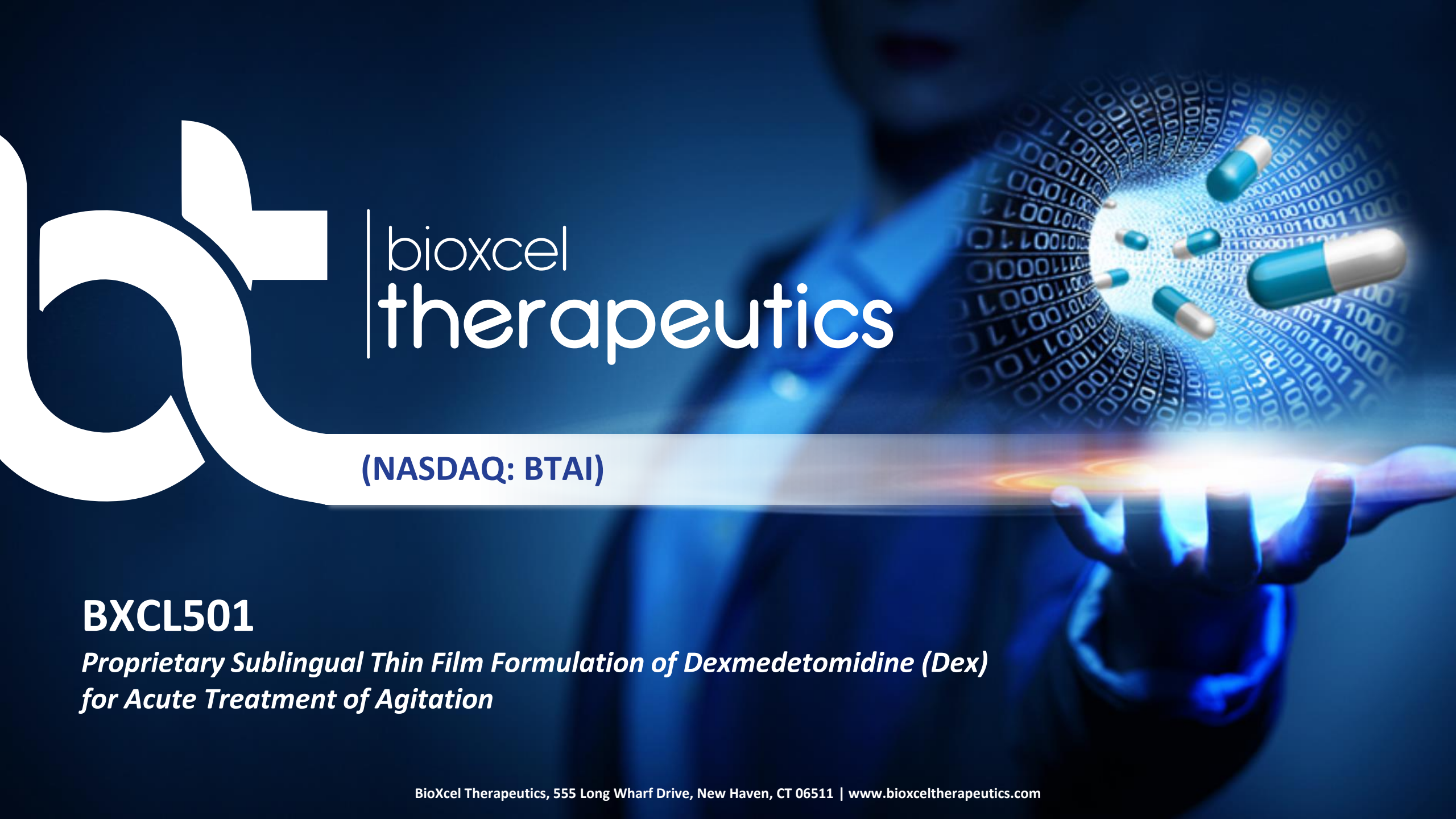
bioxcel therapeutics

(NASDAQ: BTAI)



BXCL501

Proprietary Sublingual Thin Film Formulation of Dexmedetomidine (Dex) for Acute Treatment of Agitation

Forward-Looking Statements

This presentation includes “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements in this presentation include, but are not limited to, statements that relate to the advancement and development of BXCL501 and BXCL701, the commencement of clinical trials, the availability and results of data from clinical trials, the planned timing of BioXcel Therapeutic, Inc.'s (“BTI”) submission of its first New Drug Application with the FDA and other information that is not historical information. When used herein, words including “anticipate”, “being”, “will”, “plan”, “may”, “continue”, and similar expressions are intended to identify forward-looking statements. In addition, any statements or information that refer to expectations, beliefs, plans, projections, objectives, performance or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking. All forward-looking statements are based upon BTI's current expectations and various assumptions. BTI believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BTI may not realize its expectations, and its beliefs may not prove correct. Actual results could differ materially from those described or implied by such forward-looking statements as a result of various important factors, including, without limitation, its limited operating history; its incurrence of significant losses; its need for substantial additional funding and ability to raise capital when needed; its limited experience in drug discovery and drug development; its dependence on the success and commercialization of BXCL501 and BXCL701 and other product candidates; the failure of preliminary data from its clinical studies to predict final study results; failure of its early clinical studies or preclinical studies to predict future clinical studies; its ability to receive regulatory approval for its product candidates; its ability to enroll patients in its clinical trials; its approach to the discovery and development of product candidates based on EvolverAI is novel and unproven; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; its ability to commercialize its product candidates; and the other important factors discussed under the caption “Risk Factors” in its Quarterly Report on Form 10-Q for the period ended March 31, 2019 as such factors may be updated from time to time in its other filings with the SEC, which are accessible on the SEC's website at www.sec.gov.

These and other important factors could cause actual results to differ materially from those indicated by the forward-looking statements made in this presentation. Any such forward-looking statements represent management's estimates as of the date of this presentation. While BTI may elect to update such forward-looking statements at some point in the future, except as required by law, it disclaims any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing BTI's views as of any date subsequent to the date of this presentation.

Agenda

WELCOME & INTRODUCTIONS

BXCL501 STRATEGY & VISION

ACUTE AGITATION OVERVIEW

- Schizophrenia/Bipolar Disorder
- Dementia
- Opioid Withdrawal
- Hyperactive Delirium

BXCL501 CLINICAL PROGRAM UPDATE

- Summary of Clinical Results
- Overview of Registration Trial Path
- Agitation Franchise Expansion

KOL PANEL & Q&A

CORPORATE OUTLOOK & CLOSING REMARKS

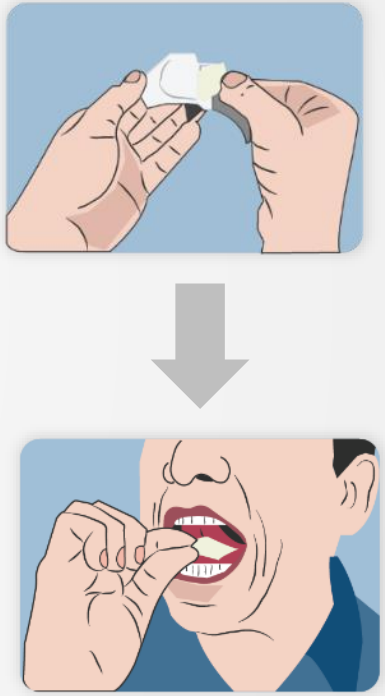
BXCL501 Strategy & Vision

Proprietary Sublingual Thin Film Technology

Automated process for scale up to Phase III and commercial readiness

Phase 3 and Commercial Readiness

- **Transitioned to automated manufacturing**
- **GMP automated manufacture initiated**
- Scale up and supply phase 3 in 2H 2019 and commercial readiness in 2020

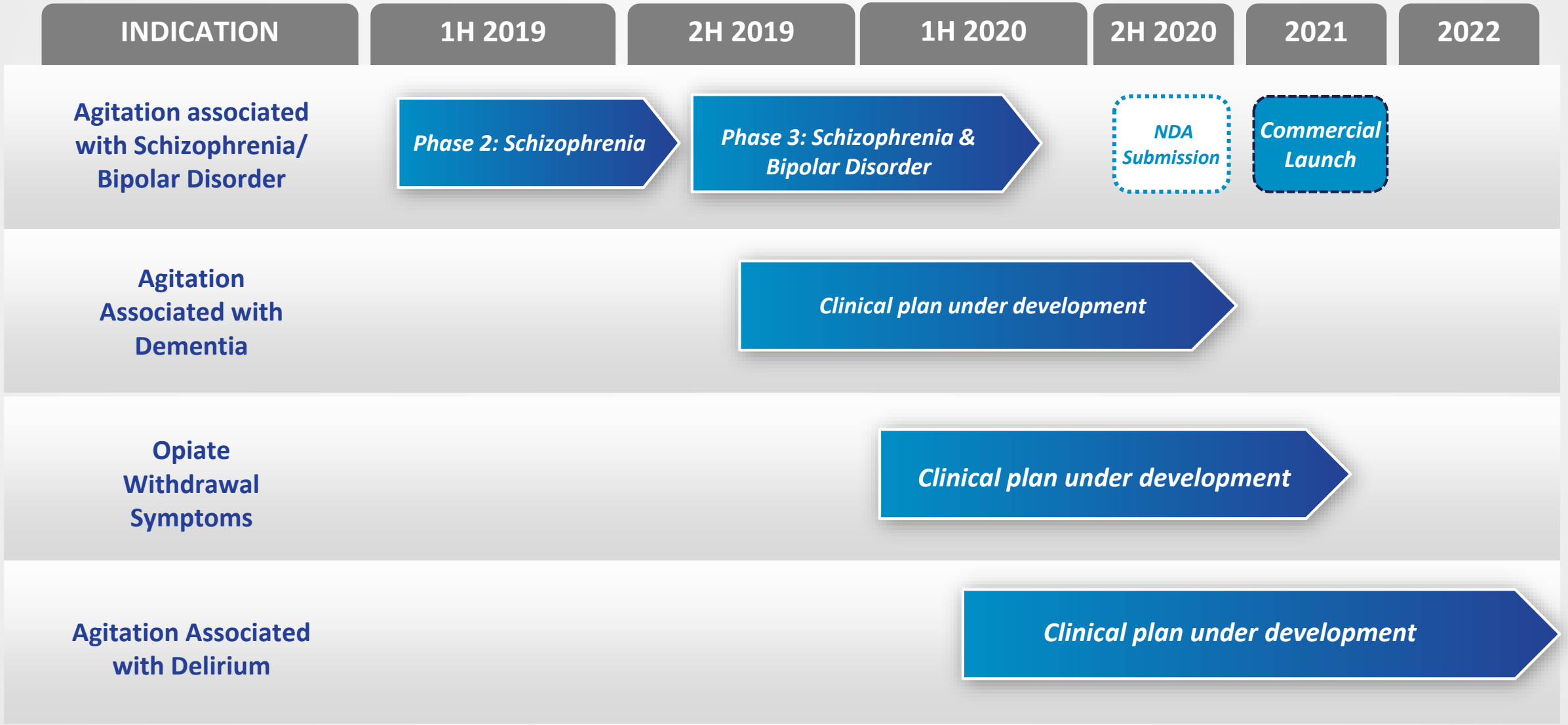


Ideal Pharmaceutical Properties for a Non-invasive Sublingual Film Formulation

- **Immediate release film** with **muco-adhesion**
- **Proprietary technology**
- Delivers **broad range of doses**
- Flexible for **combination dosing / therapy**

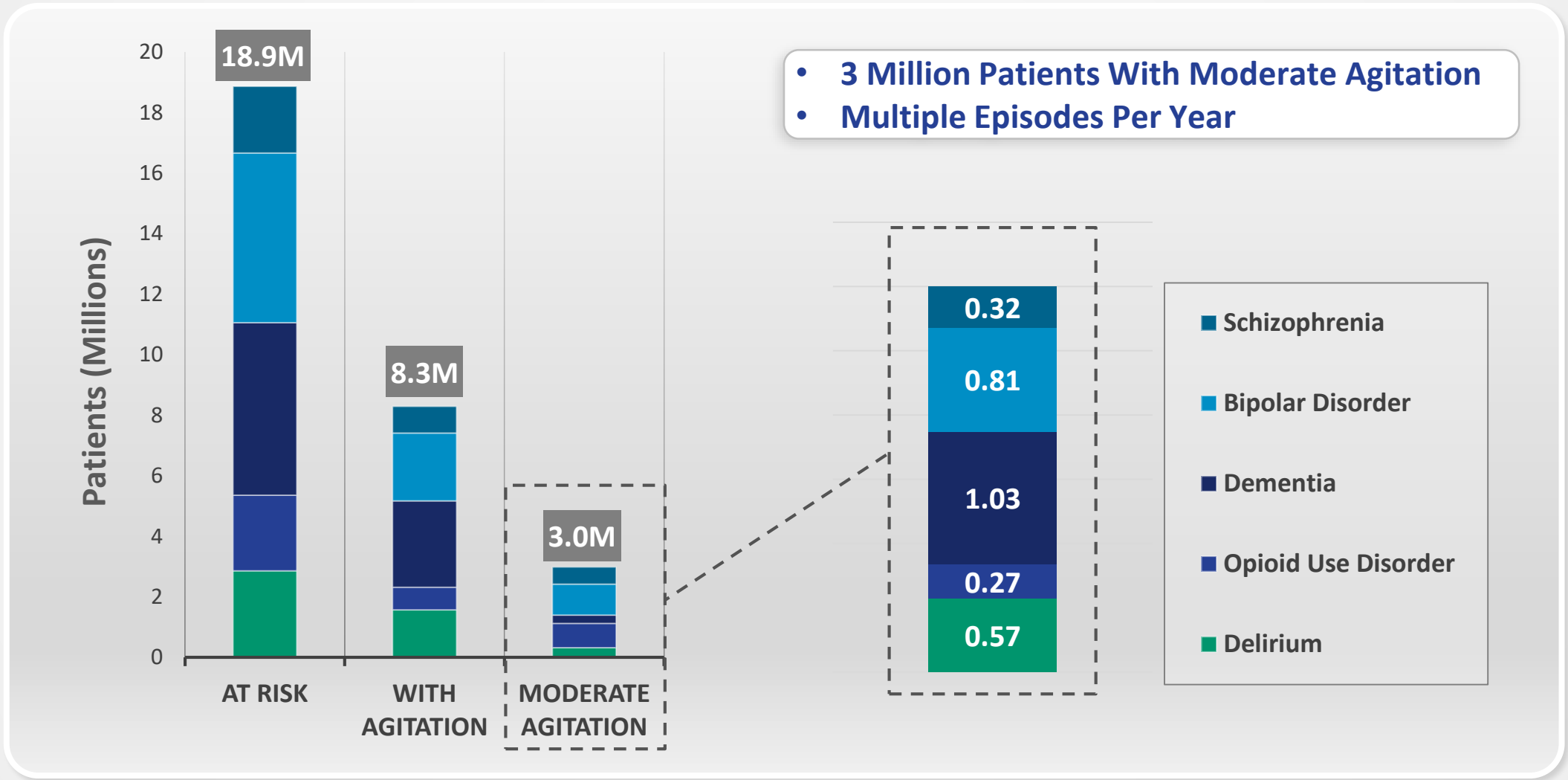
Clinical Development Plans Across Multiple Neuropsychiatric Medical Conditions

Initial NDA submission in 2H 2020



BXCL501 US Commercial Opportunity

Target Patient Population Estimated at 3 Million



Sources: -Internal Company Estimates
-https://www.sccm.org/Communications/Critical-Care-Statistics
-https://psychiatryonline.org/doi/pdf/10.1176/appi.books.9780890426807
-https://www.samhsa.gov/data/
-https://www.nimh.nih.gov/health/statistics/index.shtml

BTAI Team

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PETER MUELLER, PH.D.
Chairman of Board

BXCL501: Sublingual Thin Film Dexmedetomidine (Dex) for Acute Treatment of Agitation

Agitation: A Growing Global Healthcare Issue ($40B+)

Unmet Need

Current **Treatments are Suboptimal**

Consensus Opinion*

- ✓ **Non-invasive**
- ✓ **Calmness without sedation**
- ✓ **Easy to administer**
- ✓ **Rapid onset**
- ✓ **Non-traumatic / non-coercive**
- ✓ **Good safety profile**
- ✓ **Favorable tolerability**
- ✓ **Patient preference**

FDA ***Fast Track Designation***

BXCL501: An **innovative approach:**

- ✓ Novel mechanism of action (MoA) targets a **causal agitation pathway**
- ✓ Non-Invasive, easy to administer **sublingual film** with **rapid onset of action**

***1st International Experts' Meeting on Agitation: Conclusions Regarding the Current and Ideal Management Paradigm of Agitation, Frontiers in Psychiatry 2018**

Acute Agitation Overview

Schizophrenia/Bipolar Disorder

Sheldon Preskorn, M.D

Psychomotor Agitation

Associated with Poor Outcomes in Patients with Schizophrenia or Bipolar Disorder

Psychomotor agitation is characterized by motor restlessness and irritability (mild) progressing to aggressive and/or violent behavior (severe).

Prevalence

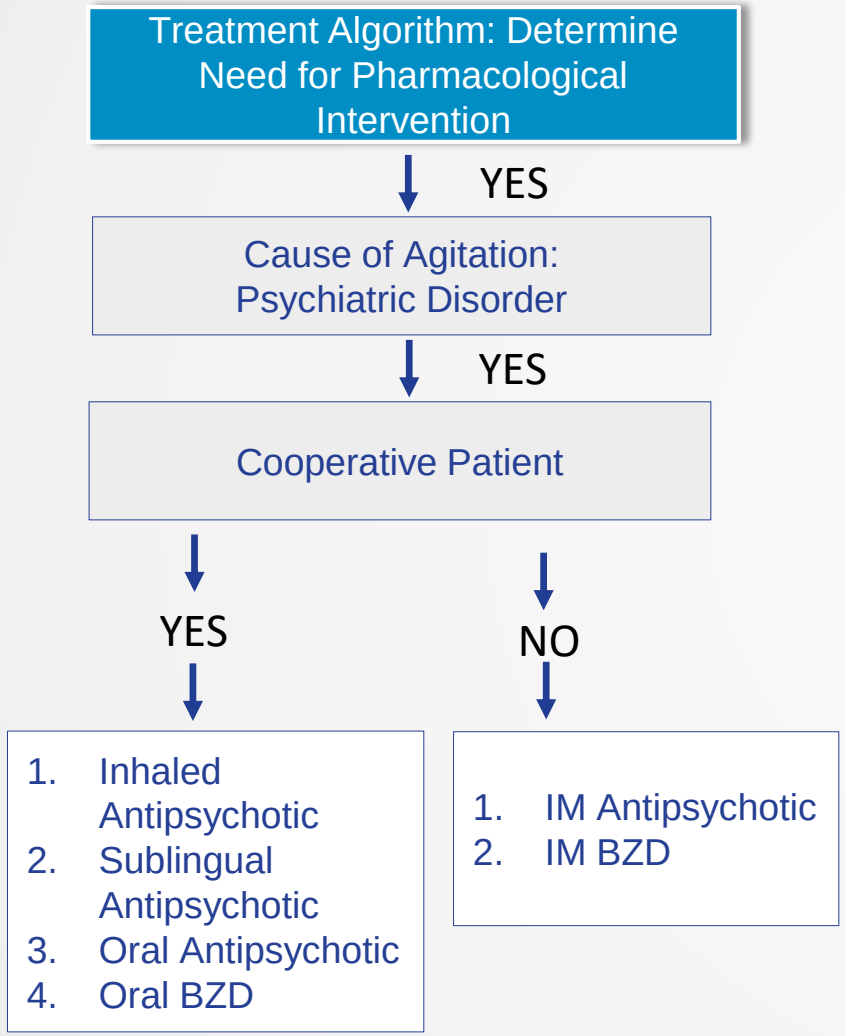
- **Approximately 8 million individuals in the United States are diagnosed with schizophrenia or bipolar disorder.**
- **10% to 31% of all patients with schizophrenia or related psychotic disorders exhibit aggressive or violent behavior.**
- **Acute episodes of psychomotor agitation represent a substantial number of emergency department visits per year in the USA.**

Agitation in hospitals associated with

- **Longer hospital stays**
- **Increased medication consumption**
- **Higher readmission rates**
- **Increased number of violent incidents against staff**

Current Treatment Paradigm for Psychomotor Agitation

What are the Unmet Needs for an Ideal Drug?

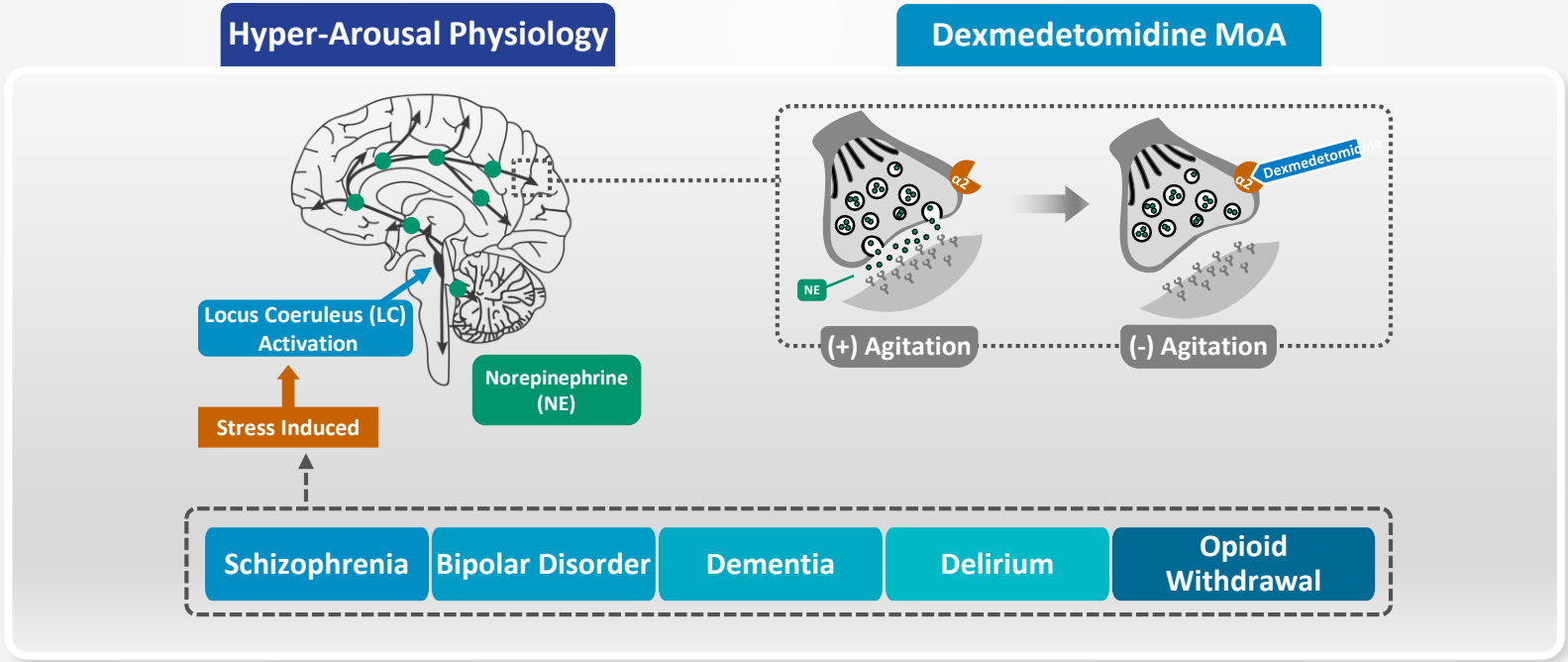


Characteristics of an Ideal Drug For Treatment of Psychomotor Agitation in Patients with Schizophrenia or Bipolar Disease			
FACTOR	**BXCL501**	**Oral BZD**	**IM Antipsychotic**
Calm without sedation	**YES**	**NO**	**NO**
Directly targets hyper-arousal cause of agitation	**YES**	**NO**	**NO**
Non-invasive, non-traumatic route of administration	**YES**	**YES**	**NO**
Rapid onset of action	**YES**	**NO**	**YES**
Unlikely Respiratory Depression	**YES**	**NO**	**YES**
Unlikely Adverse CV or Motor Events	**YES**	**YES**	**NO**

PREDICTION: *BXCL501 (Dex on a sublingual film) will exhibit a superior profile compared to currently used drugs for the acute treatment of agitation in patients with schizophrenia or bipolar disease*

Mechanism of Action of Dex

- Dex is a selective alpha-2A adrenergic agonist.
- Currently marketed as Precedex™ for intravenous (IV) administration to sedate/anesthetize patients prior to and/or during surgical procedures and to sedate intubated and mechanically ventilated patients.
- Dex may be useful for the treatment of agitation in patients with neuropsychiatric disorders like senile dementia of the Alzheimer's Type (SDAT) and schizophrenia at a much lower dose that does not cause drowsiness.



Psychomotor Agitation in Patients with Schizophrenia or Bipolar Disease

Patient Population for BXCL501

BXCL501

- Sublingual thin film formulation of Dex
- Intended for patients with mild to moderate agitation

- Treats the underlying cause of stress-induced agitation (sympathetic hyper-arousal)

Goals of Therapy:

- Increase cooperation of mildly agitated patients (shorten time in hospital)
- Prevent escalation of mild agitation to severe agitation

Degree of Agitation	Patient's Feelings	PEC Score
MILD	Nervous Tense Grumpy Anxious	13
MODERATE	Insulting Frightened In danger	19
SEVERE	Aggressive Violent Desperate Confused	31

Intended Patient Population for BXCL501

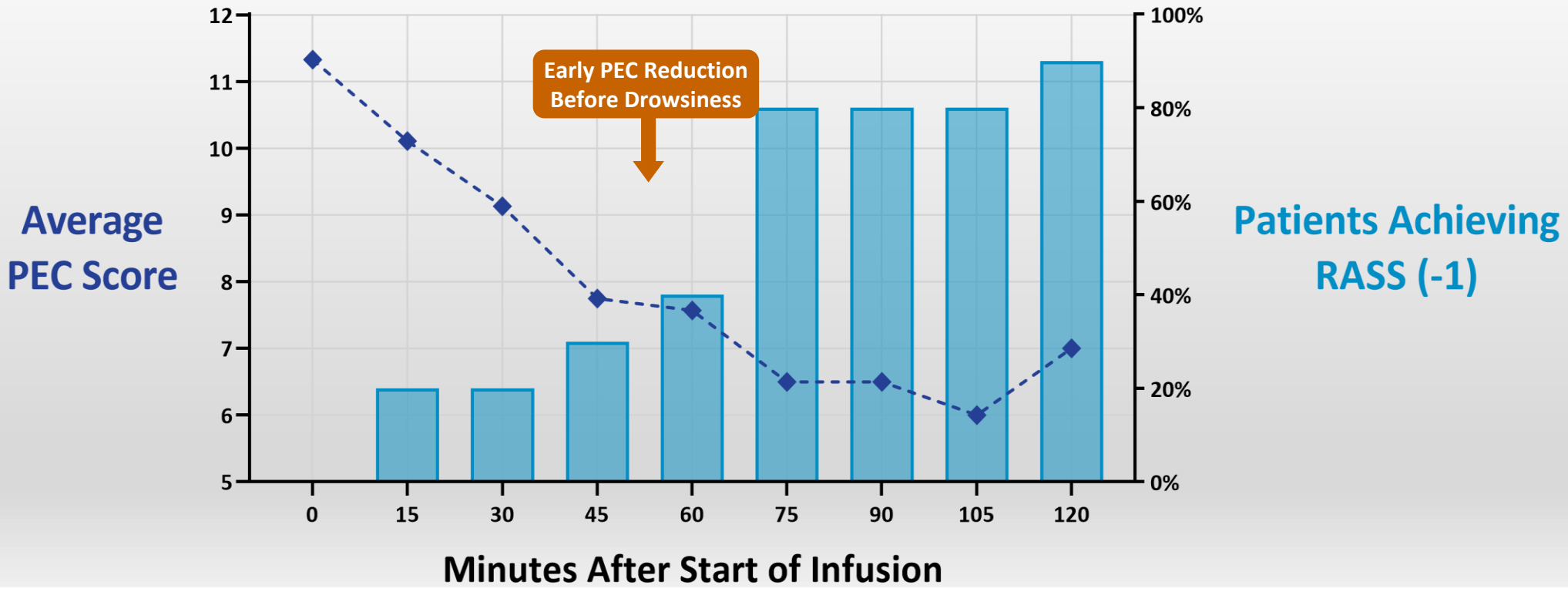
Human Proof of Concept: IV Dexmedetomidine Reduces Agitation in Schizophrenia Patients

Study results announced Nov 2018: primary endpoint met

Study Design

- Randomized, placebo-controlled dose-ranging study
- 14 patients [10 treatment + 4 placebo]
- Primary endpoint: RASS of -1
- Secondary endpoint: PEC score of 7 or below

90% Response



9/10 patients achieved RASS score of -1

9/10 patients achieved PEC score of 7 or below

No clinically relevant cardiovascular changes

Dementia

George Grossberg, M.D.

AGITATION AND ALZHEIMER'S DISEASE / DEMENTIA

George T. Grossberg, MD
Samuel W. Fordyce Professor
Director, Geriatric Psychiatry
Department of Psychiatry & Behavioral Neuroscience
St Louis University School of Medicine

Disclosures

- Consultant—Acadia, Accera, Alkahest, Allergan, Avanir, Axovant, BioXcel, GE, Genentech, Grifols, Lundbeck, Novartis, Otsuka, Roche,Takeda

- Research support— Genentech/Roche, Janssen, NIH
- Safety monitoring committee—EryDel, ITI, Merck, Newron

Alzheimer’s Disease : A World-wide Epidemic

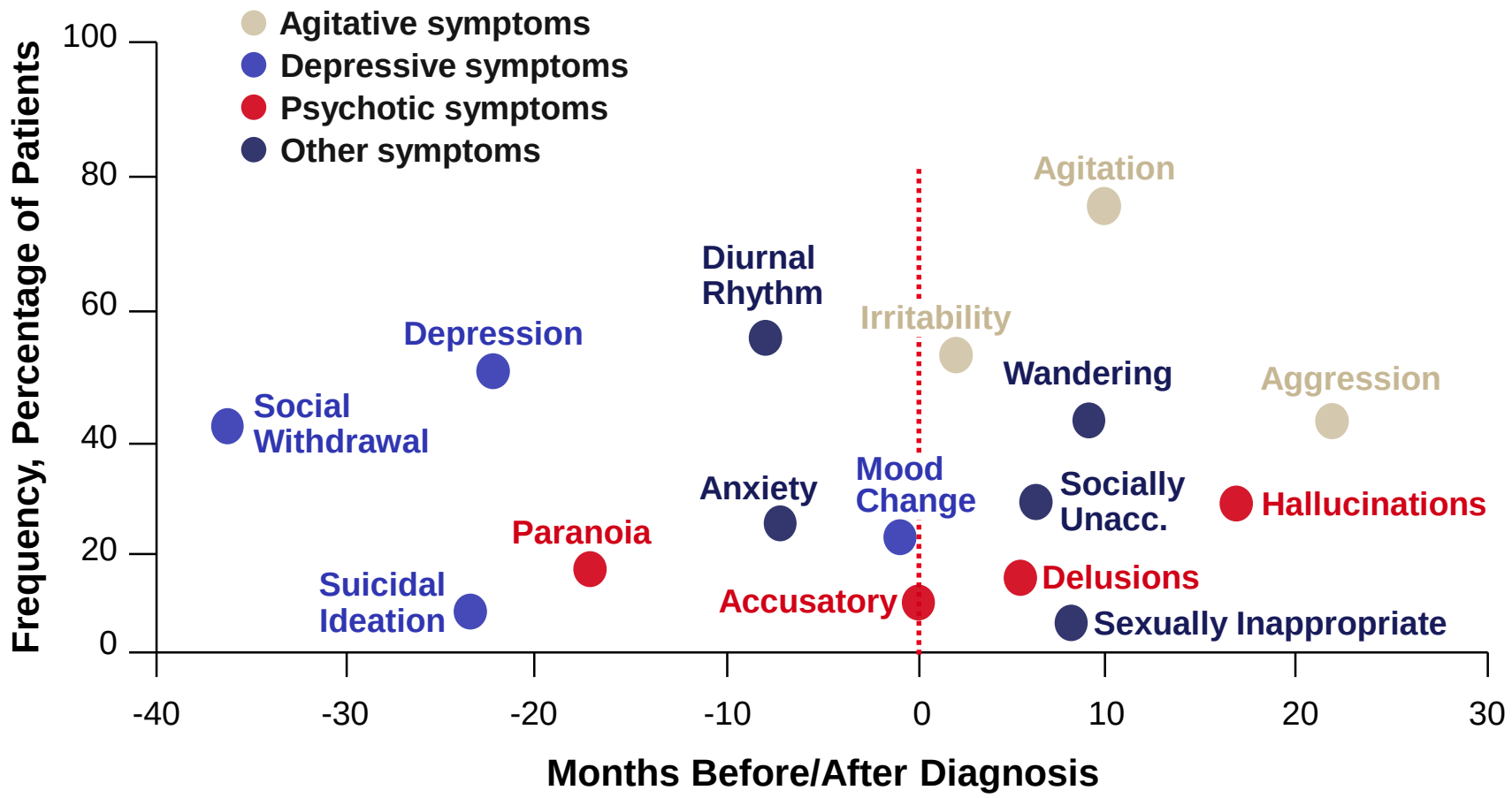
WHO & Alzheimer’s International

ALZHEIMER'S DISEASE (AD) : QUICK FACTS

- 6th leading cause of death in US
- >16 million Americans provide unpaid care. 18.5 Billion hours of care annually, worth ~ $234 Billion
- Between 2000 and 2017 deaths from heart disease declined 9% while deaths from AD increased 145%
- 1 in 3 seniors dies of AD. More than breast and prostate cancers combined
- Cost to our nation in 2019 = $290 Billion
- Every 65 seconds someone in the US develops Alzheimer's Disease

US Alzheimer's Association: Facts & Figures-2019

Timeline and Epidemiology of Psychiatric Symptoms in AD



Adapted from Jost BC,Grossberg GT. *J Am Geriatr Soc*. 1996;44:1078-1081; with permission.

IMPACT OF AGITATION IN ALZHEIMER'S DISEASE

- BEHAVIORAL SYMPTOMS IN ALZHEIMER'S DISEASE ARE THE LEADING CAUSE OF INSTITUTIONALIZATION (AFTER FALLS)

- AGITATION AND PSYCHOSIS ARE THE MOST COMMON BEHAVIORAL SYMPTOMS RESULTING IN PLACEMENT INTO ASSISTED LIVING/ MEMORY CARE AND NURSING HOMES

BALESTRERI L, GROSSBERG A, GROSSBERG GT: INTERNATIONAL PSYCHOGERIATRICS, 2000.

CURRENT TREATMENT OF AGITATION IN AD/DEMENTIA

- THERE ARE CURRENTLY NO FDA-APPROVED TREATMENTS FOR AGITATION AND BEHAVIORAL SYMPTOMS IN ALZHEIMER'S DISEASE/ DEMENTIA
- OFF-LABEL TREATMENTS MOST COMMONLY USED HAVE SAFETY AND EFFICACY LIMITATIONS
- 1) ANTIPSYCHOTICS, E.G. RISPERDAL, ZYPREXA, SEROQUEL : BLACK BOX WARNING IN DEMENTIA PATIENTS RELATIVE TO INCREASED MORTALITY. TAKE TIME TO 'KICK IN'
- 2)BENZODIAZEPINES, E.G. XANAX, ATIVAN, CLONOPIN : CAUSE INCREASED CONFUSION, IMPAIR BALANCE, INCREASE THE RISK OF FALLS. TAKE TIME TO 'KICK IN'
- ACUTE TREATMENT WITH BXCL 501- A NON-ANTIPSYCHOTIC/NON-BENZODIAZEPINE MAY HAVE DISTINCT ADVANTAGES FOR TREATING AGITATION IN AD/DEMENTIA

Opioid Withdrawal

Ismene Petrakis, M.D.

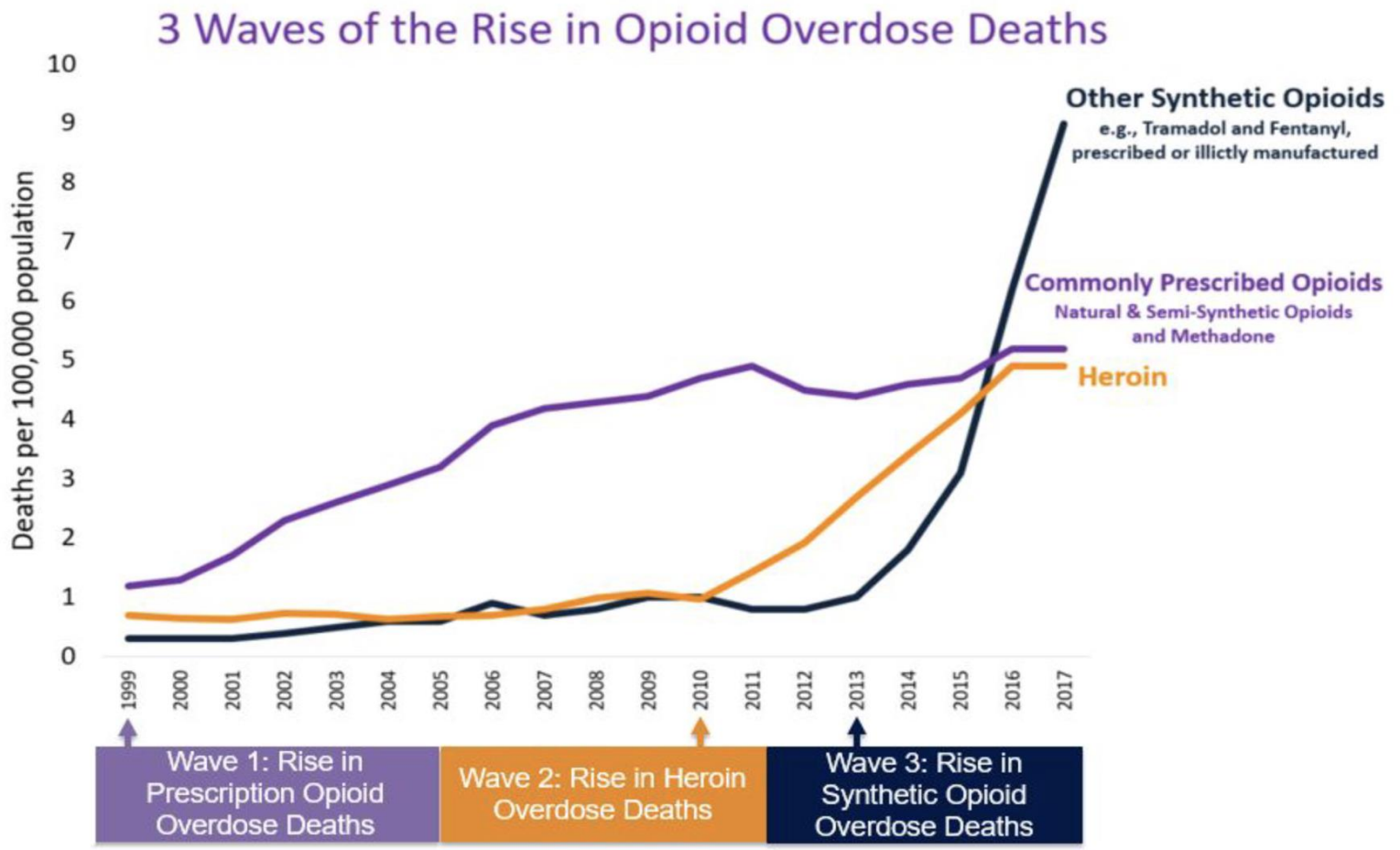
Management of Opioid Withdrawal

Ismene L Petrakis, MD

Opioid Crisis in the US

- Estimated 12 million American use prescription opioids non-medically
- 1.9 million people addicted to prescription opioids
- 600,000 addicted to heroin
- Total economic burden of prescription opioid misuse in the US is $78.5 billion a year (CDC)
- **Over 700,00 Americans died from opioid overdose from 1999-2017**
  - About *12 times* the #Americans died in Vietnam war
  - On average *130 Americans* die every day
- Medical consequences (e.g. increase in HIV, Hep infections)
- Social Consequences (e.g. increase # of children in foster care)

Opioid Crisis in the US



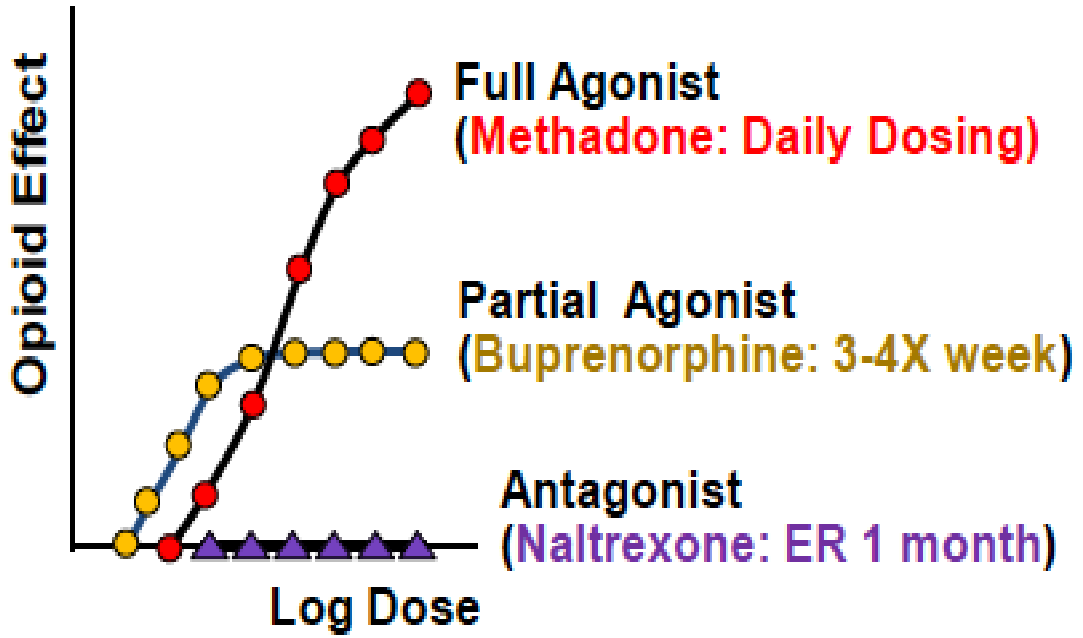
SOURCE: National Vital Statistics System Mortality File.

Opioid use disorder (DSM 5)

- Within a 12-month period:
  - Took more than intended
  - Unsuccessful efforts to cut down
  - Lots of time spent obtaining, using, or recovering
  - Craving
  - Failures to fulfill obligations at work, school, home
  - Use despite social or interpersonal problems from opioids
  - Giving up activities because of opioids
  - Use when physically hazardous
  - Use despite negative psych or physical impact
  - Tolerance (not a criteria for prescribed opioids)
  - Withdrawal (not a criteria for prescribed opioids)

Medication Assisted Treatments (MAT) for OUD

- Methadone
- Buprenorphine products (sl tablets, films)
- Naltrexone (oral and SR injectable [Vivitrol])



Opioid Withdrawal

Occurs when:

- Administration of an opioid antagonist — such as naloxone or naltrexone — after a person has used an opioid

OR

- Stopping or reducing heavy and prolonged opioid use

AND

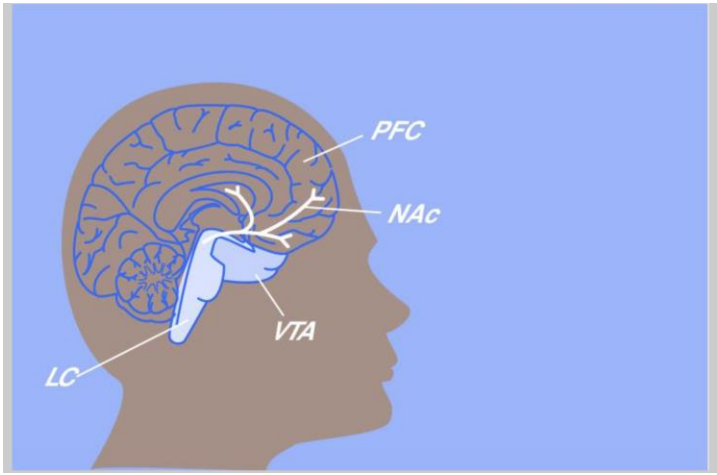
Three (3) or more of the following symptoms :

- Nausea or vomiting
- Pupils dilate, profuse sweating, or goosebumps
- An intense state of unease or dissatisfaction (dysphoria)
- Muscle aches
- Severe runny nose or tearing of the eyes
- Diarrhea
- Fever
- Yawning
- Insomnia

Management of Opioid Withdrawal: How?

- Slow taper of medications
- Substitution with longer acting medication and taper
  - Methadone
  - Buprenorphine
- Treatment of underlying neurobiology**

The Neurobiology of Opioid Dependence: Implications for Treatment
Thomas R. Kosten, M.D.[1,2] and Tony P. George, M.D.[1,3]



Management of Opioid Withdrawal

- Methadone/ Buprenorphine
- α-2-adrengergic agonists*
  - Clonidine (off-label use; .9 to 1.35 mg in divided doses)
  - Lofexidine (*Lucemyra*: Catalent Pharma Solutions) (FDA approved in 2018; 2.4 and 3.2 mg daily
  - Comparisons suggest not much different between 2 treatments in efficacy; more hypotension with clonidine
- With and without naltrexone
  - Opioid antagonist precipitates w/d and shortens treatment time
- Supportive treatment
  - Insomnia (sleep aids)
  - Muscle pains (NSAID; antispasmodics)
  - Nausea (anti-nausea medications)

Management of Opioid Withdrawal: When ?

- **Patient dependent on opioids, may not have OUD**
  - Pain patient for whom opioids may be exacerbating pain (hyperalgesia)
  - Pain patient who cannot tolerate SE

- **Patient with diagnosis of OUD patient**
  - Patient choice
  - Court ordered or otherwise mandated treatment (e.g. physicians)
  - Emergency management of OD with naloxone
  - Plan to treat with IM Naltrexone (Vivitrol)
  - Discontinue buprenorphine/ methadone

Suggested References

- Gowing L[1], Ali R[1], White JM[2], Mbewe D[1] **Buprenorphine for managing opioid withdrawal.** Cochrane Database Syst Rev. 2017 Feb 21;2:CD002025. doi: 10.1002/14651858.CD002025.pub5.

- Kosten TR, Baxter LE; **Review article: Effective management of opioid withdrawal symptoms: A gateway to opioid dependence treatment. The American Journal on Addictions, 2019 , Jan 31, 2019 https://doi.org/10.1111/ajad.12862**

- Gowing L, Farrell M, Ali R, et al. Alpha$_2$-adrenergic agonists for the management of opioid withdrawal. *Cochrane Database Syst Rev*. 2016;Cd02024.

Hyperactive Delirium

Maurizio Fava, M.D.

Delirium

- Delirium is an acute, reversible disorder of attention and cognition, as well as a disrupted sleep/wake cycle.
- There are three variants of delirium
  - the hyperactive and agitated patient (who may accidentally remove endotracheal tubes or even show violent behavior)
  - the lethargic or hypoactive patient
  - the patient who displays a combination of the two variants

Delirium in ICU

- The development of ICU delirium is associated with increased morbidity and mortality rates, prolonged ICU and hospital length of stay (LOS)
  (Marshall et al, Critical Care Nurse Quarterly 2003; 26(3):172-178; McGuire et al, Archives of Internal Medicine 2000; 160(7):906-909; Schuurmans et al, Journal of Clinical Nursing 2001; 10(6):721-729)
- A total of 185 patients in six ICUs in Australia and New Zealand were screened for delirium
  - With intensive care delirium screening checklist
  - Over two 12-hour periods per day for the duration of their ICU admission
- 84 patients (45%) developed delirium

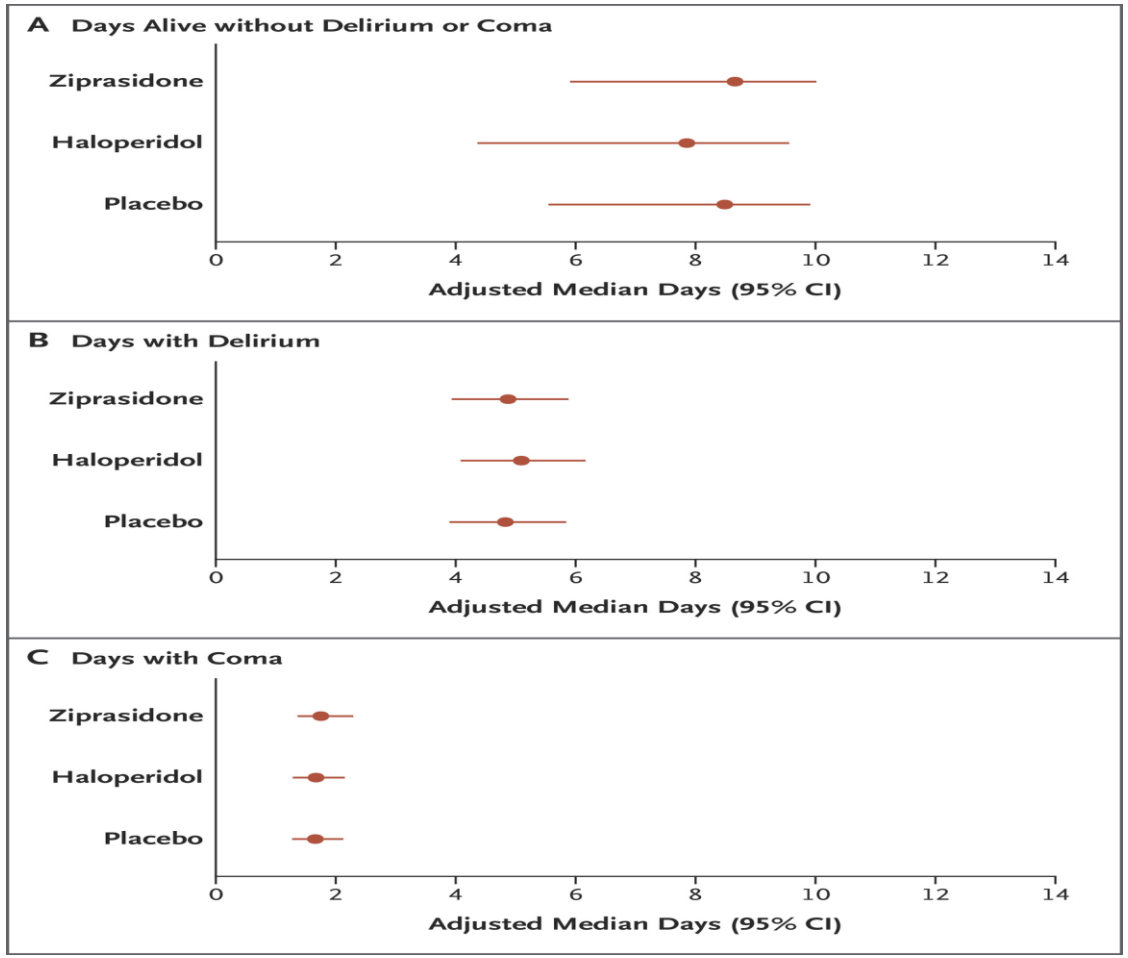
Roberts et al, Aust Crit Care. 2005 Feb;18(1):6, 8-9

Post-operative Delirium is Common and Associated with Increased 5-year Mortality

(Moskowitz et al, The American Journal of Surgery 214 (2017) 1036-1038)

- Around 40% of inpatient surgeries in the United States are performed in patients 65 years and older (Etzioni et al, Ann Surg. 2003; 238(2):170-177)
- Post-operative delirium is the most common complication of major surgery in older patients (Marcantonio et al, JAMA. 1994;271(2):134-139)
- 172 patients >50 years undergoing elective operations with planned intensive care unit (ICU) admissions were enrolled (average age: 64 years)
- The overall incidence of delirium was 44% (75/172)
- At 5-years post-operatively, mortality was higher (59%, 41/70) in patients with delirium compared to patients without delirium (13%, 12/94, $p < 0.001$)

Effects of Haloperidol, Ziprasidone, and Placebo on Days Alive without Delirium or Coma, Days with Delirium, and Days with Coma.



In analyses that were adjusted for age, preexisting cognitive impairment, Clinical Frailty Score and Charlson Comorbidity Index score at baseline, and modified Sequential Organ Failure Assessment score and Richmond Agitation–Sedation Scale score at randomization, there were no significant differences between the trial groups with respect to the primary end point (days alive without delirium or coma) and with respect to the secondary end points of mental status (durations of delirium and coma).

Girard et al, N Engl J Med. 2018 Dec 27;379(26):2506-2516.

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Dexmedetomidine for Prevention of Delirium in Elderly Patients after Non-cardiac Surgery: A Randomized, Double-blind, Placebo-controlled Trial

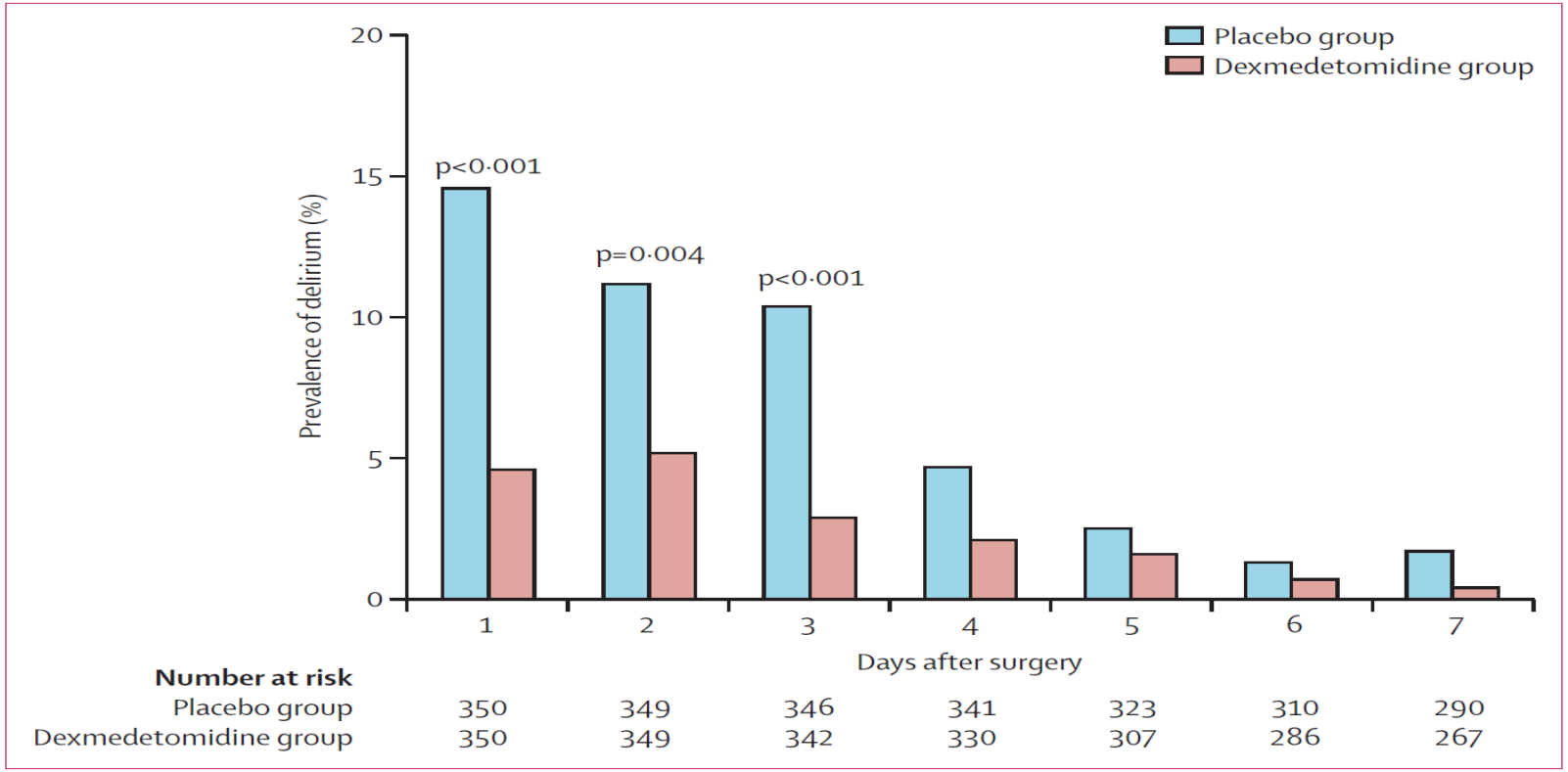

***Figure 2*: Daily prevalence of postoperative delirium**
Sample sizes differ from the first to seventh day because some patients were discharged from hospital or died during this period.

Su et al, Lancet 2016; 388: 1893–902

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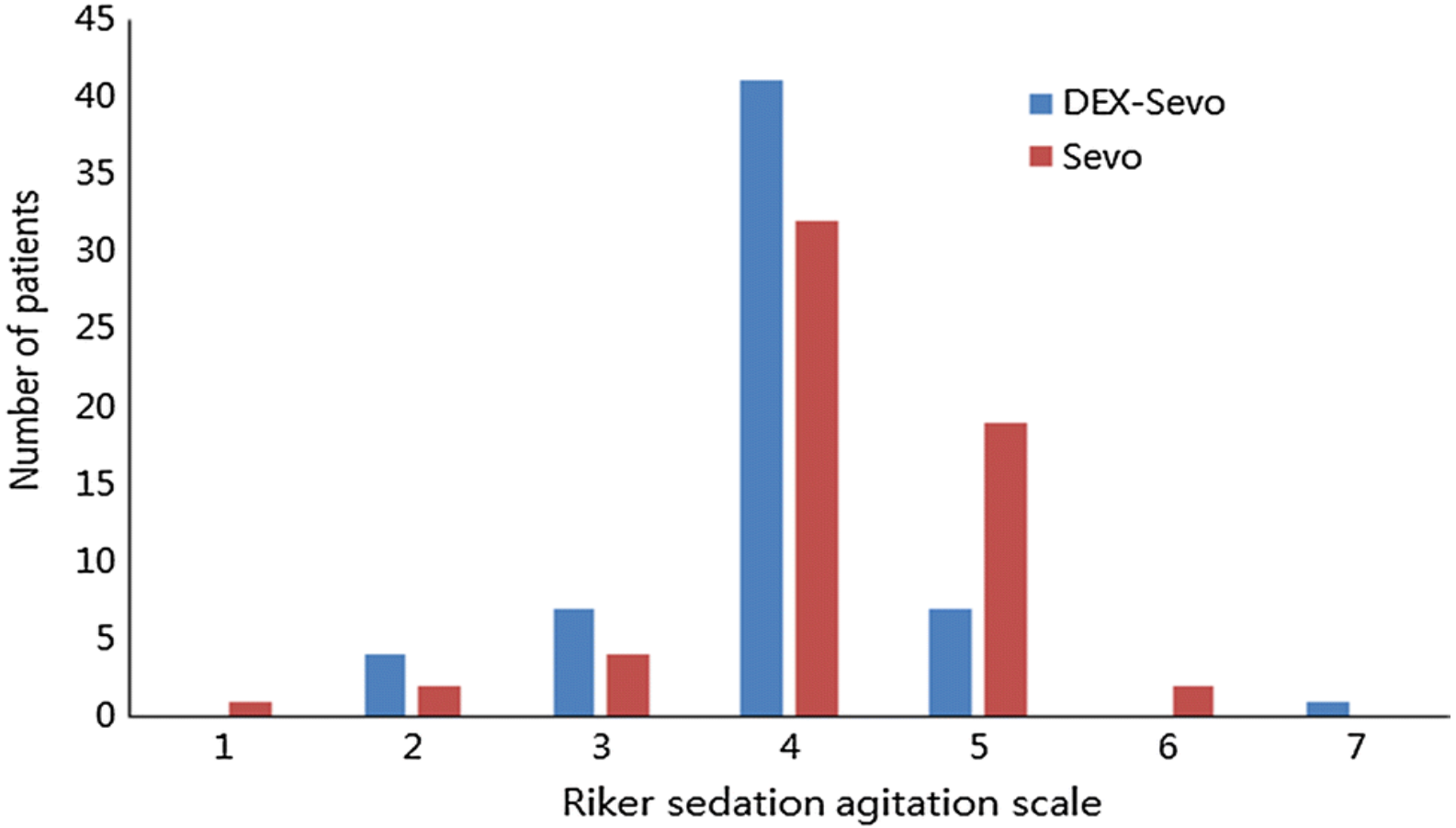
The Distribution Pattern of the Riker Sedation Agitation Scale at One Minute after Extubation (P = 0.059) (n=143) (Kim et al, Can J Anaesth. 2019 Apr;66(4):371-379.)



The DEX-Sevo group showed a lower incidence of emergence agitation than the Sevoflurane group (8 (13%) *vs* 21 (35%), respectively; relative risk, 0.38; 95% confidence interval 0.18 to 0.79; *P*= 0.011).

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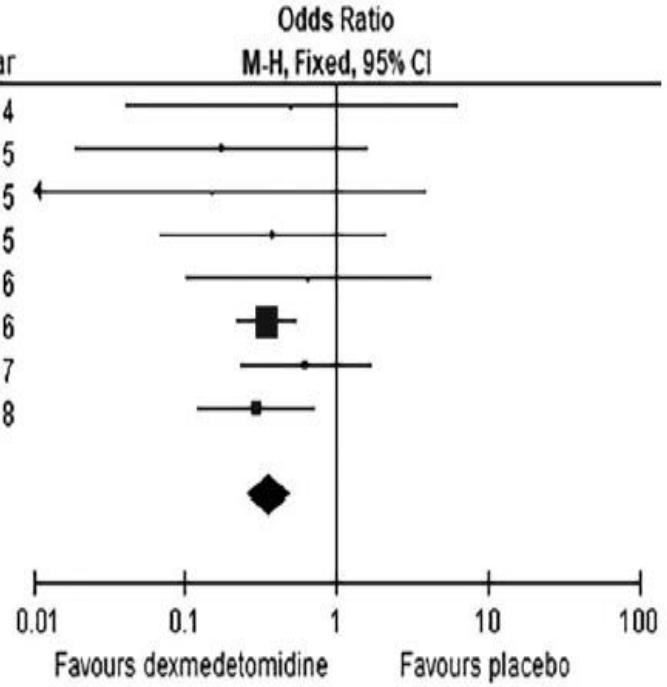
The Effect of Dexmedetomidine on Delirium and Agitation in Patients in Intensive Care: Systematic Review and Metaanalysis

Anaesthesia 2019, 74, 380-392

Study or Subgroup	Dexmedetomidine Events	Total	Placebo Events	Total	Weight	Odds Ratio M-H, Fixed, 95% CI	Year
Devlin 2014	1	16	2	17	1.6%	0.50 [0.04, 6.12]	2014
Priye 2015	1	32	5	32	4.1%	0.17 [0.02, 1.58]	2015
Balkanay 2015	0	60	1	28	1.7%	0.15 [0.01, 3.84]	2015
Yang 2015	2	39	5	40	4.0%	0.38 [0.07, 2.08]	2015
Wu 2016	2	38	3	38	2.4%	0.65 [0.10, 4.12]	2016
Su 2016	32	350	79	350	61.5%	0.35 [0.22, 0.54]	2016
Li 2017	7	142	11	143	8.9%	0.62 [0.23, 1.65]	2017
Skrobik 2018	10	50	23	50	15.8%	0.29 [0.12, 0.71]	2018
Total (95% CI)		727		698	100.0%	0.36 [0.26, 0.51]	
Total events	55		129				

Heterogeneity: $\chi^2 = 2.59$, df = 7 (p = 0.92); $I^2 = 0\%$

Test for overall effect: $Z = 5.84$ (p < 0.00001)



Forest plot of the incidence of delirium. MH, Mantel-Haenszel

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BXCL501 Clinical Program Update

Summary of Clinical Results

Sublingual Film (BXCL501) PK and Safety Study

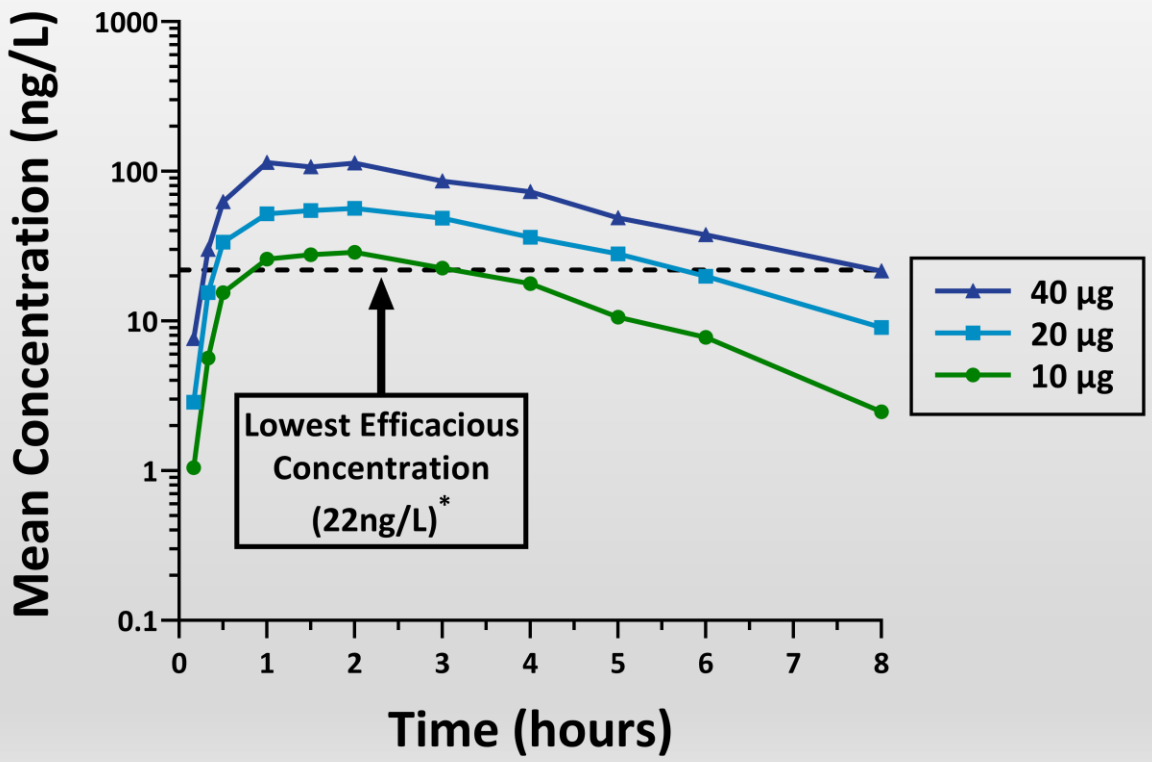
First In Human Study For Sublingual Thin Film Of Dex

Characterize Exposure Levels and Define Therapeutic Doses

- Double blind, placebo-controlled, single ascending dose, PK study
  - Healthy adult volunteers ages 18-65 (N = 42, 20 female)
  - Single center study
  - 3 Doses: 10, 20, 40 µg
- Primary objective:
  - Determine PK, safety and tolerability of various film strengths

BXCL501 Rapidly Achieved Targeted Exposures

BXCL501 Exhibited Predictable PK



* Estimated concentration level based on Company observations in prior IV Dex study.

- **Rapidly delivered targeted exposures**
  - Consistent with therapeutic responses seen in the IV Dex schizophrenia study
- **Predictable and dose proportional PK**
  - Enables dose selection for future development
- **Pharmacodynamic (PD) effects lasted 4-6 hours**
  - Optimal treatment duration

BXCL501 was Well Tolerated

Consistent Safety Profile Between Sublingual Film And IV Dex

Tolerability Observed Across Broad Range Of Doses

- No serious adverse events (AEs)
- All AEs were Grade 2 or below (mild to moderate) and transient
  - Most common AE was drowsiness, observed at rates similar to placebo
  - Cardiovascular changes were not clinically meaningful
- No clear sedative effect for treatment group vs. placebo
- Maximum tolerated dose was not reached

Positive Human Proof of Concept: Acute Reduction of Agitation in 4 Indications

Safety Profile And Exposure Levels Were Consistent Across Indications With IV Dex

SCHIZOPHRENIA

90% Response

- 14 patient study (10 treatment + 4 placebo)
- PEC/RASS scores indicate de-agitation without excessive sedation

**PEC = Positive and Negative Symptom Scale-Excitatory Component*

DEMENTIA

70% Response

- 14 patient study (10 treatment + 4 placebo)
- RASS* score of -1

**RASS = Richmond Agitation Sedation Scale*

105 Subject Experience

DELIRIUM

100% Response

- 132 patients (46 refractory to haloperidol)
- **46/46 responded to IV Dex** in reducing agitation

Carrasco et.al., Critical Care Medicine: July 2016, Vol 44, Issue 7, pp. 1295-1309

OPIOID WITHDRAWAL

100% Response

- 15 subject study (10 treatment + 5 placebo)
- 50% reduction in COWS total score

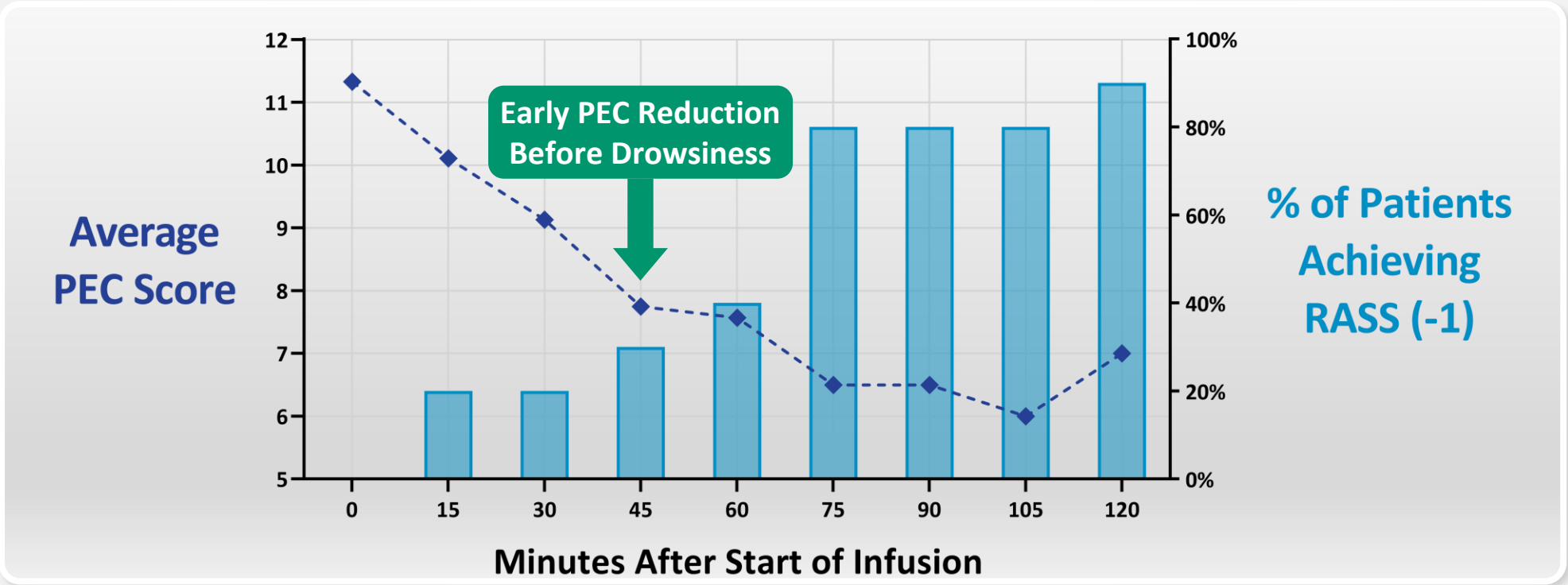
**COWS = Clinical Opiate Withdrawal Scale*

Human Proof of Concept: IV Dex Reduced Agitation in Schizophrenia Patients

Translating Efficacious Exposures From IV Dex To Sublingual Film

Study Design

- Randomized, placebo-controlled dose-ranging study
- 14 patients [10 treatment + 4 placebo]
- Primary endpoint: RASS of -1
- Secondary endpoint: PEC score of 7 or below

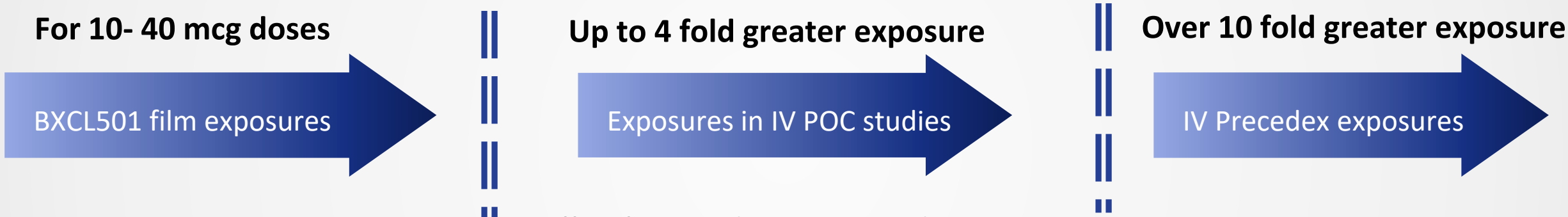


BXCL501 PK Study Exposures Consistent with Reduction in PEC Scores

Exposures with BXCL501 film significantly lower than IV Precedex

Lower exposures of the film maximizes benefit-risk

BXCL501 Film exposures are 10 fold below that of IV Precedex Label



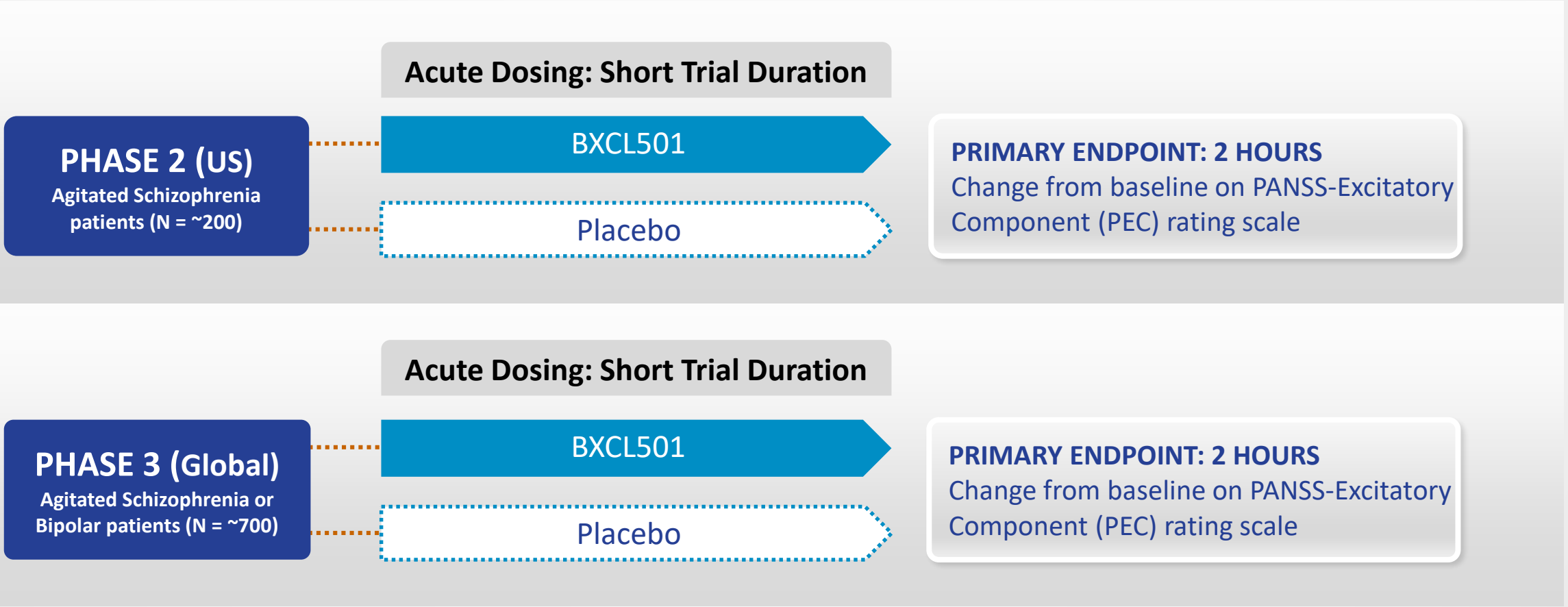
Broad therapeutic index for BXCL501 vs. current label of Precedex as a sedative

Overview of Registration Trial Path

BXCL501 Integrated Clinical Development Plan

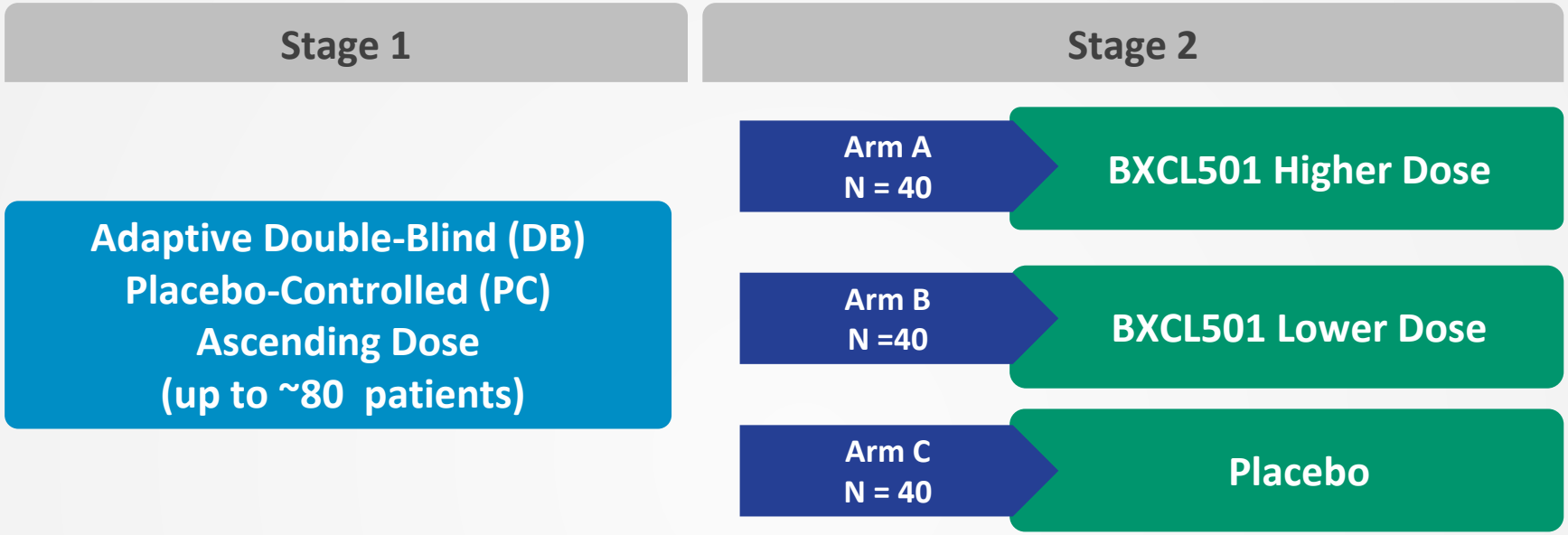
Acute Agitation Studies: Short Duration With Easily Measurable Clinical Endpoints

Randomized, Double-blind, Placebo-controlled Multi-center Studies



Efficient Adaptive Phase 2 Trial De-risks Registration studies

Initiating 2Q 2019

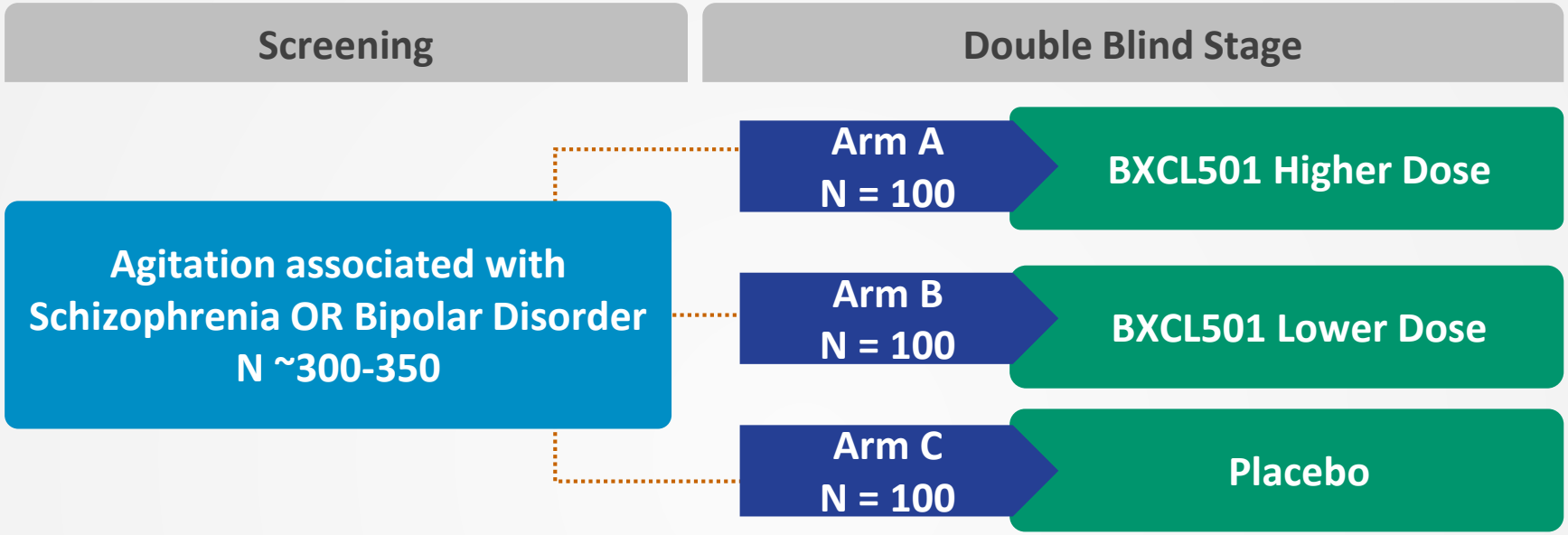


Adaptive Randomized DB PC parallel 3-arm trial
Stage 2 N = ~120

- Two-Stage efficient adaptive design
  - Stage 1 – Confirms effective doses, range and tolerability at 6 sites
  - Stage 2 – Measures variance to power Phase 3 trial at >12 sites
- Primary Endpoint; PEC change from baseline to 2 hours
- Data enable initiation of registration trials in 4Q 2019

Two Phase 3 Registration Trials

One trial in Agitation associated with Schizophrenia, one trial in Agitation associated with Bipolar Disorder, Initiating 4Q 2019

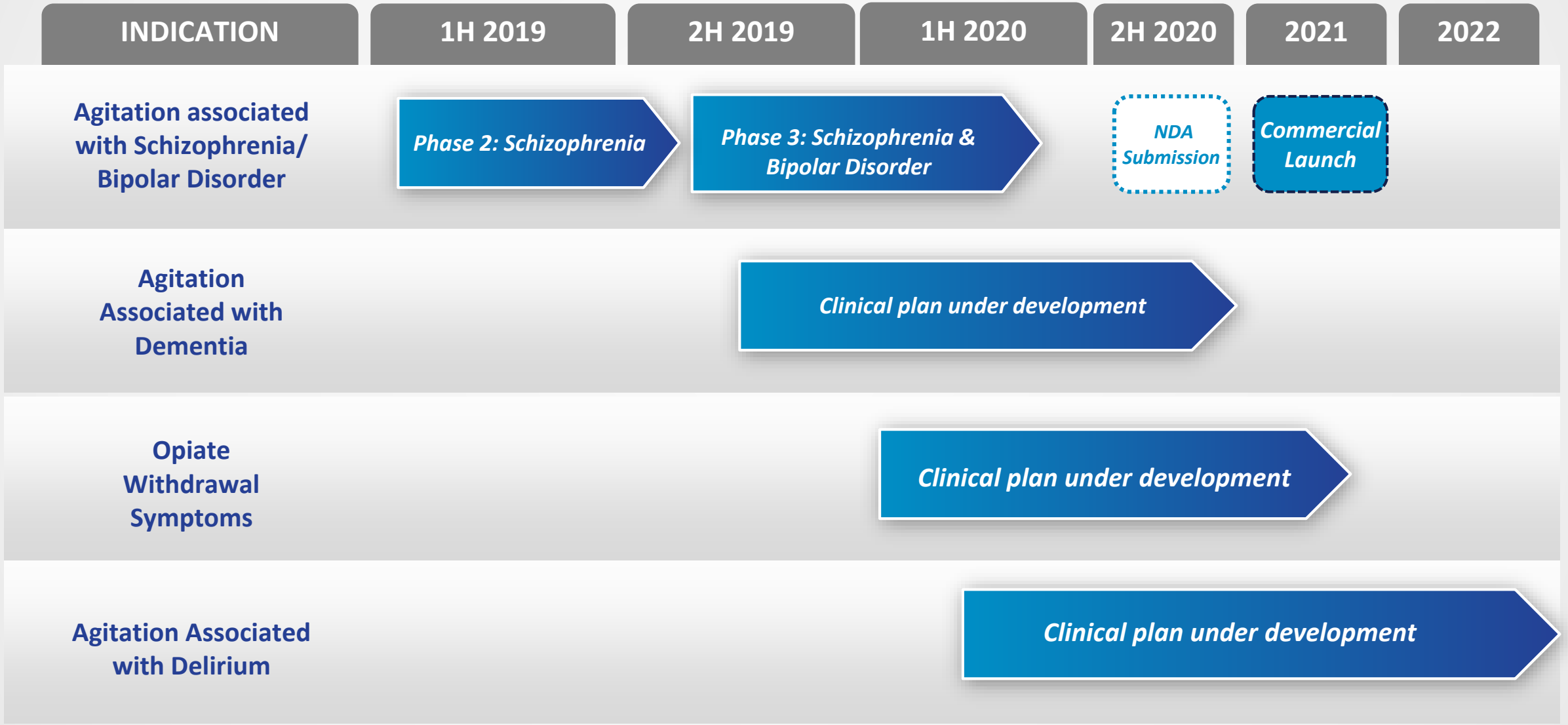


Randomized double-blind placebo controlled parallel group 3-arm trial

- Key Inclusion Criteria:
  - Schizophrenia with acute agitation; Bipolar Disorder with acute agitation
  - Baseline PANSS-Excitatory Component (PEC) total score ≥14
- Primary endpoint: Change from baseline at 2 hours in total PEC score

Clinical Development Plans Across Multiple Neuropsychiatric Medical Conditions

Initial NDA submission in 2H 2020



Agitation Franchise Expansion

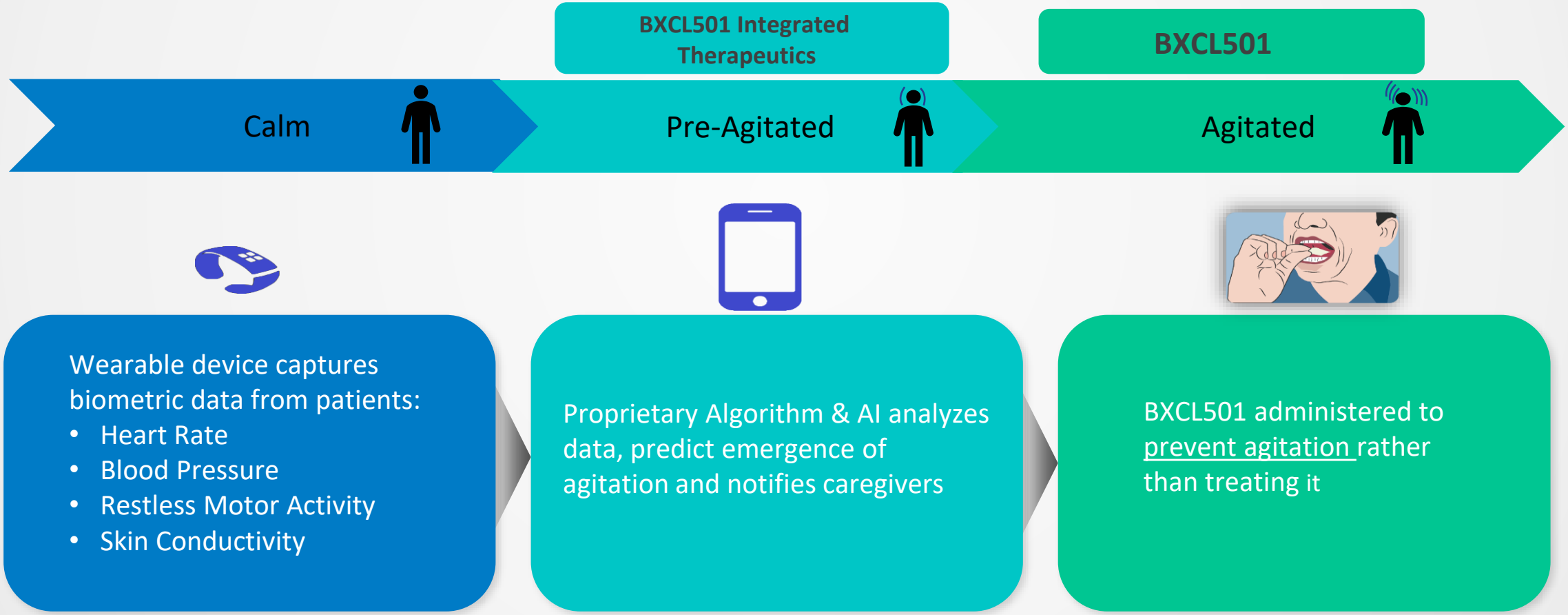
BioXcel Therapeutics: BXCL501 Pipeline

Treatment of neurological diseases and psychiatric symptoms

Product	MOA/ Treatment	Indication
BXCL501	Alpha2A Adrenergic Agonist SL FILM; Dexmedetomidine	*Acute Treatment Mild/Moderate agitation/ psychiatric diseases*
BXCL501	Alpha2 Adrenergic Agonist SL FILM; Dexmedetomidine	*Acute Treatment Agitation: Dementia/Opioid Withdrawal/Delirium*
BXCL501 PLUS+ (IM COMBO)	Alpha2 Adrenergic Agonist PLUS+	*Acute Treatment Severe agitation/ psychiatric diseases*

Digital Integration to expand BXCL501 Therapy

- BXCL501 is currently intended for acute treatment of agitation
- Next generation of integrated therapeutics for agitation prevention through complementary digital technologies



KOL Panel Q&A

Drs. Preskorn, Grossberg, Petrakis, and Fava

Moderator: Mr. Sumant Kulkarni

(Analyst, Canaccord Genuity)

Corporate Outlook And Closing Remarks

Dr. Vimal Mehta, CEO

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