



AI-Driven Transformative Medicines in Neuroscience and Immuno-oncology

September 2022

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 regarding BioXcel Therapeutics' expected timing of, and data results from, trials and clinical studies involving its product candidates; planned discussions with regulators; its commercial plan and strategy for IGALMI™ and strategic options for OnkosXcel; potential market size and opportunity for products and product candidates, and its future financial and operational results. 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 BioXcel Therapeutics' current expectations and various assumptions. BioXcel Therapeutics believes there is a reasonable basis for its expectations and beliefs, but they are inherently uncertain.

BioXcel Therapeutics 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 IGALMI™, BXCL501, BXCL502 and BXCL701 and other product candidates; the Company has no experience in marketing and selling drug products; IGALMI™ or the Company's product candidates may not be accepted by physicians or the medical community in general; 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; undesirable side effects caused by the Company's product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; its exposure to patent infringement lawsuits; its ability to comply with the extensive regulations applicable to it; impacts from the COVID-19 pandemic; 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 quarterly period ended June 30, 2022, 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 and the Investors section of our website at www.bioxceltherapeutics.com.

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 BioXcel Therapeutics 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 BioXcel Therapeutics' views as of any date subsequent to the date of this presentation.

Our Mission: Develop Transformative Medicines Utilizing AI Approaches in Neuroscience and Immuno-oncology

Neuroscience

- Symptoms from stress-related behaviors
- Neuro-psych diseases

IGALMI™ (dexmedetomidine) Sublingual Film

- Approved for acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults*
- Commercial launch under way

BXCL501 Lead Program

- Alzheimer's disease-related agitation
- At-home use: acute treatment of agitation associated with bipolar disorders or schizophrenia
- Adjunctive treatment in major depressive disorder

BXCL502 Pipeline Candidate

- Chronic agitation in Alzheimer's disease

Immuno-oncology

- Innate immunity

BXCL701 Lead Program

- Aggressive form of prostate cancer
 - SCNC clinical proof of concept
 - 33% composite response rate observed in combination with pembrolizumab in Phase 2 trial**
 - 800-patient clinical safety database



**OnkosXcel
Therapeutics™**
A subsidiary of BioXcel Therapeutics, Inc.

*The safety and effectiveness of IGALMI has not been established beyond 24 hours from the first dose.

The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established

**Interim data from Phase 2a portion of study as of Nov.24, 2021 presented at 2022 ASCO Genitourinary Cancers Symposium

Potential Market-Changing Product & Current Pipeline

Compound	Indication/Proposed Indication	Preclinical	Phase 1	Phase 2	Phase 3	Registration	Marketed
Neuroscience							
 Igalmi (dexmedetomidine) sublingual film - 120 mcg, 180 mcg	Acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults	Approved April 5, 2022					
BXCL501	At-home acute treatment of agitation associated with schizophrenia or bipolar I or II disorder in adults	SERENITY III					
	Acute treatment of agitation associated with Alzheimer’s disease*	TRANQUILITY II & III					
	Adjunctive treatment in major depressive disorder						
BXCL502	Chronic agitation in Alzheimer’s disease						
Wearable Device (+BXCL501)**	Pre & post-agitation in dementia	Phase 0 device testing					
Immuno-oncology							
 OnkosXcel Therapeutics <small>a subsidiary of Bionxe Therapeutics, Inc.</small>							
BXCL701	Metastatic castration-resistant prostate cancer (small cell neuroendocrine and adenocarcinoma)	(Combination with KEYTRUDA®)					

Pipeline as of Sept. 12, 2022

The safety and efficacy of investigational agents and/or investigational uses of approved products have not been established

*Includes intermittent chronic agitation






**Regulatory path to be determined; device + drug combination to be evaluated after further evaluation of predictive algorithm

Near-Term Catalysts & Key Events

NEUROSCIENCE: BXCL501	Timeframe
IGALMI™ U.S. Commercial Launch	July 2022
Alzheimer's Disease: TRANQUILITY III <ul style="list-style-type: none"> Expected study initiation 	2H 2022
Bipolar Disorders or Schizophrenia (at-home use): SERENITY III <ul style="list-style-type: none"> Expected study initiation 	2H 2022
Alzheimer's Disease: TRANQUILITY II <ul style="list-style-type: none"> Top-line data readout 	1H 2023
Major Depressive Disorder (MDD) <ul style="list-style-type: none"> Top-line results from Phase 1 dose-selection trial in healthy volunteers 	1H 2023
IMMUNO-ONCOLOGY: BXCL701	OnkosXcel Therapeutics
Aggressive Variant of Metastatic Castration-Resistant Prostate Cancer <ul style="list-style-type: none"> Expected enrollment completion of 28-patient SCNC cohort 	2H 2022

Strong Value Proposition and Long-Term Growth Potential

Transformative Approach With Technology, Business Model, and Medicines

 Unprecedented Value Creation*	 Clinically Validated AI Platform	 Advanced Pipeline	 Large Market Opportunity
<ul style="list-style-type: none"> Optimize R&D economics Shorten development timelines Achieve higher probability of success <p>* all 3 driven by comprehensive AI plan</p>	<ul style="list-style-type: none"> Proprietary AI Platform technology BXCL501 – IND acceptance to IGALMI™ approval in 3.5 yrs. - 3 upcoming Phase 3 trials BXCL701 – Human POC established in SCNC - Leader in DPP 8/9 biology (new checkpoint) 	<ul style="list-style-type: none"> BXCL501: Alzheimer’s-related agitation TRANQUILITY II & III Pivotal program BXCL501: Bipolar & Schizophrenia-related agitation (at-home setting) - SERENITY III pivotal trial BCXL701: SCNC clinical POC – 800-patient safety database 	<ul style="list-style-type: none"> ~39 million* annual episodes of agitation associated with schizophrenia & bipolar disorders in U.S.^{1,2,3,4} ~100 million annual episodes of agitation associated with Alzheimer’s disease in U.S.⁵ 300+ million antidepressant prescriptions filled annually⁶
 Strong Financial Position			
<ul style="list-style-type: none"> Cash runway into 2025** Well-funded to drive catalysts & long-term growth 			

1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5. Estimate based on company market research 6 NIH/WHO, SAMHSA, NIMH Pratt et al, 2017

*Includes 16 million institutional episodes, 9 million at-home Rx episodes, as well as 14 million self-managed episodes

**Assumes full execution of strategic financing agreements announced on April 19, 2022, including funding of remaining tranches subject to regulatory and financial milestones and certain other conditions .

Our Journey to Becoming a Leading Neuroscience Drug Development & Commercialization Company

5-Year Vision for Growth



Senior Management Team



Vimal Mehta, Ph.D.
Chief Executive Officer & Founder



Richard I. Steinhart
Senior Vice President &
Chief Financial Officer



Frank D. Yocca, Ph.D.
Chief Scientific Officer



Robert Risinger, M.D.
Chief Medical Officer, Neuroscience



Vincent J. O'Neill, M.D.
Senior Vice President &
Chief Medical Officer



Chetan D. Lathia, Ph.D.
Senior Vice President &
Head of Translational Medicine
Clinical Pharmacology and Regulatory Affairs



Matt Wiley
Senior Vice President &
Chief Commercial Officer



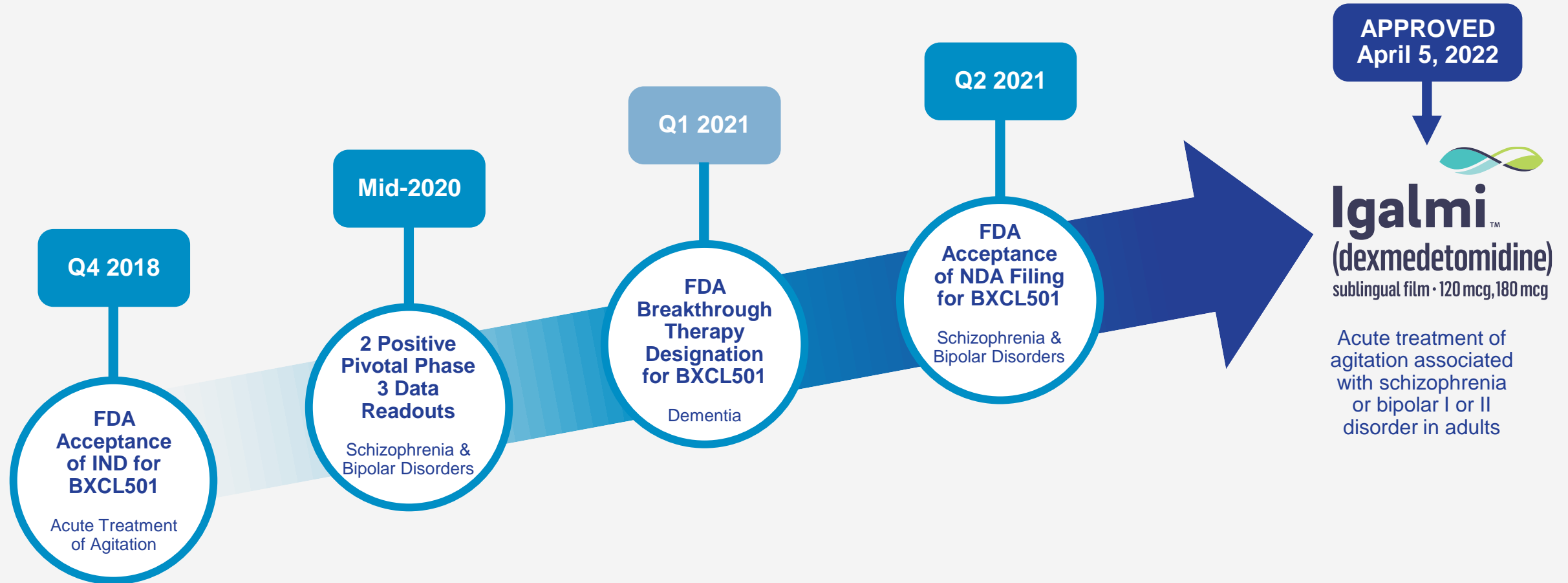
Javier Rodriguez
Senior Vice President, Chief Legal
Officer & Corporate Secretary

AI Innovation Engine



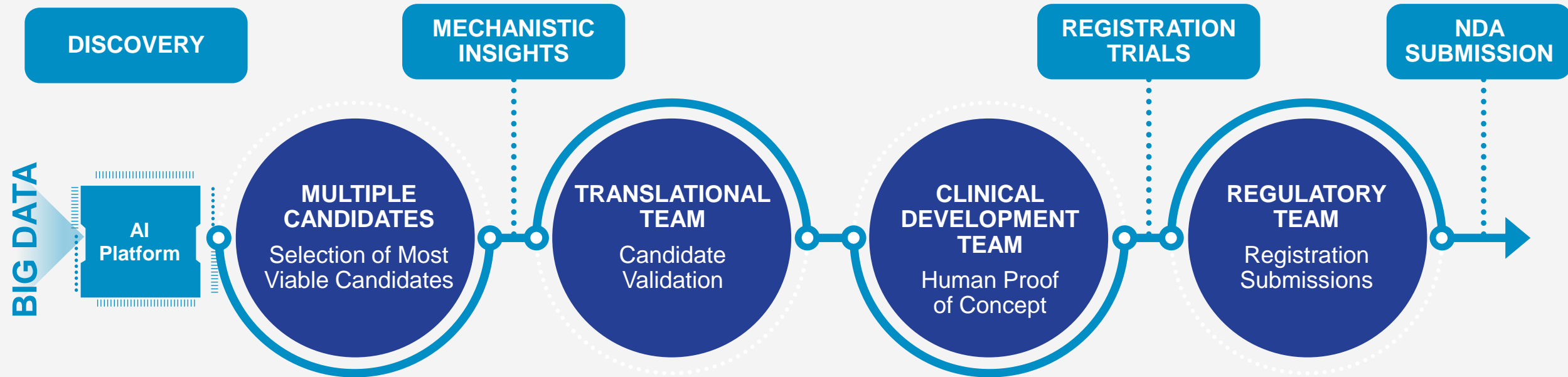
From IND Acceptance to Approval of IGALMI™ in 3.5 years

First AI-Derived, FDA-Approved Drug With Novel Mechanism of Action



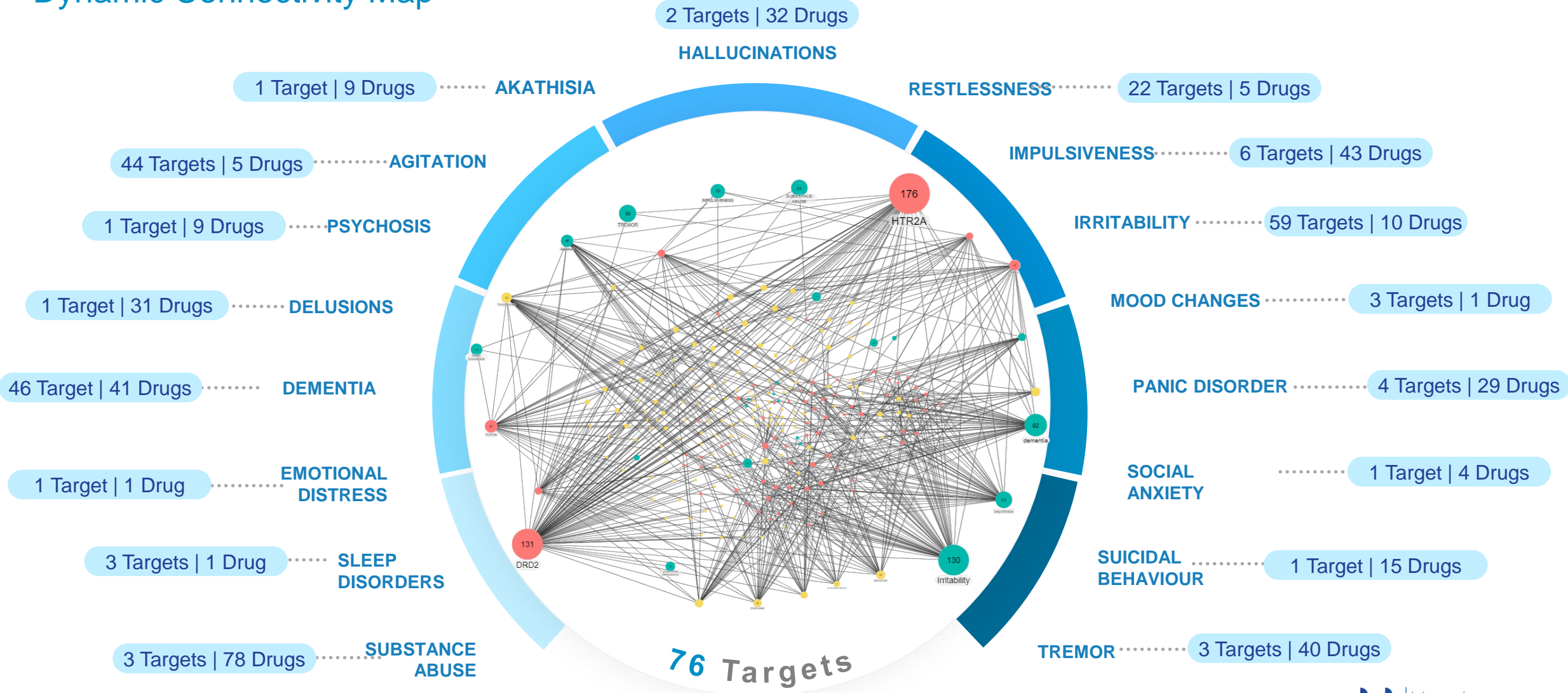
Uniquely Integrated Drug Discovery & Development Capability

Utilizing Proprietary AI Platform



AI-Driven Insights Into Universe of Stress-related Symptoms, Targets & Drugs

Dynamic Connectivity Map



Commercialization

First and only FDA-approved sublingual film for acute treatment of agitation associated with schizophrenia or bipolar I or II disorders in adults



IgalmiTM
(dexmedetomidine)
sublingual film • 120 mcg, 180 mcg

Agitation: A Common and Difficult-to-Manage Symptom

Debilitating for Patients and Threatening for Healthcare Providers



Characterized by recurring episodes requiring frequent treatments



Symptoms differ by patient, vary between episodes, and range from mild to severe¹⁻⁶



Multi-billion-dollar healthcare burden



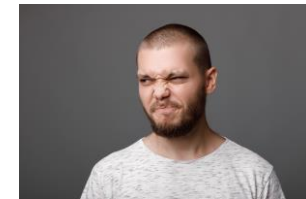
Best-practice guidelines recommend agitation be treated by:

- behavioral calming techniques
- verbal de-escalation
- medications voluntarily accepted by patients without coercion, with pharmacologic goal of calming without unarousable sedation⁷



Current treatment approaches:

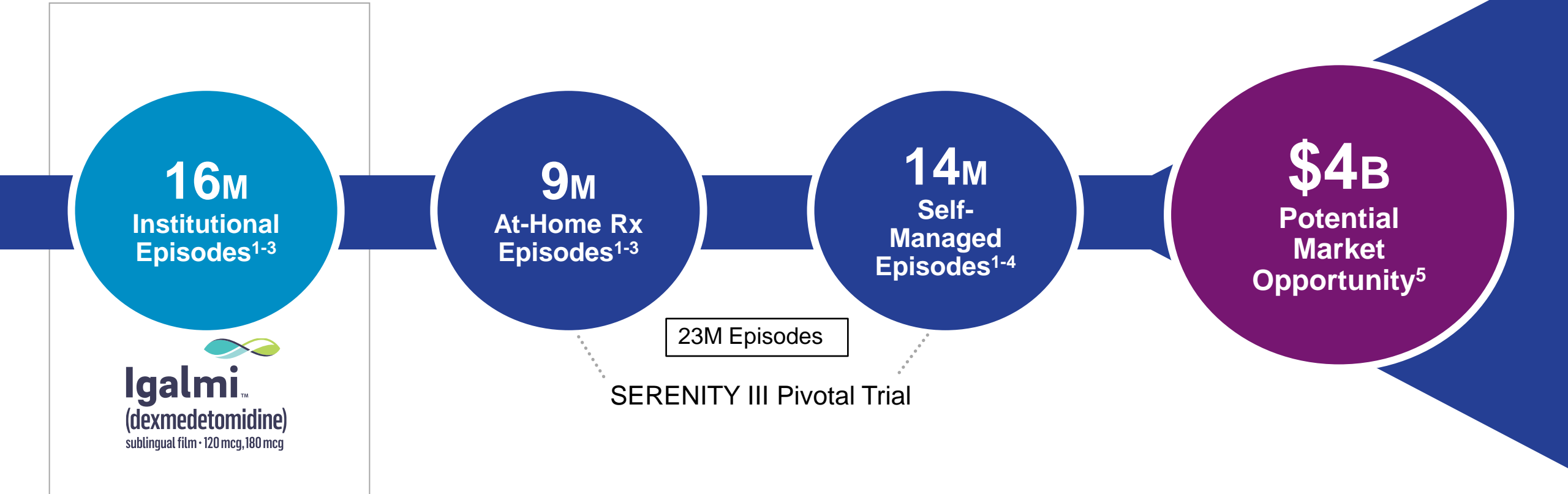
- May involve physically restraining patients
- Over-sedating therapies such as antipsychotics and benzodiazepines
- Antipsychotic drugs have black box warnings for elderly



1. Dunder Y, Greenhalgh J, Richardson M, et al. Pharmacological treatment of acute agitation associated with psychotic and bipolar disorder: a systematic review and meta-analysis. *Hum. Psychopharmacol.* 2016;31(4):268-285.
 2. Garriga M, Pacchiarotti I, Kasper S, et al. Assessment and management of agitation in psychiatry: expert consensus. *World J Biol Psychiatry.* 2016;17(2):86-128.
 3. Nordstrom K, Zun LS, Wilson MP, et al. Medical evaluation and triage of the agitated patient: consensus statement of the American association for emergency psychiatry project Beta medical evaluation workgroup. *West J Emerg Med.* 2012;13(1):3-10.
 4. Martinez-Raga J, Amore M, Di Sciascio G, et al. 1st international experts' meeting on agitation: conclusions regarding the current and ideal management paradigm of agitation. *Front. Psychiatry.* 2018;9(54):1-9.
 5. Depression and Bipolar Support Alliance (DBSA). *Understanding agitation: recognizing the signs of agitation and knowing what to do when they appear.* 2014.
 6. Sacchetti E, Amore M, Di Sciascio G, et al. Psychomotor agitation in psychiatry: an Italian expert consensus. *Evidence-based Psychiatric Care.* 2017;1:1-24.
 7. Wilson MP, Pepper D, Currier GW, et al. The psychopharmacology of agitation: consensus statement of the American Association for Emergency Psychiatry Project Beta Psychopharmacology Workgroup. *West J Emerg Med.* 2012;13(1):26-34.

Significant Market Opportunity: Agitation in Bipolar Disorders & Schizophrenia

Institutional Episodes



1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpd/ncs-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5. 39M episodes @ \$105/episode

IGALMI™ (Dexmedetomidine) Sublingual Film

Approved for Acute Treatment of Agitation Associated with Schizophrenia or Bipolar I or II Disorder in Adults



First and only FDA-approved orally dissolving sublingual film for adults with **mild, moderate or severe agitation**

If agitation persists, up to **two additional doses** may be administered at least two hours apart.

Packaged as individual films in **10- and 30-count** cartons for 120 mcg and 180 mcg.

First new market entrant in nearly a decade for this indication¹.

¹ Drugs@FDA <http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varAppNo=022549>; accessed March 31, 2022.

HCPs Have Positive Impressions of IGALMI™



80%

of HCPs surveyed find that promotional message encourages them to prescribe IGALMI¹



Overall, HCPs surveyed indicated they would use IGALMI for

~ 40%

of schizophrenia or bipolar disorder patients with acute agitation¹

¹ HCP Quantitative Detail Aid Research (n=150), January 2022

Strong Early Commercial Progress



GPO contracting in process covering >90% of target hospital beds

Hospital interest growing and actively scheduling P&T reviews



Strong market reception to IGALMI™ from key hospital stakeholders

~70% of sales interactions in person



Precision targeting and predictive analytics for smart market expansion

Commercial data lake augmented with 81B claims records



Sales force expansion in tandem with market access in H2 2022

70 geographies covering 1700 target hospitals

National Territory Expansion Across 70 Territories to Reach Priority Targets



~1,700 target institutions represent
~75% in volume

- Includes 59 high-control, high-potential **integrated delivery networks**

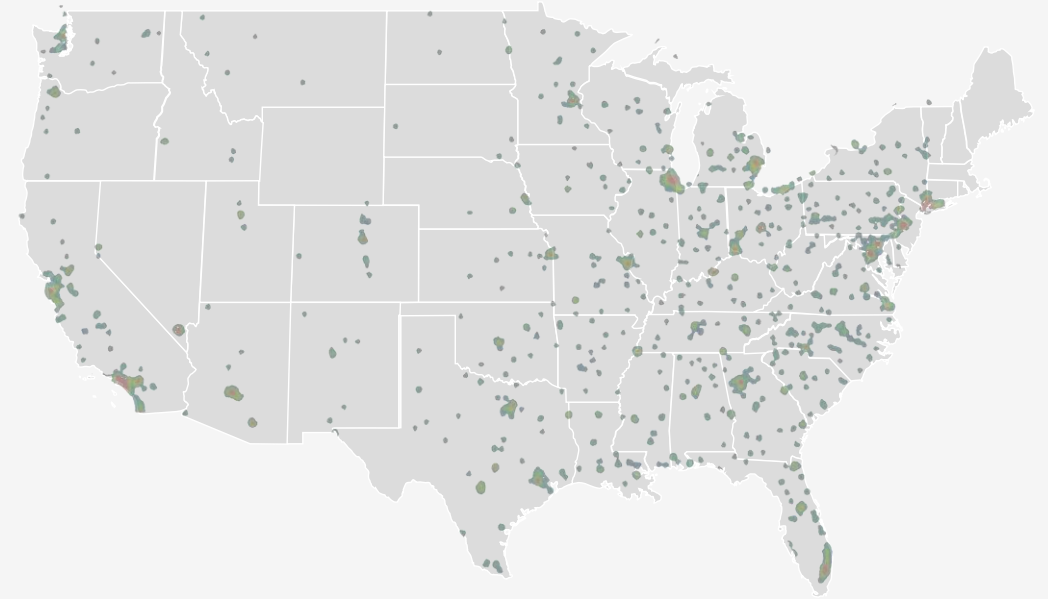


High Potential Provider targets at launch within these institutions



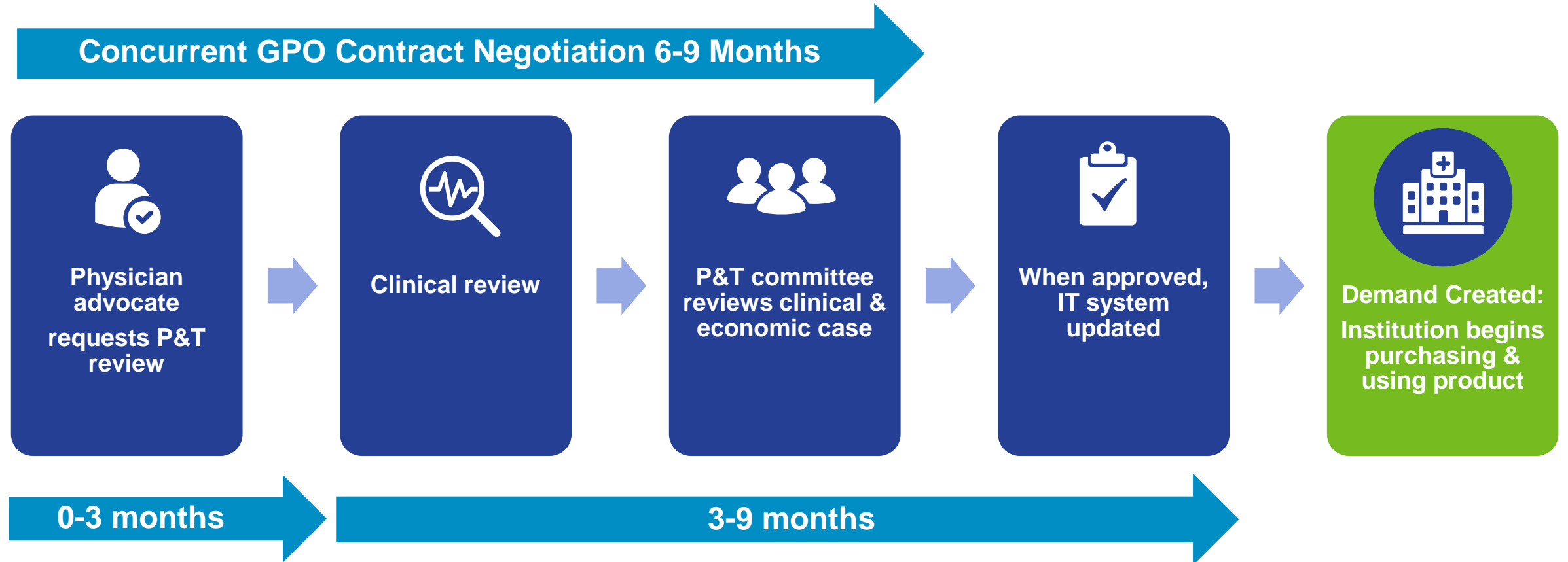
Primary focus: **Emergency Medicine & Psychiatry** specialties
Secondary focus: **Clinical Pharmacy**

Target U.S. Locations



Positioned to Gain Hospital Formulary Access & Generate Demand

P&T Approval Process



Market Environment Favorable to IGALMI Value Proposition

HCP Desire to Increase Use of Oral, Less-invasive Medications for Managing Agitation, Consistent With Consensus Guidelines

- Challenges surrounding administration of intramuscular injections
- Use of physical restraint often required to inject agitated patients
- Increased expenses and safety risk to staff: ~\$1,500 per patient¹, which typically surpasses reimbursement



Agitated-patient outbursts may result in:

- Patient, caregiver, and staff injuries
- Lost work time, transfers, lawsuits and unsafe work environments

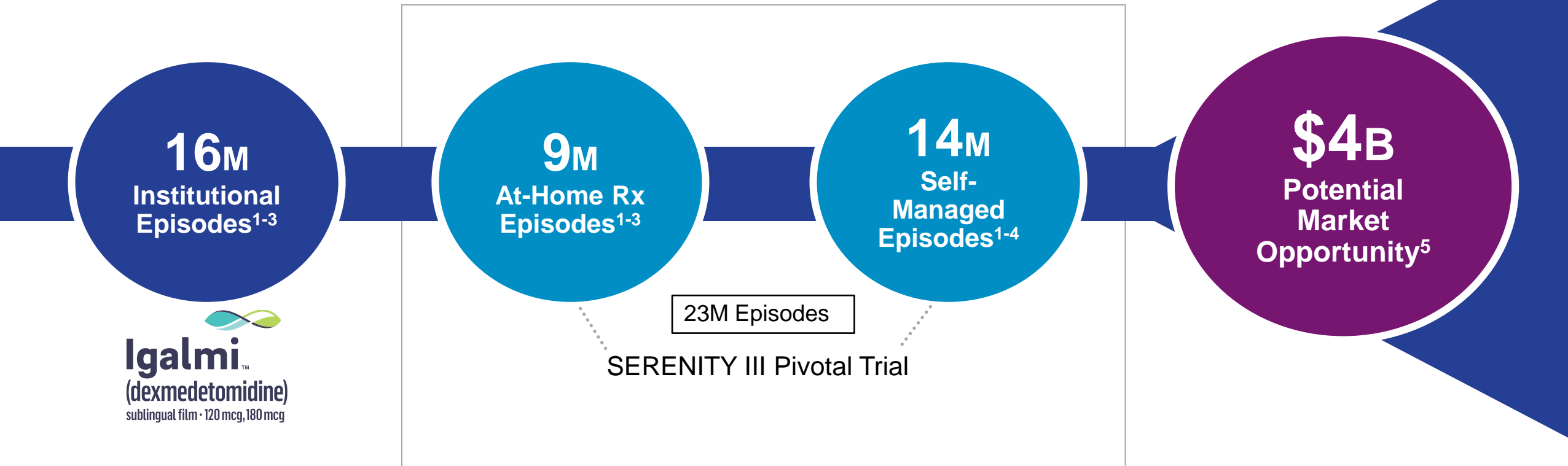


¹ Hokett S and Kwong M. Direct medical cost-estimator tool – Economic Burden of Physically Restraining Patients With Agitation and Schizophrenia in Emergency Departments. *ISPOR*, May 2022

Neuroscience Portfolio

Significant Market Opportunity: Agitation in Bipolar Disorders & Schizophrenia

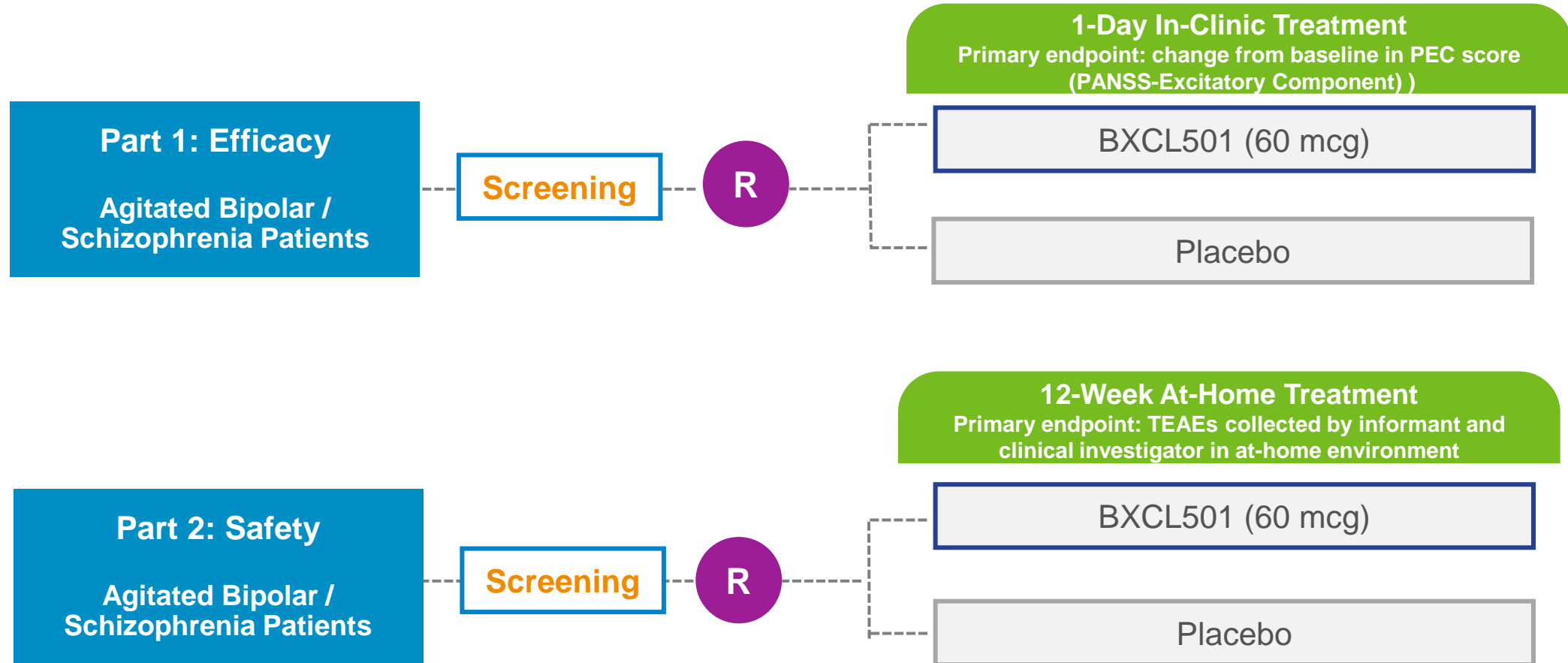
At-Home & Self-Managed Episodes



1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5. 39M episodes @ \$105/episode

SERENITY III Pivotal Trial

Evaluating At-Home use of BXCL501 for Acute Treatment of Agitation in Bipolar and Schizophrenia Patients

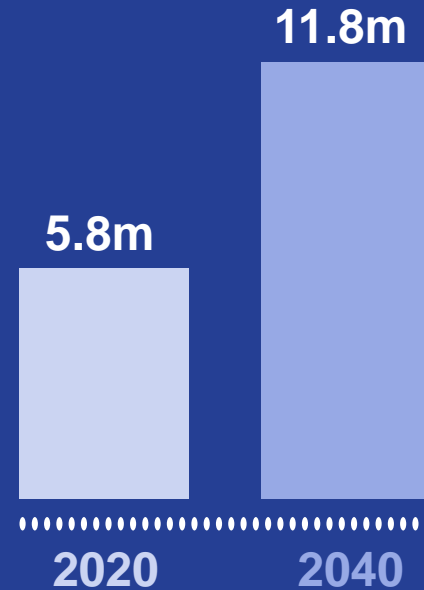


Significant Market-Expansion Opportunity: Alzheimer's Disease



~100M

agitation episodes per year in the U.S.¹

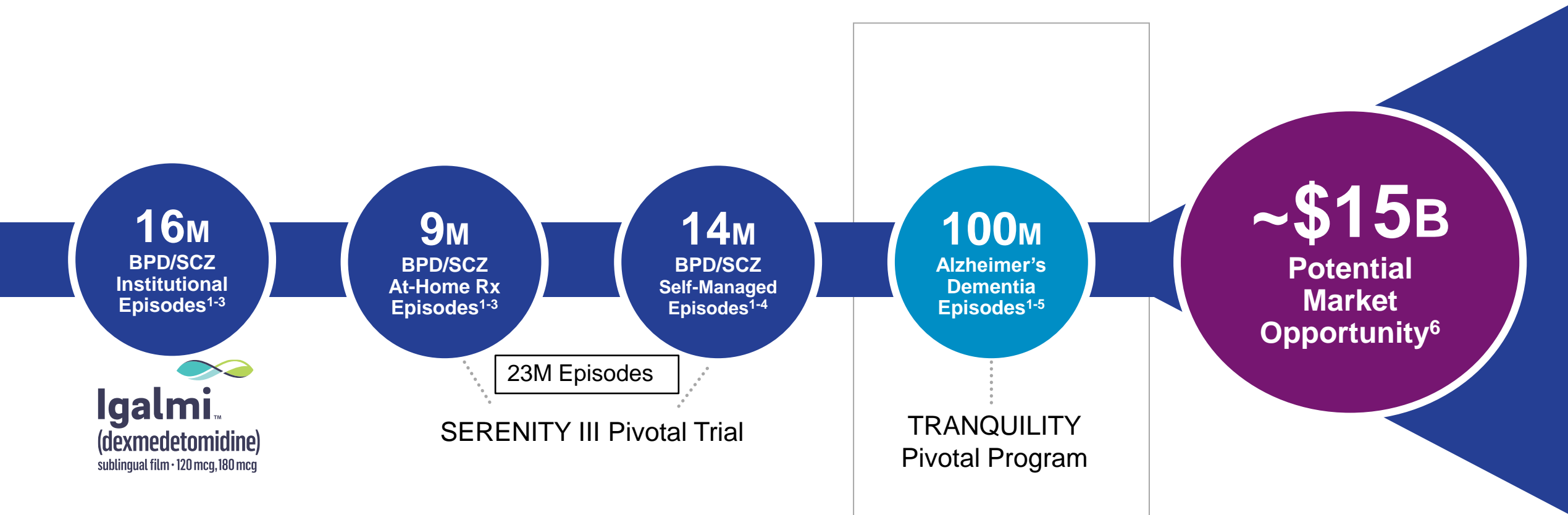


U.S. adults 65+
with AD to
Double
by 2040²

¹ Estimate based on company market research ² Alzheimer's Association .

Significant Market Opportunity: Agitation Overall

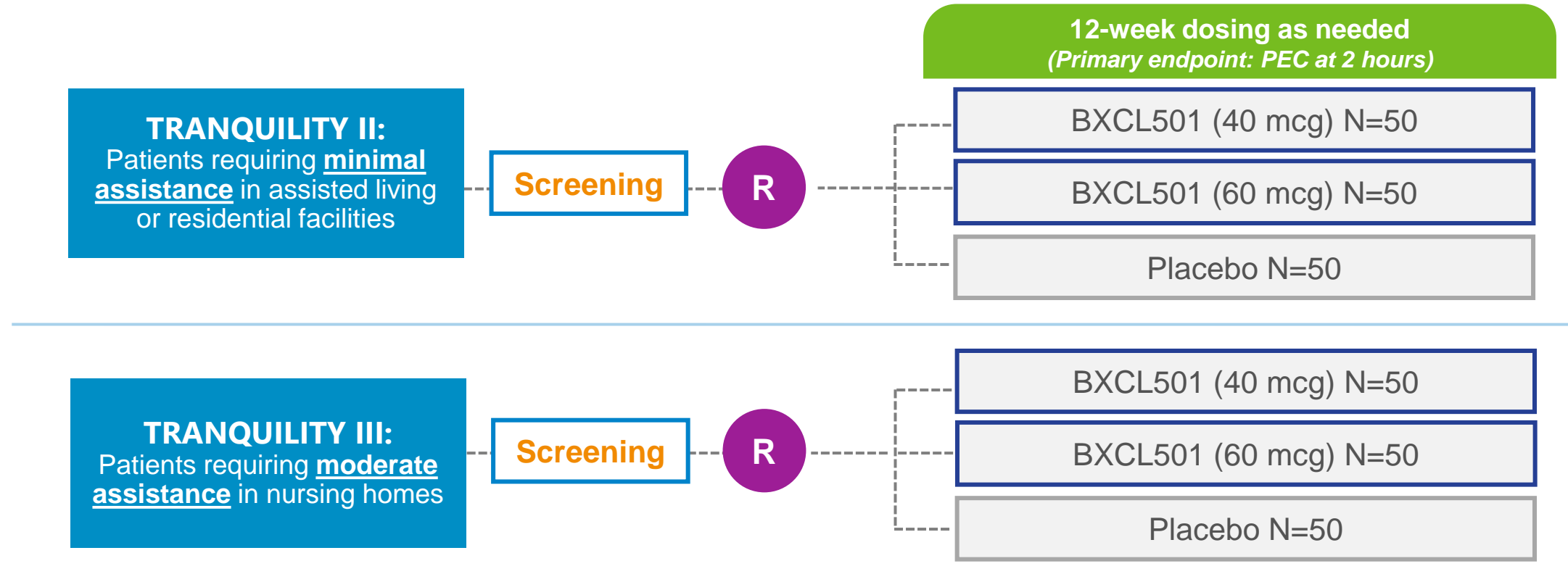
Alzheimer's Dementia Episodes



1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5. Data on File. 6 139M episodes @ \$105/episode

TRANQUILITY II and TRANQUILITY III Pivotal Trials

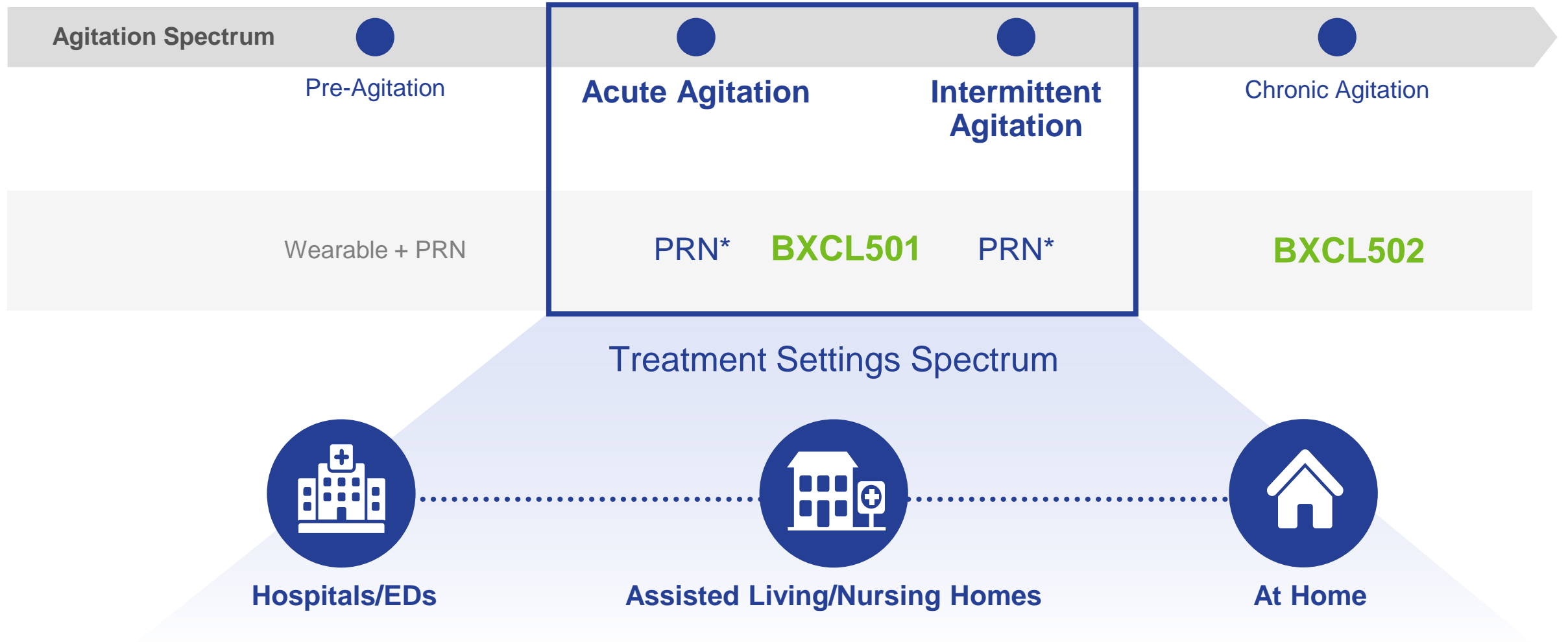
Pivotal Program of BXCL501 for Acute Treatment of Agitation in Patients with Alzheimer's Disease



Rollover Safety Study

Open-label, long-term, one-year safety study dosed as needed

Comprehensive Alzheimer's Disease Program Strategy



*As needed

Depression Represents a Considerable Societal Burden

300M+

Antidepressant
prescriptions filled
annually

Major limitation of slow onset
and incomplete response



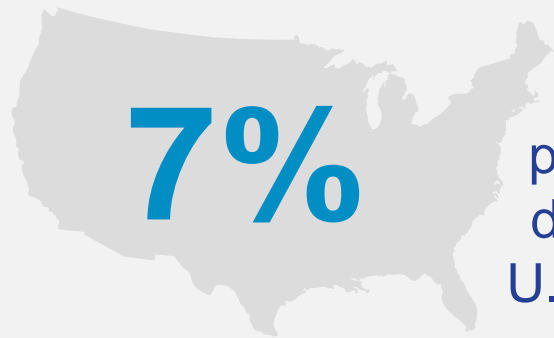
30M+

Americans currently
prescribed antidepressants



12.7%

U.S. population over
12 years old took
antidepressants in
prior month



12-month
prevalence of
depression in
U.S. population



25%

Remain ill one year after
starting treatment

Almost two-thirds are on antidepressants for >2 years

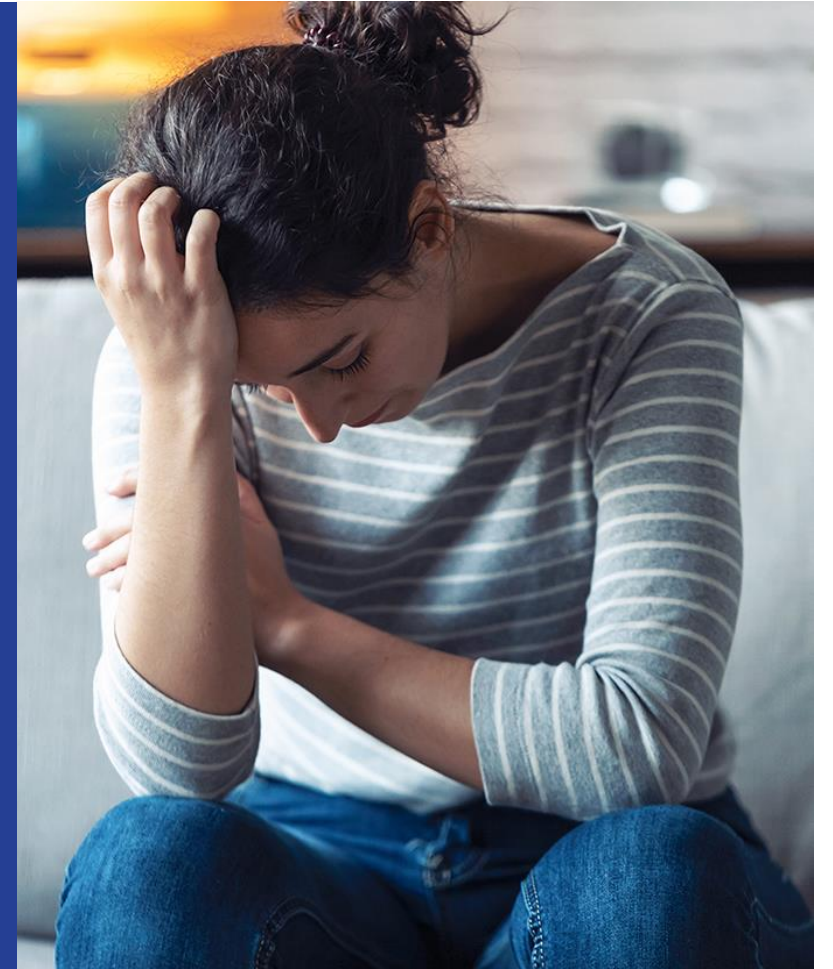


BXCL501: Being Investigated for Short-term Treatment of Depression Symptoms While Starting Antidepressant Medication

- During first weeks after starting SSRI/SNRI regimen, ~50% of patients showed symptoms of anxiety¹ leading to poor compliance and clinical outcomes.
- Preclinical and clinical data suggest BXCL501 could potentially address symptoms of depression not adequately treated by existing antidepressants.



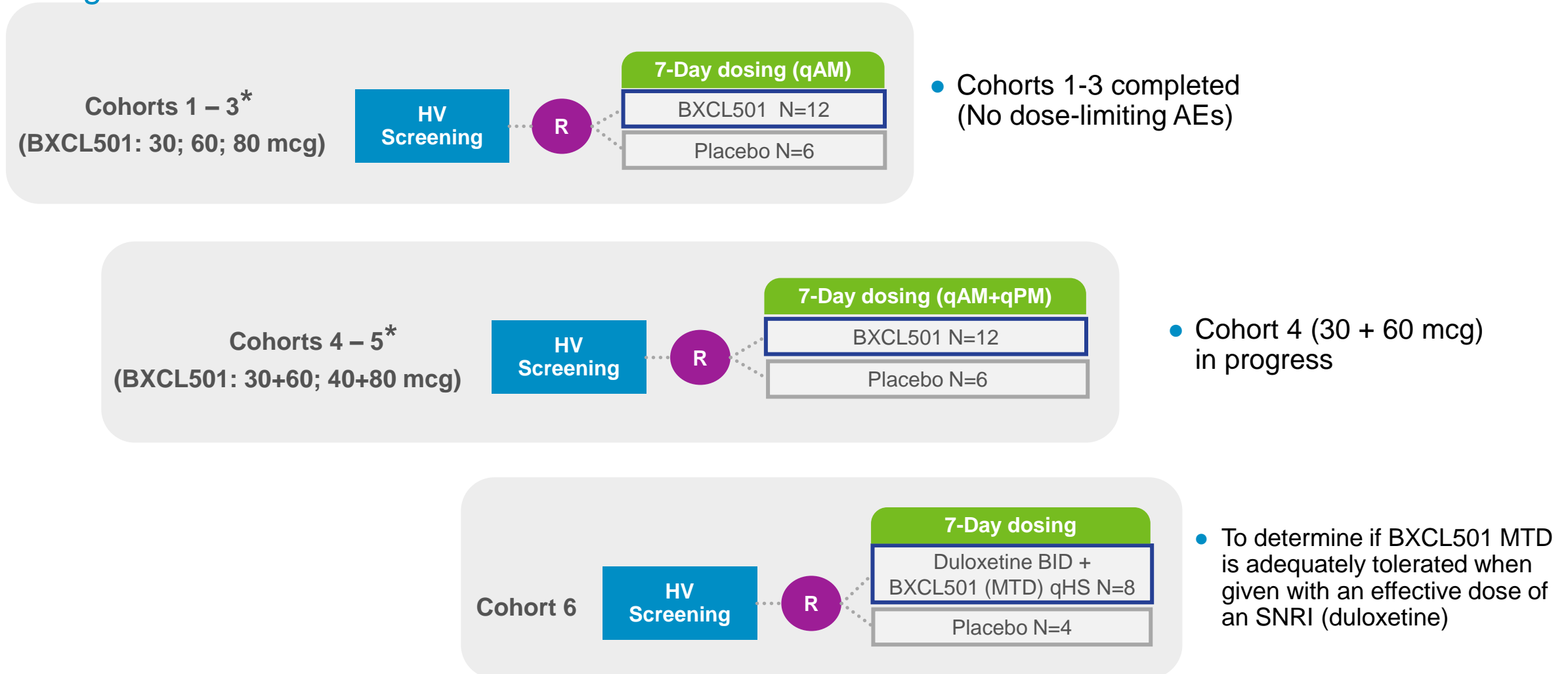
- ✓ **Anxiety**
- ✓ **Restlessness**
- ✓ **Irritability**
- ✓ **Panic**
- ✓ **Sleep disturbances**
 - Suicidality
 - Sadness
 - Concentration / Decision-making
 - Diminished energy
 - Anhedonia / Diminished interests
 - Appetite
 - Self worth
 - Bodily symptoms
 - Rejection sensitivity



¹ Gaspersz R, Lamers F, Kent JM, Beekman ATF, Smit JH, van Hemert AM, Schoevers RA, Penninx BWJH. Anxious distress predicts subsequent treatment outcome and side effects in depressed patients starting antidepressant treatment. J Psychiatr Res. 2017 Jan;84:41-48. doi: 10.1016/j.jpsychires.2016.09.018. Epub 2016 Sep 21. PMID: 27693981.

Major Depressive Disorder: Multiple Ascending Dose Study With Concomitant Treatment With Antidepressant

Designed to Inform Dose Selection in Future Proof-of-Concept Study Evaluating Daily BXCL501 Dosing in MDD Patients



*Cohorts to be completed sequentially

Multi-Billion-Dollar Neuroscience Market Opportunity



Global Expansion

Bipolar I or II Disorder/ Schizophrenia-related Agitation

~16 million¹⁻³ annual institutional episodes of agitation associated with bipolar disorders & schizophrenia in U.S.

At-Home Setting Expansion*

~23 million¹⁻⁴ annual at-home Rx/self-managed agitation episodes in U.S.

*Bipolar I or II Disorder
Schizophrenia-related
Agitation

Alzheimer's-Related Agitation

~100 million⁵ annual episodes of agitation associated with Alzheimer's disease in U.S.⁵

U.S. adults 65+ with AD to double by 2040⁶

Major Depressive Disorder

300+ million antidepressant prescriptions filled annually⁷

Digital technologies for developing potential preventative therapies



1. Wu, 2006, NAMI 2. NIMH- Prevalence of bipolar disorder in adults. November 2017. Accessed June 24, 2021. https://www.hcp.med.harvard.edu/ncs/ftpdir/NCS-R_12-month_Prevalence_Estimates.pdf 3. Data on File 4. inVibe Patient Agitation Market Research, July 2022 (n=57) 5 Estimate based on company market research 6 Alzheimer's Association 7 NIH/WHO, SAMHSA, NIMH Pratt et al, 2017 7 NIH/WHO, SAMHSA, NIMH Pratt et al, 2017


Immuno-Oncology

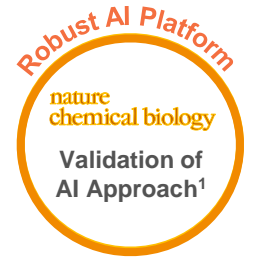
OnkosXcel
Therapeutics™

A subsidiary of BioXcel Therapeutics, Inc.



BXCL701: A Differentiated First-in-Class Investigational Oral Innate Immune Activator

Candidate	<ul style="list-style-type: none"> One of most advanced orally available innate activator candidates in the clinic Single agent activity in Phase 2 + large safety database
Function / MoA Biomarker	<ul style="list-style-type: none"> Designed to: <ul style="list-style-type: none"> Mediate increase in key pro-inflammatory cytokines Activate inflammasome via DPP 8/9 Indications chosen based on frequency of DPP mutations
Clinical Effect	<ul style="list-style-type: none"> Pro-inflammatory activity inflames tumor microenvironment and is designed to: <ul style="list-style-type: none"> Augment and deepen responses in checkpoint inhibitor naïve patients Reverse resistance in patients who have progressed on checkpoint inhibitor Extend activity into cold tumors
Proposed Indications	<ul style="list-style-type: none"> Metastatic castration-resistant prostate cancer — adenocarcinoma and small-cell/neuroendocrine Relapsed Solid Tumors (Hot Tumors)
External Benchmark	



BXCL701 is an investigational product. The safety and efficacy has not been established.

1. Nature Chemical Biology, volume 13, pages 46–53 (2017) 2 Journal for ImmunoTherapy of Cancer 2021; 9:e002837. doi:10.1136/jitc-2021-002837"

Interim Data for BXCL701 Suggest Clinical Proof of Concept Currently in Phase 2

ASCO[®] Genitourinary
Cancers Symposium
2022

SCNC — aggressive variant of metastatic castration-resistant prostate cancer

- 93% enrolled SCNC patients pre-treated with platinum

SCNC 33% composite response rate (n = 15)

- 33% RECIST-defined PR — all responders MSS/TMB low
- 58% disease control rate (CR + PR + SD)

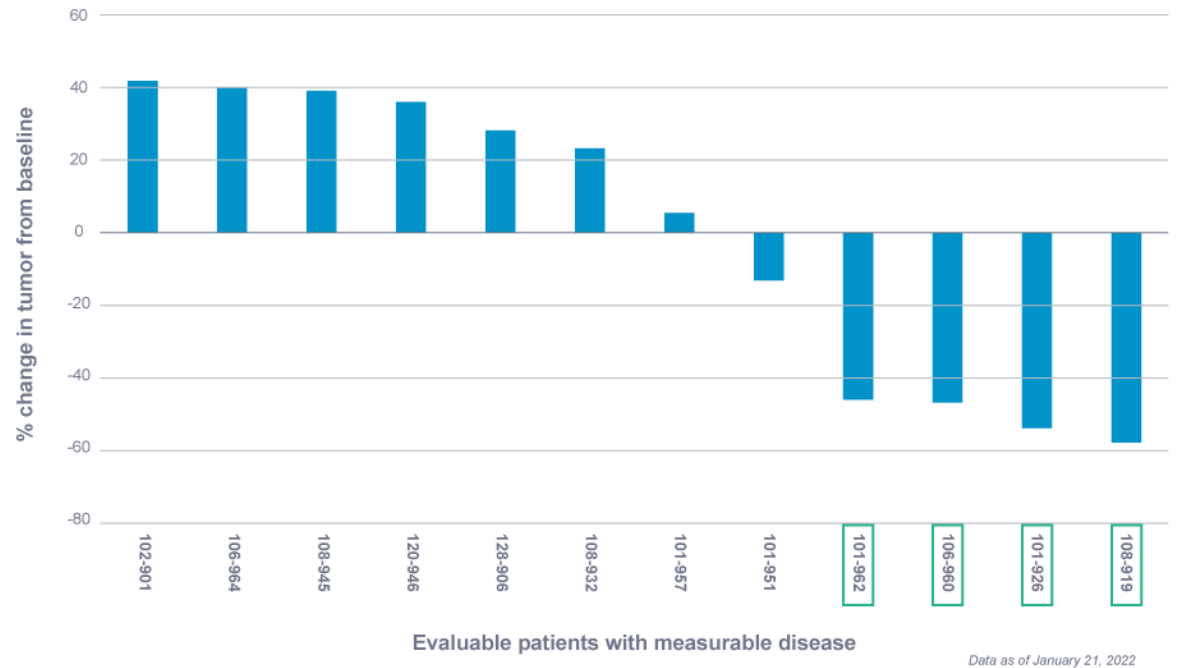
PD-L1 inhibitor single agent historic data in SCNC

- Objective response rate 6.7% — 1/15 patients
 - ♦ Responder was microsatellite instability-high^{1*}
- No response observed in microsatellite stable patients

**BXCL701 + KEYTRUDA[®] (pembrolizumab)
demonstrated manageable safety profile**

- Majority of AEs were low grade
- No evidence of increased immune-related AEs

SCNC Tumor Best Response (N=12)



*FOR ILLUSTRATIVE PURPOSES ONLY: no head-to-head studies have been conducted comparing OXCL701 to checkpoint inhibitors as a single agent. Differences exist between trial designs and subject characteristics, and caution should be exercised when comparing data across studies.





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Value Proposition / Growth Potential



Strong Value Proposition and Long-Term Growth Potential

Transformative Approach With Technology, Business Model, and Medicines

 Unprecedented Value Creation*	 Clinically Validated AI Platform	 Advanced Pipeline	 Large Market Opportunity
<ul style="list-style-type: none"> Optimize R&D economics Shorten development timelines Achieve higher probability of success <p>* all 3 driven by comprehensive AI plan</p>	<ul style="list-style-type: none"> Proprietary AI Platform technology BXCL501 – IND acceptance to IGALMI™ approval in 3.5 yrs. <ul style="list-style-type: none"> - 3 upcoming Phase 3 trials BXCL701 – Human POC established in SCNC <ul style="list-style-type: none"> - Leader in DPP 8/9 biology (new checkpoint) 	<ul style="list-style-type: none"> BXCL501: Alzheimer's-related agitation <ul style="list-style-type: none"> - TRANQUILITY II & III Pivotal program BXCL501: Bipolar & Schizophrenia-related agitation (at-home setting) <ul style="list-style-type: none"> - SERENITY III pivotal trial BCXL701: SCNC clinical POC <ul style="list-style-type: none"> – 800-patient safety database 	<ul style="list-style-type: none"> ~39 million* annual episodes of agitation associated with schizophrenia & bipolar disorders in U.S.^{1,2,3,4} ~100 million annual episodes of agitation associated with Alzheimer's disease in U.S.⁵ 300+ million antidepressant prescriptions filled annually⁶



Strong Financial Position

- Cash runway into 2025****
- Well-funded to drive catalysts & long-term growth

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Thank you!

