Igalmi™
(dexmedetomidine)
sublingual film · 120 mcg, 180 mcg

FDA Approves IGALMI™ Sublingual Film For Acute Treatment of Agitation Associated with Schizophrenia or Bipolar I or II Disorder in Adults

April 6, 2022

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

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 the timing of commercial launch of IGALMI, the benefits of treatment with IGALMI, the market for IGALMI, clinical development plans 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 BioXcel Therapeutics' current expectations and various assumptions. BioXcel 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, and BXCL501, BXCL502, 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; undesirable side effects caused by BioXcel's products and product candidates; its novel approach to the discovery and development of product candidates based on EvolverAI; regulatory agencies may not accept or agree with the Company's assumptions, estimates, calculations, conclusions or analyses or may interpret or weight the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the Company in general; the Company has no experience in marketing and selling drug products and has not entered into arrangements for the sale and marketing of IGALMI; IGALMI or the Company's other product candidates may not be accepted by physicians or the medical community in general; 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 products and product candidates; and the other important factors discussed under the caption "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2021, 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.

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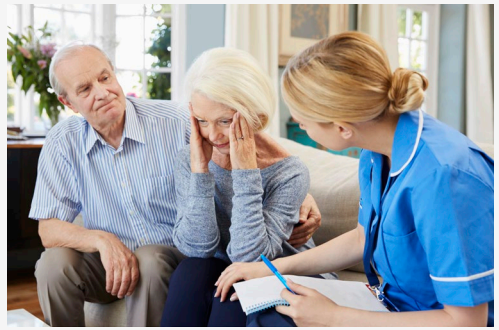
Agitation Associated with Schizophrenia & Bipolar Disorders: A Significant Unmet Need for a Large Population

- Approximately 7.3 million estimated diagnosis in adult patients[1,2]
- Up to 25 million agitation episodes per year based on diagnosed prevalence in the U.S.[3]
- Characterized by recurring episodes requiring frequent treatments
- A challenging condition for healthcare professionals to treat
- Current treatment options may come with trade-offs
  - Physically restraining patients
  - Potentially over-sedating therapies such as antipsychotics and benzodiazepines
  - Antipsychotic drugs have black box warnings for elderly
- IGALMI offers a novel option to help control agitation



Sources:
1. Wu, 2006, NAMI
2. 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. BioXcel Therapeutics, Inc. New Haven, CT. Based on claims databases and published data, estimates were derived based on annual estimated percent of U.S. patients diagnosed with schizophrenia or bipolar disorders, annual percentage of diagnosed patients experiencing episodes of agitation, and estimated frequency of agitation episodes.

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IGALMI™ 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 indication[1].

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

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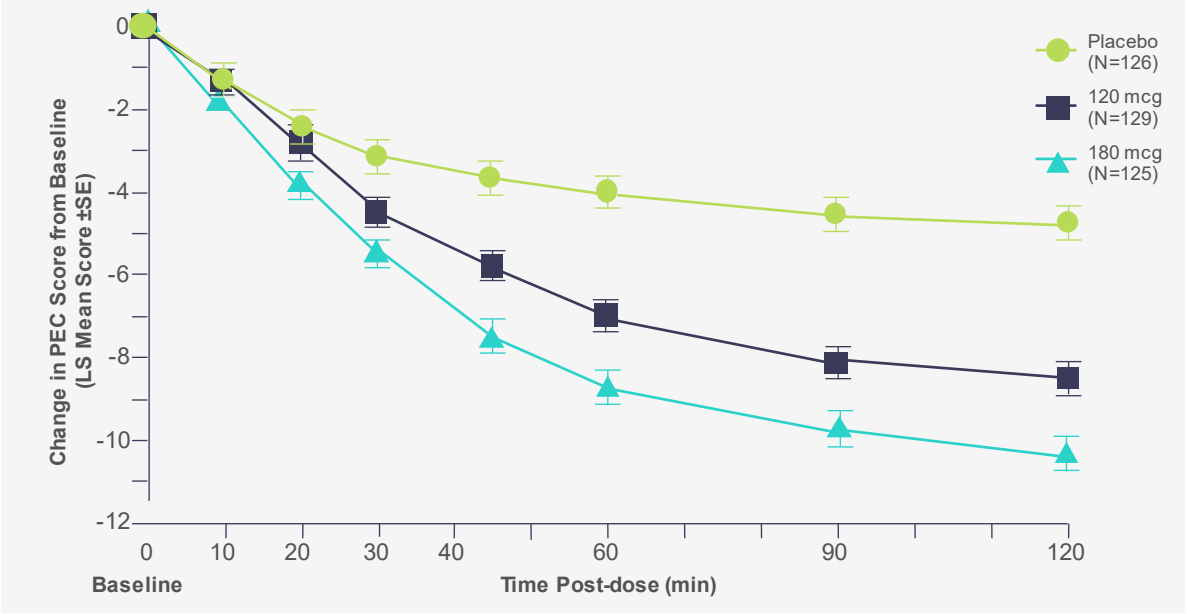
Basis for Final Label and Approval: SERENITY I and II Trials Demonstrated Onset of Action as Early as 20 Minutes and High Response Rate

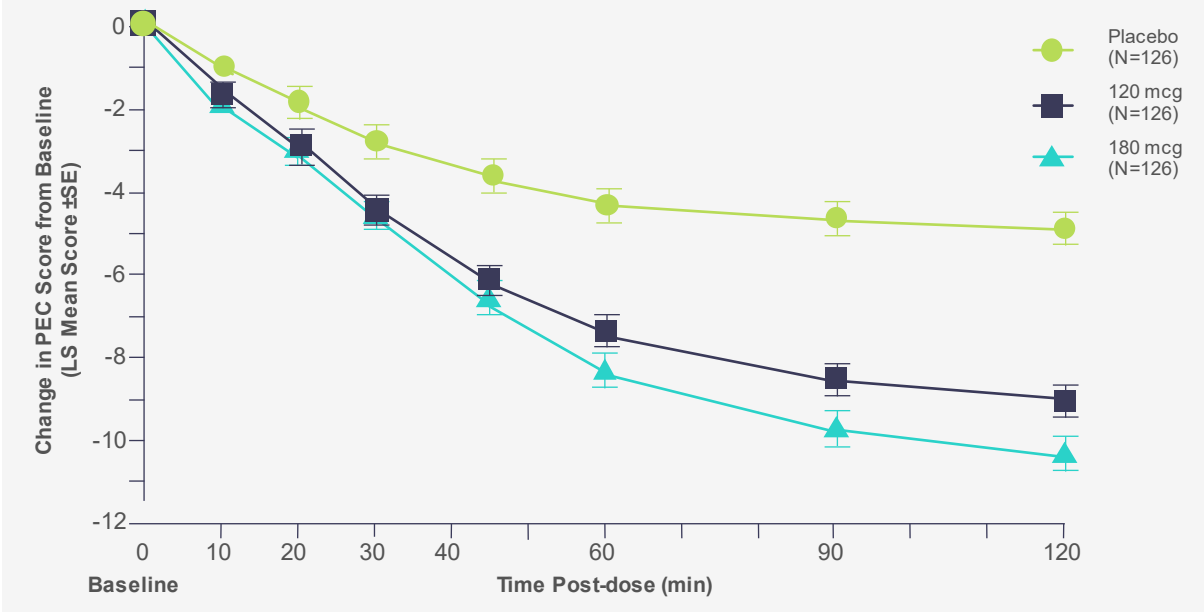
SERENITY I: Change in PEC Score from Baseline



PEC baseline scores were 17.6, 17.5, and 17.6 in the placebo, IGALMI 120 mcg, and IGALMI 180 mcg groups, respectively.

Note: Statistical significance vs. placebo was not observed until 30 minutes for the 120 mcg dose.

SERENITY II: Change in PEC Score from Baseline



PEC baseline scores were 17.9, 18.0, and 18.0 in the placebo, IGALMI 120 mcg, and IGALMI 180 mcg groups, respectively.

IGALMI met the primary and key secondary endpoint at the 120 mcg and 180 mcg doses, demonstrating statistically significant improvements from baseline

LS = least square; PEC = Positive and Negative Syndrome Scale – Excited Component; SE = standard error

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Commercial Readiness: Launch Field Force in 2Q, Focus on High Value Targets

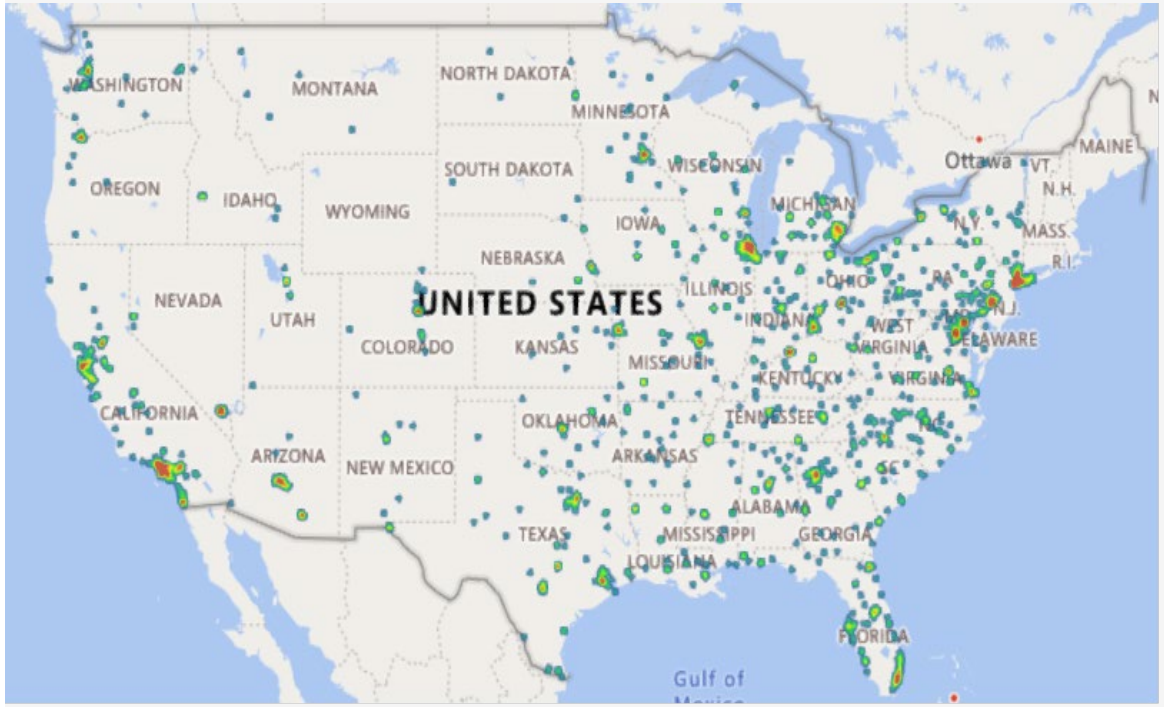
~1,700 target institutions represent **~75%** in volume

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

High Value Provider targets at launch within these institutions

Primary focus on **Emergency Medicine & Psychiatry** specialties

Secondary Focus on **Clinical Pharmacy**



Internal Company data and analysis.

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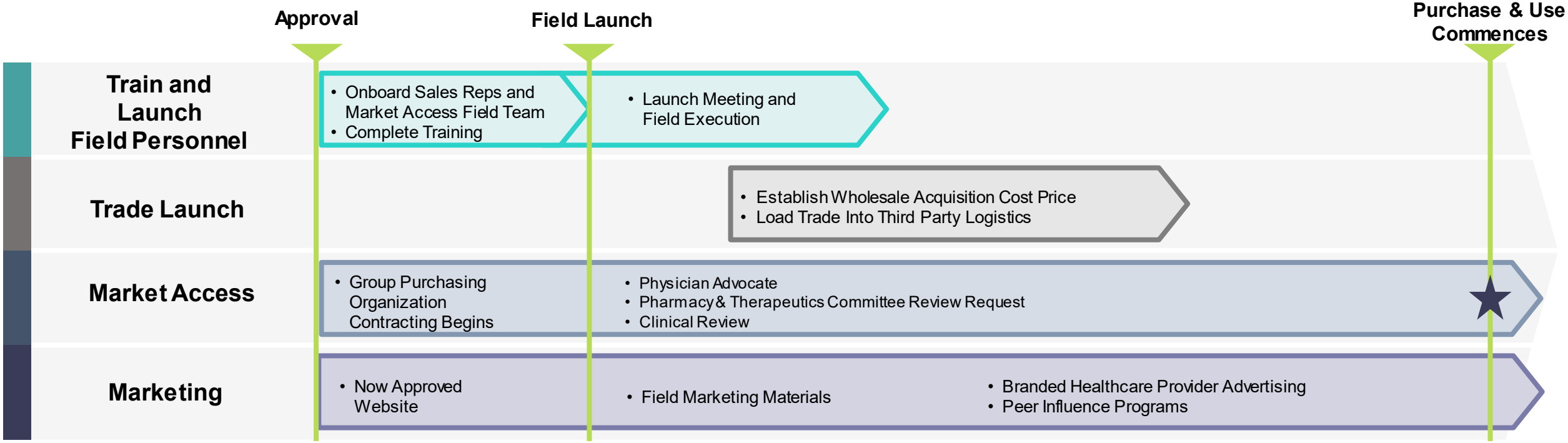
Integrated Sales Rollout With Expected Trade Launch in Q3



ALIGNING COMMERCIAL EXECUTION TO NEAR- AND LONG-TERM GROWTH STRATEGY

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Land and Expand Strategy

** The Company cannot guarantee that IGALMI will be approved for these or any other indications by the FDA or any comparable health authority, and the Company will not be able to promote or commercialize IGALMI for any expanded indications unless and until such approvals are obtained.*

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Important Safety Information

WARNINGS AND PRECAUTIONS

Hypotension, Orthostatic Hypotension, and Bradycardia: IGALMI causes dose-dependent hypotension, orthostatic hypotension, and bradycardia. Because IGALMI decreases sympathetic nervous system activity, hypotension and/or bradycardia may be more pronounced in patients with hypovolemia, diabetes mellitus, or chronic hypertension, and in geriatric patients. Avoid use of IGALMI in patients with hypotension, orthostatic hypotension, advanced heart block, severe ventricular dysfunction, or history of syncope. After IGALMI administration, patients should be adequately hydrated and should sit or lie down until vital signs are within normal range. If a patient is unable to remain seated or lying down, precautions should be taken to reduce the risk of falls. Ensure that a patient is alert and not experiencing orthostatic hypotension or symptomatic hypotension prior to allowing them to resume ambulation.

QT Interval Prolongation: IGALMI prolongs the QT interval. Avoid use of IGALMI in patients at risk of torsades de pointes or sudden death, including those with known QT prolongation, a history of other arrhythmias, symptomatic bradycardia, hypokalemia, or hypomagnesemia, and in patients receiving other drugs known to prolong the QT interval.

Somnolence: IGALMI can cause somnolence. Patients should not perform activities requiring mental alertness, such as operating a motor vehicle or operating hazardous machinery, for at least eight hours after taking IGALMI.

Risk of Withdrawal Reactions, Tolerance, and Tachyphylaxis: IGALMI was not studied for longer than 24 hours after the first dose. There may be a risk of physical dependence, a withdrawal syndrome, tolerance, and/or tachyphylaxis if IGALMI is used in a manner other than indicated.

ADVERSE REACTIONS

The most common adverse reactions (incidence ≥5% and at least twice the rate of placebo) were somnolence, paresthesia or oral hypoesthesia, dizziness, dry mouth, hypotension, and orthostatic hypotension.

DRUG INTERACTIONS

Drugs That Prolong the QT Interval: Avoid use.

Anesthetics, Sedatives, Hypnotics, and Opioids: Concomitant use may cause enhanced CNS-depressant effects. Reduction in dosage of IGALMI or the concomitant medication should be considered.

USE IN SPECIFIC POPULATIONS

Hepatic Impairment and Geriatric Patients (≥65 years old): A lower dose is recommended in patients with hepatic impairment and geriatric patients. See the full Prescribing Information for the recommended dosage depending on the agitation severity.

Please see full Prescribing Information.

To report SUSPECTED ADVERSE REACTIONS, contact BioXcel Therapeutics, Inc. at 1-833-201-1088 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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Thank You!

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