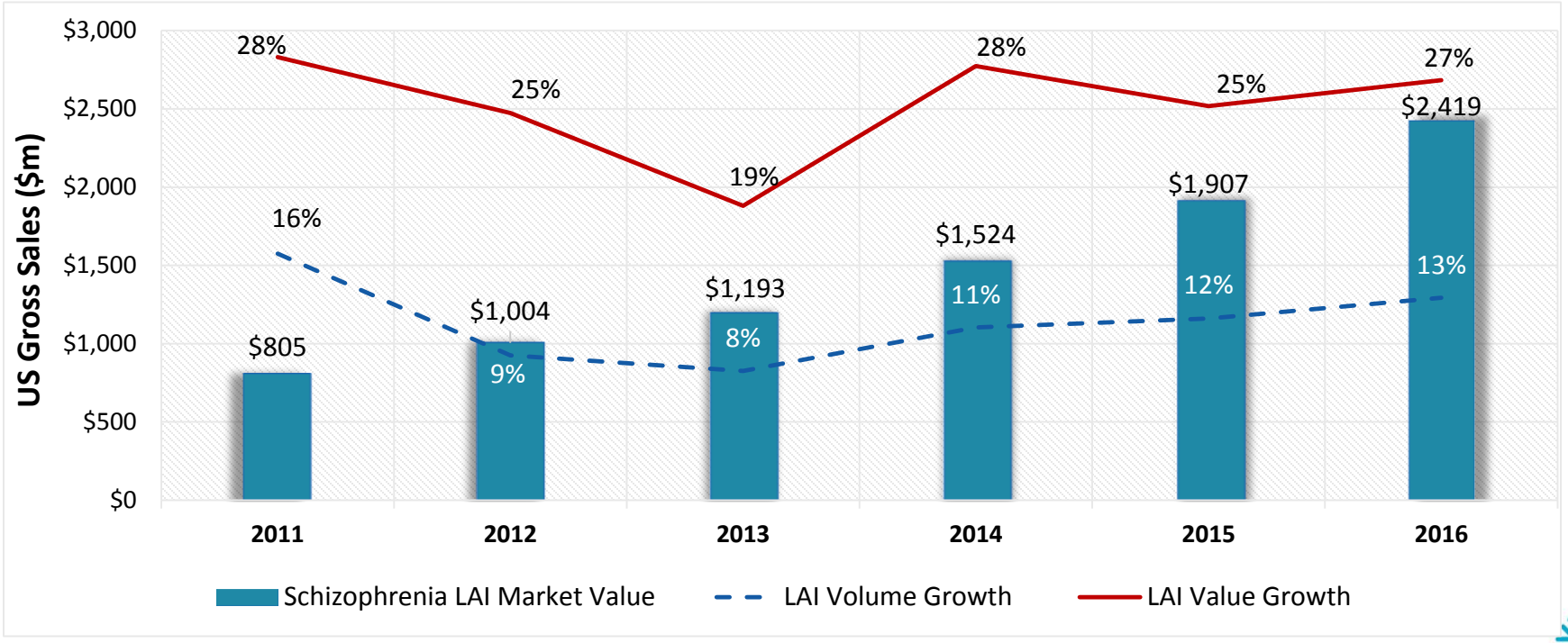
Source: INDV quantitative market research, Jan 2016, n=121
Any statements about RBP-7000 are for discussion and planning purposes only.

RISPERIDONE REMAINS THE MOST COMMONLY USED ANTIPSYCHOTIC TO TREAT SCHIZOPHRENIA



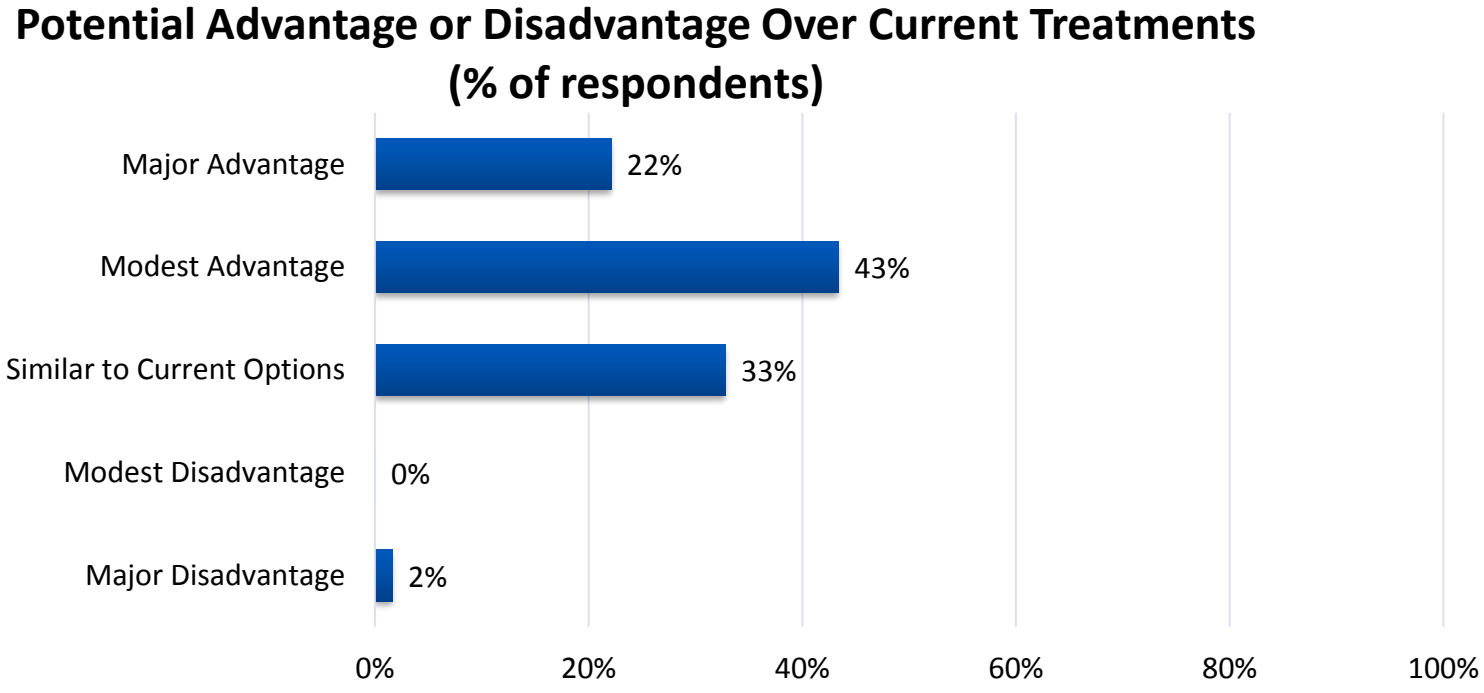
Source: IMS and Source Healthcare, MAT April 2016

LONG-ACTING INJECTABLE SCHIZOPHRENIA MARKET GROWING BY BOTH VOLUME AND VALUE YEAR-OVER-YEAR



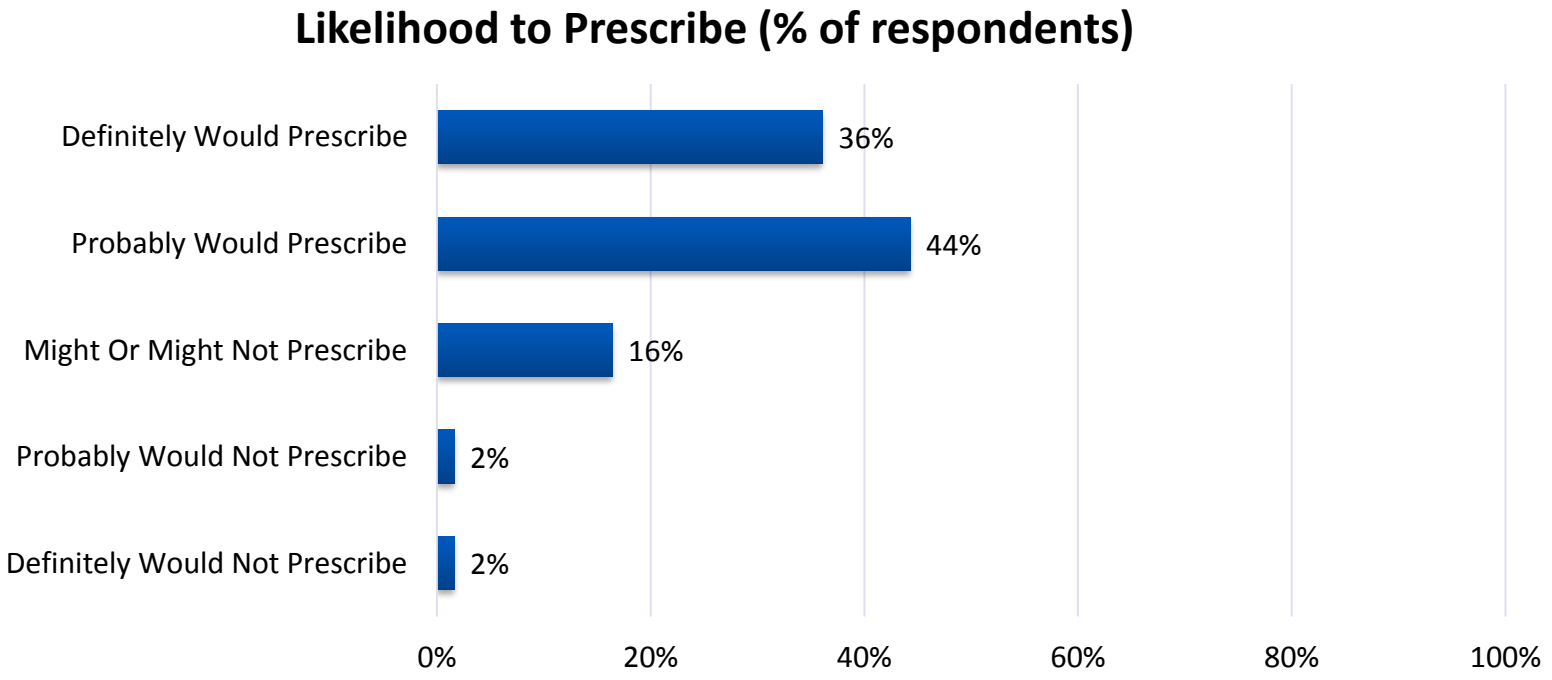
Source: IMS sales, factored for schizophrenia, MAT April 2016

Market research reflecting psychiatrists' Perception of RBP-7000



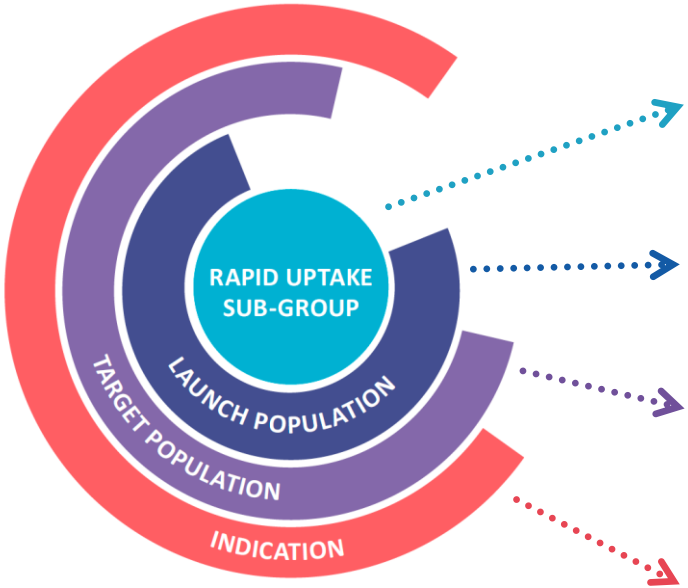
Source: INDV quantitative market research study, Dec 2015 – N=122
Any statements about RBP-7000 are for discussion and planning purposes only.

MARKET RESEARCH REFLECTING LIKELIHOOD TO PRESCRIBE RBP-7000



Source: INDV quantitative market research, Dec 2015 – N=122
Any statements about RBP-7000 are for discussion and planning purposes only.

RBP-7000 Potential Patient Build



	POPULATION DESCRIPTION	MOST COMPELLING DIFFERENTIATOR RELEVANT TO THIS POPULATION
RAPID UPTAKE SUB-GROUP	• Patients with schizophrenia new to LAIs for whom a risperidone-containing LAI is physician target • Patients with schizophrenia currently on risperidone-containing LAI with bi-weekly dosing	Delivers once-monthly risperidone with a pharmacokinetic (PK) profile that may help patients achieve stability and potentially reduce relapse and hospitalizations
LAUNCH POPULATION	Patients with schizophrenia taking oral or injectable risperidone with multiple relapses and/or adherence challenges	Novel method of delivery for the most common and preferred molecule for treatment of schizophrenia
TARGET POPULATION	Schizophrenia patients with multiple relapses and/or adherence challenges, i.e. patients in need of an LAI	Delivers known LAI benefits of lower relapse/hospitalization costs in schizophrenia patients[1]
INDICATION	Schizophrenia patients seeking maintenance treatment	Provides potential benefit to a population for whom relapse is highly debilitating

[1]INDV analysis of Truven Health Marketscan® Commercial and Medicare Supplemental Databases and The Multi-state Medicaid Database Time Period: July 1, 2009 - April 30, 2015
Any statements about RBP-7000 are for discussion and planning purposes only.

INDIVIOR R&D DAY DECEMBER 9TH, 2016

STRENGTHENING OUR GLOBAL LEADERSHIP IN TREATMENT OF ADDICTION

Shaun Thaxter, *Chief Executive Officer*

INDIVIOR

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction

INDIVIOR R&D DAY

STRATEGY & INVESTMENT

How does Indivior best drive growth and thereby shareholder value?

INDIVIOR

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction

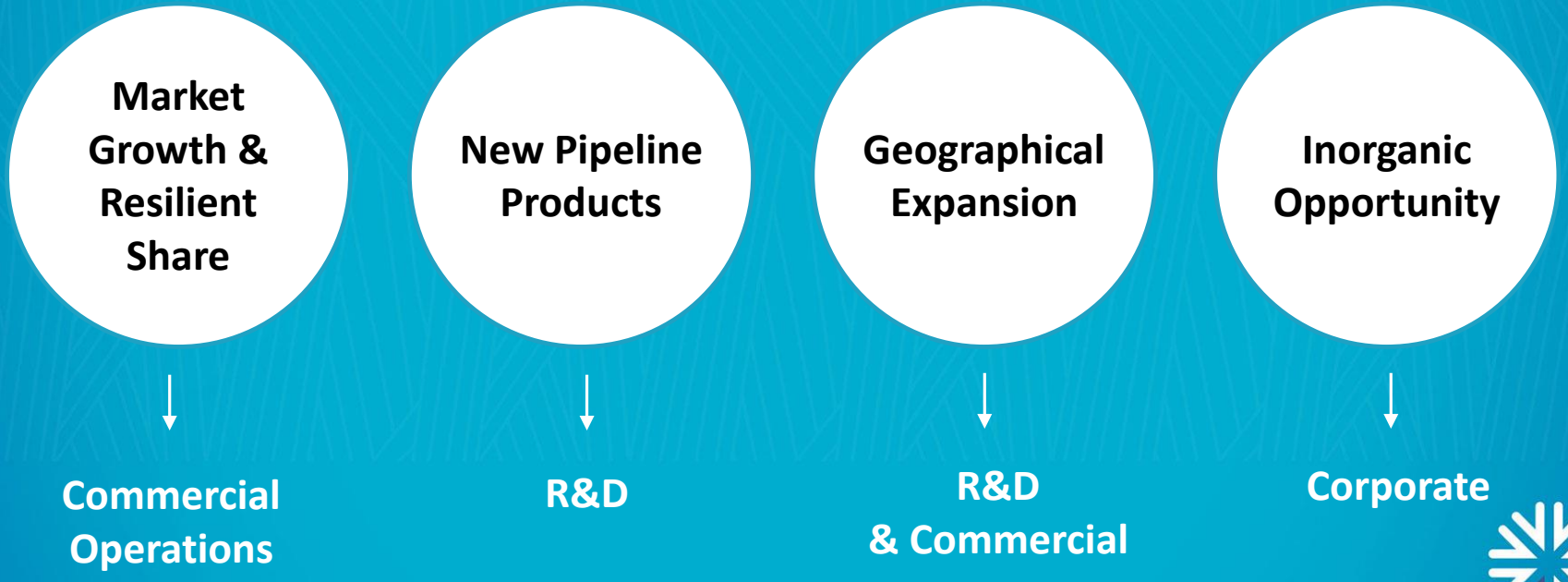
OUR VISION

That all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction

Drivers of Growth for Indivior

- Market Growth & Resilient Share
- New Pipeline Products
- Geographical Expansion
- Inorganic Opportunity

Role of R&D in Generating Drivers of Growth for Indivior



INDIVIOR PLC – PRIORITIES FOR 2016 (AS SHOWN IN FEBRUARY & JULY)

Resolve litigation & investigations and secure long-term certainty for Company

1.SUBOXONE® Film Resilience

Preserve leadership position in USA against 5 (now 7) generic and 3 branded competitors

2. Develop the pipeline

- Transformational lifecycle products for Buprenorphine
- Treatments for other addictions and addiction rescue

3. Finance ready for BD / M&A

- Expand business
- Diversify risk

through targeted business development

US Listing process

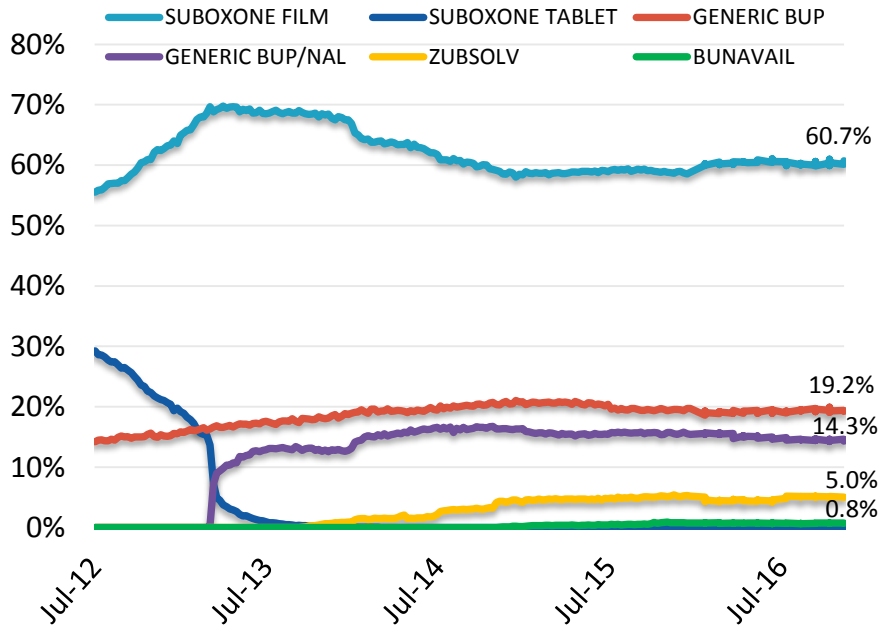
BD/M&A and US listing on hold until litigation/investigation is clarified / resolved

4. Expand Global treatment

- New treatment areas of addiction and related morbidities
- Expand treatment access in USA
- Opioid painkiller dependence in Europe
- File NDA in China

EXISTING BUSINESS

2016 a strong year – resumption of growth implicit in raised guidance



- Market growth is picking up helped by public focus on opioid epidemic.
- Implementation of CARA Act and other regulatory change should create new growth opportunities
- SUBOXONE® Film share has been very resilient
  - ✓ Multiple generic tablet entries and sliding generic pricing
  - ✓ Branded competition not making headway
- Net pricing has been more resilient in 2016
  - ✓ Price increase in January has held (first since 2012)
  - ✓ Formulary access has been maintained

R&D Pipeline Delivery

Success with the major projects

- RBP-6000: Phase 3 efficacy & safety trials concluded
  - ✓ Efficacy achieved all endpoints
- RBP-7000: Phase 3 efficacy & safety trials concluded
  - ✓ Efficacy achieved all endpoints
- Arbaclofen Placarbil: Reformulating and plan for next steps in 2017

Scale of Market Opportunity as indicated on demerger [1]

Product	Potential Peak NR**
RBP-6000	$400m - $700m
RBP-7000	$100m - $200m
Arbaclofen Placarbil	$500m - $900m

- 2014 estimates – markets have grown since then and our knowledge base has increased
- Will revisit peak NR estimates in 2017

[1] *Indivior PLC investor day November 21, 2014, slide 184*

FIRST PRIORITY IS ALWAYS TO INVEST IN ORGANIC GROWTH

Lower risk, investing in what we know

Pre-commercialisation for RBP-6000

Medical education
Healthcare professional & patient preparation
Development of distribution channels
Salesforce training

SUBOXONE® Tablet in China

NDA preparation ongoing
Investing in pre-commercial infrastructure

Accelerating growth in treatment USA

Significant investment in driving patients into treatment opportunities arising from legislative and regulatory change

- Nurse practitioners and physician assistants
- Patient cap raised for certain qualified, waivered doctors

RBP-7000 strategy

Still open minded on route forward – internal or external – and there is no rush to resolve this, NDA not filed until H2-2017

However, time to start education, marketing and medical affairs investment is 2017 whichever route is taken

Business Development – so what have we done?

Reviewed all assets in addiction

Most are competing products with what we already have

There are one or two complimentary products but embedded in other companies

Looked at sensible adjacencies

Reviewed dozens of potential add-on opportunities

Across several different CNS disease spaces

Rejected most

Most make no strategic sense – we would not necessarily add value to them

Or they make no financial sense – they just compound our profile

We have maintained strong capital discipline despite encouragement to diversify fast

Short list of interesting assets

There are several early stage opportunities

But no BD is executable at this time

So we continue to monitor these opportunities and will be prepared to move when opportunity arises.

IMPLICATIONS FOR 2017

- We have already increased our investment by <$35m in 2016 in pre-commercialisation activities primarily for RBP-6000.
- We will likely be looking to step up pre-launch investment in RBP-6000, in China and in driving more access to treatment in US in 2017. The quantum of additional investment for 2017 will be confirmed in February.
- To help offset this increasing P&L cost of the business
  - ✓ Indirect cost project in 2016 (Project Jumpstart) has baked in savings of $8m (some in 2016)
  - ✓ Looking to other aspects of the cost optimisation project to help contain inflation in base business costs.
- Will give detailed guidance on this as part of the 2017 guidance in February.

SUMMARY

We face the future with renewed confidence

INDIVIOR R&D DAY DECEMBER 9TH, 2016

Q&A SESSION

INDIVIOR

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction


INDIVIOR
Focus on you.

ADDENDA

INDIVIOR R&D DAY DECEMBER 9TH, 2016

CLINICAL TRIALS 2016

INDIVIOR

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction

INDIVIOR R&D DAY

SUBOXONE® TABLET CHINA

Single Ascending Dose (RB-CN-10-0012)
Multiple Ascending Dose (RB-CN-10-0013)
Efficacy & Safety (RB-CN-10-0015)

INDIVIOR

Our vision is that all patients around the world will have unrestricted access to high-quality treatment services for the chronic relapsing conditions and co-morbidities of addiction

Single Ascending Dose (RB-CN-10-0012)

Title	A single ascending dose, open-label study to examine the pharmacokinetic profile of SUBOXONE® sublingual tablets 2mg/0.5mg, 4mg/1mg, 8mg/2mg, 12mg/3mg 16mg/4mg and 24mg/6mg in healthy Chinese subjects under a naltrexone block.
Study Phase	Phase 1
Design	Single-dose escalation, open-label PK study
# of patients	82
Primary endpoints	PK profiles of buprenorphine, norbuprenorphine and naloxone
Status	Completed
NCT ref.	N/A

Multiple Ascending Dose (RB-CN-10-0015)

Title	An open-label, parallel-group, multiple-dose, steady-state pharmacokinetic study of SUBOXONE® 16 mg/4 mg and 24mg/6 mg administered to patients who are in withdrawal treatment of opioid dependence
Study Phase	Phase 1
Design	Open-label, multiple-dose study
# of patients	32
Primary endpoints	PK profiles of buprenorphine, norbuprenorphine and naloxone at steady state
Status	Completed
NCT ref.	N/A

EFFICACY & SAFETY (RB-CN-10-0013)

Title	A randomized, double-blind, placebo-controlled multi-center outpatient maintenance study comparing buprenorphine HCl/naloxone HCl dihydrate (SUBOXONE®) versus placebo for treatment of opioid dependence in Chinese subjects stabilized on sublingual buprenorphine hydrochloride/naloxone hydrochloride dihydrate (SUBOXONE®)
Study Phase	Phase 3
Design	Randomized, double blind, placebo controlled
# of patients	260
Primary endpoints	Treatment retention time: Defined as time from randomization to treatment completion or treatment failure
Status	Completed
NCT ref.	N/A

INDIVIOR R&D DAY

RBP-6000 Monthly Buprenorphine

Efficacy & Safety (RB-US-13-0001)
Long-term safety extension (RB-US-13-0003)
Open label extension (INDV-6000-301)
Molecular Weight (RB-US-13-0006)
RECOVER®

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EFFICACY & SAFETY (RB-US-13-0001)

Title	A Randomized, Double-blind, Placebo-Controlled, Multicenter Study to Assess the Efficacy, Safety, and Tolerability of Multiple Subcutaneous Injections of RBP-6000 [100 mg and 300 mg] Over 24 Weeks in Treatment-Seeking Subjects with Opioid Use Disorder
Study Phase	Phase 3
Design	Multi-center, Multi-dose, Randomized, Double-blind, Placebo-controlled, 24-week efficacy, safety, and tolerability study
# of patients	N = 489
Primary endpoints	Abstinence Rate (CDF of the percentage of urine samples combined with self-reports negative for illicit opioid use collected from Week 5 through Week 24). Key Secondary: Responder analysis (defined as ≥80% abstinent rate)
Status	Complete
NCT ref.	NCT02357901

RBP-6000: Comparative Primary & Secondary Endpoints[2]

	RBP-6000	CAM2038	Probuphine	Key differentiators
Primary endpoints	Superiority to placebo on abstinence rate (from illicit opioids)	Non-inferiority to SL BUP on responder rate	Non-inferiority to SL BUP on responder rate	Superiority to placebo is a higher efficacy bar for RBP-6000 trial
Definition of primary endpoint	▪ Abstinence rate week 5-24 ▪ Urines measured weekly. ▪ Missing urines assumed positive. ▪ Supplemental buprenorphine use not allowed.	▪ A responder is defined as a subject with at least: 33% abstinence from illicit opioids during the 12-week induction phase and 67% abstinence during the 12-week treatment phase. ▪ Urines measured weekly during induction phase and twice monthly during treatment phase.	▪ Responder rate (≥ 4 of 6 months -abstinence from illicit opioids). ▪ Urines measured monthly + 4 random measures ▪ Missing urines not counted (20% penalty applied in analysis). ▪ Supplemental buprenorphine use allowed.	RBP-6000 trials set higher bar for primary efficacy endpoints: 1) More rigid definitions of no illicit opioid use 2) RBP-6000 abstinence endpoint was regulatory authority agreed
Definition of Responder	▪ Responder rate (80% abstinence week 5-24) (Key secondary)	▪ A subject with at least: 33% abstinence from illicit opioids during the 12-week induction phase and 67% abstinence during the 12-week treatment phase.	▪ Responder rate (≥ 4 of 6 months -abstinence from illicit opioids).	▪ RBP-6000 higher order responder rate definition
FDA Definition of Responder	▪ Abstinence rate week 5-24	• 75% abstinent rate weeks 9-12 and 83% abstinent rate weeks 13-24.	▪ No illicit opioid use over 6 months with ≤ 2 episodes of rescue medication	▪ The primary endpoint for RBP-6000 was the regulatory-agreed primary endpoint of the study, with dosing designed to achieve opioid blockade
Craving and withdrawal measures	▪ Opioid craving VAS[1] ▪ COWS[1] & SOWS[1]	▪ Unknown	▪ Opioid craving* VAS[1] ▪ COWS[1] & SOWS[1] ▪ Supplemental use of sublingual buprenorphine	▪ Clear measures for craving for treatment-duration ▪ Prescribed supplemental treatment not allowable

*Described as "desire and need to use" in protocol.

[1]VAS: Visual Analog Scale; COWS: Clinical Opiate Withdrawal Scale; SOWS: Subjective Opiate Withdrawal Scale; [2](RB-US-13-0001)

LONG-TERM SAFETY EXTENSION (RB-US-13-0003)

Title	Open-Label, Long-Term Safety and Tolerability Study of RBP-6000 in Treatment-Seeking Subjects With Opioid Use Disorder
Study Phase	Phase 3
Design	Multi-center, Multi-dose, Open-label, long-term safety and tolerability study (extension of RB-US-13-0001)
# of patients	N = 672 (415 de novo, 257 rollover)
Primary endpoints	Adverse events, local injection site tolerability, injection site pain, suicidality, changes in laboratory results, vital signs, ECGs.
Status	Ongoing; interim analysis ongoing for the 500 exposed for 6 months and 100 for 12 months
NCT ref.	NCT02510014

OPEN LABEL EXTENSION (INDV-6000-301)

Title	An Open-Label RBP-6000 Treatment Extension Study in Subjects With Opioid Use Disorder
Study Phase	Phase 3
Design	Multi-center, Multi-dose, Open-label, long-term safety (extension of RB US 13-0003)
# of patients	N = 600 (planned)
Primary endpoints	Safety assessments including AEs, local injection site tolerability, injection site pain, suicidality, changes in clinical laboratory results, vital signs
Status	Ongoing
NCT ref.	NCT02896296

Molecular Weight (RB-US-13-0006)

Title	Pharmacokinetics, Safety, and Tolerability of RBP-6000 at Three Different Molecular Weights in Treatment-Seeking Subjects With Opioid Use Disorder
Study Phase	Phase 1
Design	Randomized, Single-dose, Open-label, PK study using PLGH Polymer of 2 Different Molecular Weights (Low and High) in Comparison to Intermediate Molecular Weight (Reference Treatment)
# of patients	N= 47
Primary endpoints	Bioavailability
Status	Completed
NCT ref.	NCT02559973

RECOVER®

Title	REmission from Chronic Opioid Use: Studying EnVironmental and socioEconomic factors on Recovery
Study Phase	Observational study
Design	12-month multicenter, observational study of subjects either discontinuing or completing RB-US-13-0001 and/or RB-US-13-0003 studies
# of patients	475 (planned)
Primary endpoints	• Periods of abstinence over a 12-month observational window, i.e., # days abstinent, time to relapse, # relapses, and time to return to abstinence after relapse • Biological, psychosocial and environmental factors associated with periods of abstinence and relapse • Health economics impact of treatments for opioid use disorder
Status	Ongoing
NCT ref.	NA

INDIVIOR R&D DAY

RBP-7000 Monthly Risperidone

Long-term safety extension (RB-US-13-0005)
Molecular Weight (RB-US-13-0006)

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LONG-TERM SAFETY EXTENSION (RB-US-13-0005)

Title	An Open-Label, Long-Term Safety and Tolerability Study of RBP-7000 in the Treatment of Subjects With Schizophrenia
Study Phase	Phase 3
Design	An open-label study to assess the long-term safety and tolerability of 120 mg of RBP-7000 subcutaneous (SC) injections administered monthly for up to one year in subjects with schizophrenia. Subjects included rollover subjects from RB-US-09-0010 and *de novo* subjects stabilized on 3 or 4 mg of risperidone prior to treatment. This study also continued collecting clinical outcome data (PANSS & CGI-S) and HEOR data
# of patients	500
Primary endpoints	Evaluation of treatment emergent adverse events (TEAE)
Status	Completed
NCT ref.	NCT02203838

Molecular Weight (RB-US-15-0001)

Title	A Multicenter, Randomized, Open-Label, Single-Dose Study to Evaluate the Pharmacokinetics, Safety, and Tolerability of RBP-7000 Using Poly (DL-lactide-co-glycolide) Polymer of Two Different Molecular Weights (MW) (Low and High MW as Test Treatments) Compared to Intermediate MW (Reference Treatment) Polymer in clinically stable Subjects with schizophrenia not currently taking risperidone
Study Phase	Phase 1
Design	44 subjects (~14 per group) were randomized to receive a single SC injection of RBP-7000 120 mg formulated with PLGH polymer of either 21 kilodaltons (kDa) (low MW group), 29 kDa of PLGH polymer (high MW group), or 26 kDa of PLGH polymer (intermediate MW group).
# of patients	44
Primary endpoints	PK endpoints of AUC and Cmax for initial burst parameters, secondary peak parameters, and overall PK parameters
Status	Completed
NCT ref.	NCT02687984

INDIVIOR R&D DAY

ARBACLOFEN PLACARBIL

Dose-escalation (RB-US-14-0001)
Bioavailability (INDV-AP-102)

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DOSE-ESCALATION (RB-US-14-0001)

Title	A Randomized, Double-Blind, Placebo Controlled, Dose Escalation Study to Determine the Maximum Tolerated Dose of Arbaclofen Placarbil (AP) in Subjects with Alcohol Use Disorder (AUD)
Study	Phase 2A
Design	Randomized Double Blind AP:Placebo 2:1
# of subjects	18
Primary endpoints	To determine the maximum tolerated dose (MTD) of arbaclofen placarbil (AP) in the treatment of subjects with AUD confirmed by Diagnostic and Statistical Manual of Mental Disorders-5 (DSM-5) criteria. To assess the pharmacokinetics (PK) of AP and R-baclofen in subjects with AUD confirmed by DSM-5 criteria, following AP administration
Status	Completed
NCT ref.	NCT02511886

BIOAVAILABILITY (INDV-AP-102)

Title	Phase 1 Bioavailability Study of Arbaclofen Placarbil Modified Release Formulations in Healthy Volunteers
Study Phase	1B
Design	Open Label
# of subjects	12 to 36 depending on success of first formulation
Primary endpoints	To evaluate PK and safety/tolerability of arbaclofen in 2-4 different formulations in HV and its bioavailability with food and alcohol
Status	Planned first dosing 1Q2017
NCT ref.	N/A yet

INDIVIOR R&D DAY DECEMBER 9TH, 2016

PEER-REVIEWED PUBLICATIONS

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INDIVIOR R&D DAY

Peer-Reviewed Publications

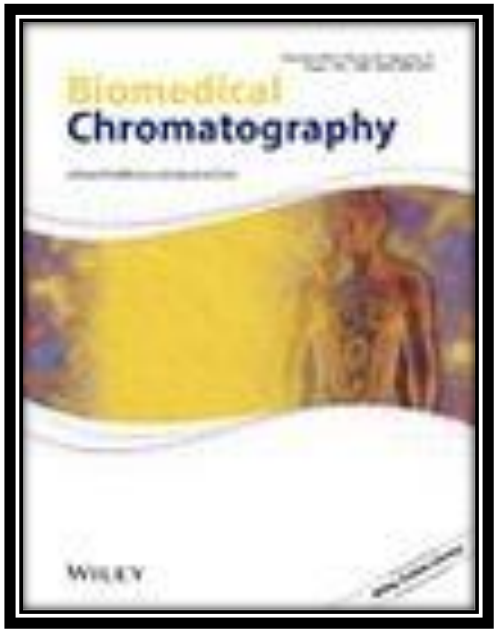
Method Development

METHOD DEVELOPMENT - I

Liu Y, Li X, Xu A, Nasser AF, Heidbreder C (2016) Simultaneous determination of buprenorphine, norbuprenorphine and naloxone in human plasma by liquid chromatography/tandem mass spectrometry. J. Pharm. Biomed. Analysis, 120:142-152.
http://dx.doi.org/10.1016/j.jpba.2015.12.008

- A simple, sensitive and rapid liquid chromatography/electrospray ionization tandem mass spectrometry (LC-ESI-MS/MS) method for **simultaneous quantification of naloxone, buprenorphine and norbuprenorphine** in human plasma.

METHOD DEVELOPMENT - II



Joshi A, Parris B, Liu Y, Heidbreder C, Gerk P, Halquist M (2016) Quantitative determination of buprenorphine, naloxone and their metabolites in rat plasma using hydrophilic interaction liquid chromatography coupled with tandem mass spectrometry. Biomed Chromatogr. Jul 7, Electronic Publication ahead of print. http://dx.doi.org/10.1002/bmc.3785

- A rapid and sensitive LC-MS/MS method for the simultaneous determination of **buprenorphine** and its three metabolites (**buprenorphine glucuronide, norbuprenorphine and norbuprenorphine glucuronide**) as well as **naloxone** and its metabolite **naloxone glucuronide** in the rat plasma.

METHOD DEVELOPMENT - III

Joshi A, Halquist M, Konsoula Z, Liu Y, Jones JP 3rd, Heidbreder C, Gerk PM (2016) Improving the oral bioavailability of buprenorphine: an in-vivo proof of concept. J Pharm Pharmacol. Oct 26, Electronic Publication ahead of print. http://dx.doi.org/10.1111/jphp.12652

- Improve the oral bioavailability of buprenorphine (BUP) by inhibiting presystemic metabolism via the oral co-administration of **generally recognized as safe (GRAS) compounds**, thus providing an orally administered drug product with less variability and comparable or higher exposure compared to the sublingual route.

INDIVIOR R&D DAY

Peer-Reviewed Publications

RBP-6000 Monthly Buprenorphine

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RBP-6000 - I

Nasser AF, Greenwald MK, Vince B, Fudala PJ, Twumasi-Ankrah P, Liu Y, Jones JP III, Heidbreder C (2016) Sustained-Release Buprenorphine (RBP-6000) Blocks the Effects of Opioid Challenge with Hydromorphone in Subjects with Opioid Use Disorder. J Clin Psychopharmacol. 36(1):18-26. http://dx.doi.org/10.1097/JCP.0000000000000434

- Demonstrate that **RBP-6000 blocks the subjective effects and reinforcing efficacy of hydromorphone** in subjects with moderate or severe opioid use disorder (OUD).
- RBP-6000 at a 300 mg dose provides durable and potent blockade of the subjective effects and reinforcing efficacy of hydromorphone in subjects with moderate or severe OUD.

RBP-6000 - II

Laffont CM, Gomeni R, Heidbreder C, Jones JP 3rd, Nasser AF (2016) Population Pharmacokinetic Modeling After Repeated Administrations of RBP-6000, a New, Subcutaneously Injectable, Long-Acting, Sustained-Release Formulation of Buprenorphine, for the Treatment of Opioid Use Disorder. J Clin Pharmacol. 56(7):806-815.
http://dx.doi.org/10.1002/jcph.665

- A **population pharmacokinetic (PK) model** associated with predicted levels of μ-opioid receptor occupancy described the time course of buprenorphine plasma concentrations after repeated SC injections of RBP-6000 at 50 mg, 100 mg, 200 mg, or 300 mg in treatment-seeking opioid-dependent subjects previously on SUBUTEX® treatment.
- The model provided quantitative criteria for clinical dose selection of RBP-6000 with a dosage strength of 300 mg every 28 days immediately achieving effective exposure after the first SC injection and maintaining effective levels of exposure during chronic treatment.

INDIVIOR R&D DAY

Peer-Reviewed Publications

RBP-7000 Monthly Risperidone

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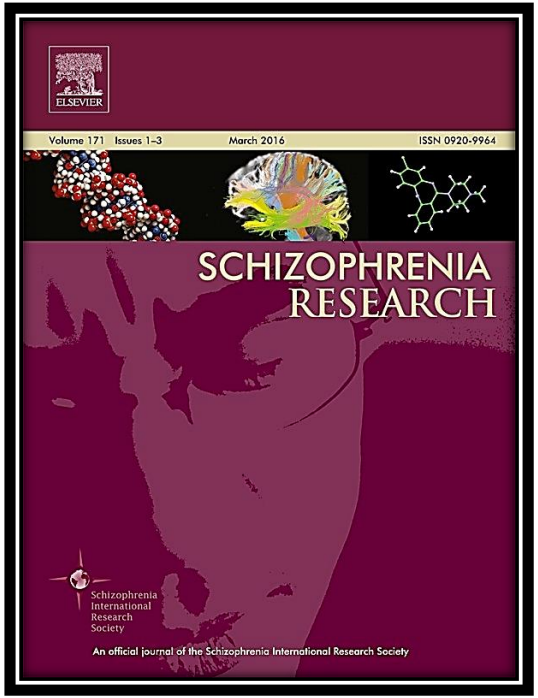
RBP-7000 - I

Nasser AF, Henderson DC, Fava M, Fudala PJ, Twumasi-Ankrah P, Kouassi A, Heidbreder C (2016) Efficacy, safety and tolerability of RBP-7000 once monthly risperidone for the treatment of acute schizophrenia: An 8-week, randomized, double-blind, placebo-controlled, multicenter Phase 3 study. J. Clin. Psychopharmacology, 36(2):130-140.
http://dx.doi.org/10.1097/JCP.0000000000000479

- Assess the **efficacy, safety, and tolerability of RBP-7000** (90, 120 mg) compared to placebo in subjects with acute exacerbation of schizophrenia over an 8-week period.
- Efficacy was evaluated as a change from baseline to EOS in Positive and Negative Syndrome Scale (PANSS) total score (*primary endpoint*) and Clinical Global Impression – Severity (CGI-S) score (*secondary endpoint*).
- RBP-7000 significantly reduced PANSS total scores and significantly improved CGI-S scores. Both RBP-7000 dosages were well tolerated.

RBP-7000 - II



Isitt JJ, Nadipelli VR, Kouassi A, Fava M, Heidbreder C (2016) Health-related quality of life in acute schizophrenia patients treated with RBP-7000 once monthly risperidone: An 8-week, randomized, double-blind, placebo-controlled, multicenter phase 3 study. Schizophr Res. 174(1-3):126-131. *http://dx.doi.org/10.1016/j.schres.2016.03.020*

- **Health-Related Quality of Life data** derived from pivotal Phase 3 trial.
- Significantly greater improvements in HRQoL and overall well-being were demonstrated in patients randomized to RBP-7000 vs. placebo.
- Patient satisfaction improved significantly and patient preference for their medicine favored RBP-7000 90 mg and 120 mg vs. Placebo.

INDIVIOR R&D DAY

Peer-Reviewed Publications

Early Stage Asset Development

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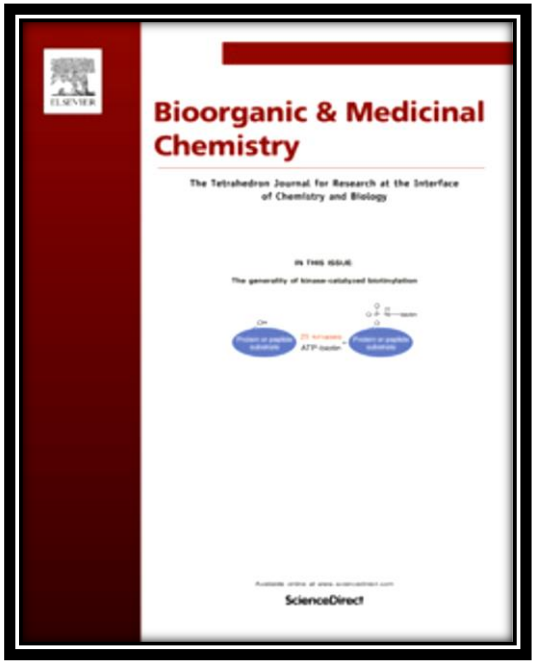
EARLY STAGE ASSET DEVELOPMENT - I

Micheli F, Cremonesi S, Semeraro T, Tarsi L, Tomelleri S, Cavanni P, Zonzini L, Feriani A, Braggio S, Heidbreder C (2016) Novel morpholine scaffolds as selective dopamine (DA) D3 receptor antagonists. Bioorganic & Medicinal Chemistry, 26(4): 1329-1332.
http://dx.doi.org/10.1016/j.bmcl.2015.12.081

- Selective DA D3 receptor antagonists have been shown to reduce or block drug-induced **incentive motivation**, attenuate drug's **rewarding efficacy**, and reduce **reinstatement** of drug-seeking behavior.
- A joint **computational-medicinal chemistry "scaffold hopping" strategy** resulted in the discovery of novel, selective and developable DA D3 receptor antagonists.
- The **lead optimization** of this new class is currently ongoing.

EARLY STAGE ASSET DEVELOPMENT - II



Micheli F, Bernardelli A, Bianchi F, Braggio S, Castelletti L, Cavallini P, Cavanni P, Cremonesi S, Cin MD, Feriani A, Oliosi B, Semeraro T, Tarsi L, Tomelleri S, Wong A, Visentini F, Zonzini L, Heidbreder C (2016) 1,2,4-Triazolyl Octahydropyrrolo[2,3-b]pyrroles: A New Series of Potent and Selective Dopamine D3 Receptor Antagonists. Bioorganic & Medicinal Chemistry, 24(8): 1619-1636. http://dx.doi.org/10.1016/j.bmc.2016.02.031.

- A detailed **structure activity relationship (SAR) and pharmacokinetic (PK) *in vitro* and *in vivo* strategy** was described to characterize this new series of highly potent and selective DA D3 receptor antagonists.
- The **lead optimization** of this new class is currently ongoing.

EARLY STAGE ASSET DEVELOPMENT - III

Micheli F, Bacchi A, Bernardelli A, Braggio S, Castelletti L, Cavallini P, Cavanni P, Cremonesi S, Dal Cin M, Feriani A, Kajbaf M, Marchió L, Oliosi B, Pellacani A, Perdona E, Sava A, Semeraro T, Tarsi L, Tomelleri S, Wong A, Visentini F, Zonzini L, Heidbreder C (2016) 1,2,4-Triazolyl 5-Azaspiro[2.4]heptanes: Lead Identification and Early Lead Optimization of a New Series of Potent and Selective Dopamine D3 Receptor Antagonists. J. Med. Chem. 59(18):8549-8576. *http://dx.doi.org/10.1021/acs.jmedchem.6b00972*

- A novel series of **1,2,4-Triazolyl 5-Azaspiro[2.4]heptanes** with high affinity and selectivity at the DA D3 receptor was described.
- A few derivatives with overall favorable developability characteristics were selected for further late lead optimization studies.

INDIVIOR R&D DAY

LITIGATION UPDATE

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LITIGATION PROVISION

The Company has recorded a charge of $220m in the third quarter of 2016 for the investigative and antitrust litigation matters noted below. Because these matters are in various stages, the Company cannot predict with any certainty the ultimate resolution or cost of all of the matters. The final amount might be materially different from this reserve.

Department of Justice Investigation

A federal criminal grand jury investigation of Indivior initiated in December 2013 is continuing, and includes marketing and promotion practices, pediatric safety claims, and overprescribing of medication by certain physicians. The U.S. Attorney's Office for the Western District of Virginia has served a number of subpoenas relating to SUBOXONE® Film, SUBOXONE® Tablet, SUBUTEX® Tablet, buprenorphine and our competitors, among other issues. We are in the process of responding by producing documents and other information in connection with this on-going investigation, and in preliminary discussion about a possible resolution of the investigation. It is not possible at this time to predict with any certainty the potential impact of this investigation on us or to quantify the ultimate cost of a resolution. We are cooperating fully with the relevant agencies and prosecutors and will continue to do so.

State Subpoenas

On October 12, 2016, the Company was served with a subpoena for records from the state of Connecticut Office of the Attorney General under its Connecticut civil false claims act authority. The subpoena requests documents related to the Company's marketing and promotion of SUBOXONE® products and its interactions with a non-profit third party organization. On November 16, 2016, the Company was served with a subpoena for records from the state of California Department of Insurance under its California insurance code authority. The subpoena requests documents related to SUBOXONE® Film, SUBOXONE® Tablet, and SUBUTEX® Tablet. The Company is cooperating in these investigations.

FTC Investigation

The Judge overseeing the legal privilege dispute in the FTC investigation has appointed a Special Master (an independent external lawyer) to investigate the claims of legal privilege and provide a recommendation to the Court on how the documents at issue should be treated. An initial report and recommendation relating to the first tranche of privileged documents reviewed by the Special Master was finalized in April 2016 and adopted by the Court on August 1st, 2016. Pursuant to this report and the Court's order, Indivior produced certain additional documents. A second tranche of documents remains under review. Following that review, the Court's decision then may be subject to appeal by either party.

Antitrust Litigation

Fact discovery is continuing in the antitrust class action litigation described on our Annual Report ("Class Action Litigation"). Plaintiffs allege, among other things, that Indivior violated federal and state antitrust laws in attempting to delay generic entry of alternatives to SUBOXONE®® tablets, and plaintiffs further allege that Indivior unlawfully acted to lower the market share of these products.

Amneal Pharmaceuticals LLC, a manufacturer of generic buprenorphine / naloxone tablets, filed a complaint against the Company in December 2015. This case has been coordinated with the Class Action litigation. Amneal's complaint contains antitrust allegations similar in nature to those set out in the class action complaints, and Amneal has also alleged violations of the Lanham Act.

On September 22, 2016, 35 states and the District of Columbia filed a complaint against the Company in the same district where the Class Action and *Amneal* litigation is pending. The States' complaint is similar to the other pending complaints, and alleges violations of state and federal antitrust and consumer protection laws.

On November 16, 2016 the States served an amended complaint, adding six additional states as plaintiffs. This lawsuit relates to the investigation conducted by various states, as discussed in previous filings.

ANDA Litigation

The ruling after trial against **Actavis** and **Par** in the lawsuit involving the Orange Book-listed patents for SUBOXONESUBOXONE® Film issued on June 3rd, 2016. Ruling found the asserted claims of the '514 patent valid and infringed; the asserted claims of the '150 patent valid but not infringed; and the asserted claims of the '832 patent invalid, but found that certain claims would be infringed if they were valid.

Based on the ruling as to the '514 patent, **Actavis** and **Par** are currently enjoined from launching a generic product. Par has appealed and **Actavis** is expected to appeal this ruling. The generics have also moved to reopen the judgment based on a more stringent claim construction in the **Dr Reddy's** case. In light of the motions to reopen, **Par's** appeal has been deactivated until the District Court rules on the motions, and the deadline for **Actavis** to file a notice of appeal has been postponed.

Trial against **Dr. Reddy's, Actavis and Par** in the lawsuits involving the process patent (US Patent No. 8,900,497) took place on November 16th and 21st-23rd, 2016.

Trial against **Dr. Reddy's** in the lawsuit involving the Orange Book-listed patents for SUBOXONESUBOXONE® Film took place on November 7th, 16th, and 21st-23rd, 2016, with **Dr. Reddy's** 30-month stay of FDA approval on ANDA No. 20-5806 expiring April 17th, 2017. Indivior believes **Dr. Reddy's** 30-month stay of FDA approval on ANDA No. 20-5299 also expires on April 17th, 2017, however, **Dr Reddy's** disputes the applicability of the stay to this ANDA.

Trial against **Alvogen** in the lawsuit involving the Orange Book-listed patents and **the '497** process patent for SUBOXONESUBOXONE® Film has been postponed and is presently expected to take place in September 2017, with Alvogen's 30-month stay of FDA approval expiring October 29th, 2017.

By a Court order dated August 22nd, 2016, Indivior's SUBOXONE® Film patent litigation against **Sandoz** has been dismissed without prejudice because Sandoz is no longer pursuing Paragraph IV certifications for its proposed generic formulations of SUBOXONE® film.

Trial against **Mylan** in the lawsuit involving the Orange Book-listed patents and the '497 process patent for Suboxone® Film is scheduled for September 25th, 2017, with Mylan's stay expiring March 24, 2018

Indivior received a Paragraph IV notification from **Teva**, dated February 8, 2016, indicating that Teva had filed a 505(b)(2) New Drug Application (NDA) for a 16mg/4mg strength of Buprenorphine/naloxone sublingual film. The Indivior Group and Teva agreed that infringement by Teva's 16 mg/4 mg dosage strength will be governed by the infringement ruling on the accused 8 mg/2 mg dosage strength in its ANDA currently scheduled for trial in November 2016.

Inter-Partes Reviews

The USPTO declined to institute **Teva's** petitions for inter partes review of the three Orange Book-listed patents on procedural grounds.

Dr. Reddy's has filed an inter partes review petition on each of the three Orange Book Patents. These petitions are substantively similar to those filed by Teva. The USPTO denied the petitions, finding Dr. Reddy's had failed to establish a reasonable likelihood of showing the challenged claims are unpatentable as obvious.

Certain claims of the '832 patent were found invalid in an IPR proceeding brought by **BioDelivery Sciences International (BDSI)**, a decision that has been affirmed by the Court of Appeals for the Federal Circuit.

ALL-UM-M-1000-1612

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