AtaiBeckley Doses Last Patient in VLS-01 Phase 2b TRD Study; Plans Phase 3 in Major Depressive Disorder

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- 156 patients randomized in multi-center, double-blind, placebo-controlled Phase 2b Elumina trial; topline data anticipated in Q4 2026 (ClinicalTrials.gov: NCT06524830)
- AtaiBeckley plans to advance VLS-01 into major depressive disorder (MDD) in Phase 3, with generalized anxiety disorder (GAD) as a potential follow-on indication
- VLS-01 and BPL-003 (in Phase 3 development for treatment-resistant depression with Breakthrough Therapy Designation) together positioned to address patients across the spectrum of mood and anxiety disorders

NEW YORK, July 06, 2026 (GLOBE NEWSWIRE) -- AtaiBeckley Inc. (NASDAQ: ATAI) (“AtaiBeckley” or “Company”), a clinical-stage biotechnology company on a mission to transform patient outcomes by developing rapid-acting, durable and convenient mental health treatments, today announced that the last patient has been dosed in Elumina, its Phase 2b clinical trial evaluating VLS-01 in adults living with treatment-resistant depression (TRD). The study randomized 156 patients, with topline data expected in Q4 2026.

Study Overview

Investigational product:	VLS-01
Formulation:	Proprietary oral transmucosal film formulation of N,N-Dimethyltryptamine (DMT)
Mechanism of action:	Serotonin agonist at $5HT_{1/2/6/7}$ receptors
Indication:	Treatment-resistant depression
Study name:	Elumina
Design:	Multi-center, double-blind, randomized, placebo-controlled Phase 2b. 156 patients randomized 1:1
ClinicalTrials.gov identifier	NCT06524830
Primary outcome:	VLS-01 versus placebo mean change from Baseline in Montgomery-Åsberg Depression Rating Scale (MADRS) total score at Day 29
Secondary and exploratory outcomes:	Placebo-adjusted mean change from Baseline in MADRS total score at weeks 6 and 14, Columbia-Suicide Severity Rating Scale (C- SSRS) scores, safety and tolerability
Upcoming milestones:	Topline data readout anticipated Q4 2026

Management Commentary

Srinivas Rao, Co-Founder and Chief Executive Officer at AtaiBeckley, said: *“Completing enrollment and dosing the last patient in Elumina keeps us on track for an anticipated topline readout in Q4 2026 and marks the strategic moment to articulate where this program goes next. With BPL-003 advancing in treatment-resistant depression through our recently initiated Phase 3 program, we have the opportunity to direct VLS-01 toward patients across the broader spectrum of depressive illness. We intend to advance VLS-01 into major depressive disorder in Phase 3, subject to supportive Phase 2 results, where the same mechanistic rationale applies and where we can reach patients who fall outside the TRD definition but carry a similar burden of disease. We also see generalized anxiety disorder as a significant future opportunity for VLS-01, given the scale of unmet need, the mechanistic profile of the compound, and VLS’s design to fit within a two-hour treatment session - a meaningful advantage for a chronic indication where patients could require repeat visits over time. Together, BPL-003 and VLS-01 position AtaiBeckley to serve patients across the spectrum of mood and anxiety disorders, from the most severe and refractory to those who have yet to see a meaningful advance in care.”*

Study Design

Elumina is an international Phase 2b, multi-center, double-blind, randomized, placebo-controlled clinical trial designed to evaluate the efficacy, safety, and tolerability of repeated dosing of VLS-01 in adults living with treatment-resistant depression (TRD). Participants are randomized 1:1 to receive VLS-01-BU (a buccal oral transmucosal film formulation of VLS-01) or placebo during the placebo-controlled treatment period. Participants receive a total of two double-blind administrations, delivered via the buccal

transmucosal route, with a two-week interval between each administration. Following the second dose, all participants enter a 12-week placebo-controlled follow-up period, during which depressive symptoms, safety, and tolerability are systematically monitored. After completion of the placebo-controlled treatment and observation period, all participants are re-randomized 1:1 to receive a single additional double-blind administration of VLS-01-BU during a non-placebo-controlled treatment period. In this phase, participants receive either dose strength 1 or dose strength 2 of VLS-01-BU, enabling further characterization of safety and efficacy across dose levels. Final safety and efficacy assessments are conducted two weeks following administration of the third dose.

Subject to a supportive Phase 2 readout and regulatory alignment, AtaiBeckley intends to advance VLS-01 into major depressive disorder (MDD) in a Phase 3 program. TRD and MDD share substantial clinical and mechanistic overlap, and a positive result in the TRD population would provide a strong scientific basis for the MDD program. The Company also sees generalized anxiety disorder (GAD) as a potential fast follower indication for VLS-01, given the serotonergic mechanism and the scale of unmet need in that space.

FAQ
Q1: Is this announcement an efficacy readout?
A1: No. This announcement reports a clinical operations milestone. Efficacy and safety data will be reported with topline results in Q4 2026.

Q2: What patient populations could VLS-01 target?
A2: The Elumina trial is focused on treatment-resistant depression. Subject to a supportive Phase 2 readout, AtaiBeckley intends to advance VLS-01 into major depressive disorder (MDD) in Phase 3. TRD and MDD share significant mechanistic and clinical overlap, and a positive result in TRD would provide a strong scientific basis for an MDD program. The Company also sees generalized anxiety disorder (GAD) as a potential fast follower. BPL-003, AtaiBeckley's other late-stage asset, is concurrently advancing through Phase 3 in TRD, giving the Company the potential for differentiated coverage across the spectrum of depressive illness.

Q3: Why is AtaiBeckley targeting MDD with VLS-01 rather than BPL-003?
A3: BPL-003 and VLS-01 are distinct investigational compounds being developed as complementary assets. BPL-003 has received FDA Breakthrough Therapy Designation for TRD and is advancing through Phase 3 in that indication. VLS-01, as a differentiated compound currently in Phase 2b in TRD, offers a separate development pathway into the broader MDD population subject to supportive results.

Q4 When will results be available?
A4: AtaiBeckley anticipates reporting topline Phase 2 data from Elumina in Q4 2026.

About VLS-01
VLS-01 is a proprietary oral transmucosal film formulation of N,N-Dimethyltryptamine (DMT) being developed by AtaiBeckley as a potential treatment for depression. Initial Phase 2 clinical development is focused on treatment-resistant depression (TRD), with Phase 3 development in major depressive disorder (MDD) planned subject to Phase 2 results. Pharmacologically, VLS-01 is a partial to full agonist of the 5-HT1/2/6/7 sub-receptors and is being developed to potentially offer rapid, robust, and durable efficacy with a favorable safety profile. VLS-01 is designed to fit within the established two-hour interventional psychiatry treatment paradigm, positioning it for integration into existing care models. VLS-01 is an investigational product and has not been approved by the FDA or any other regulatory body.

About AtaiBeckley Inc.
AtaiBeckley is a clinical-stage biotechnology company on a mission to transform patient outcomes by developing rapid-acting, durable and convenient mental health treatments. AtaiBeckley's pipeline of novel therapies includes BPL-003 (mebufotenin benzoate nasal spray) for treatment-resistant depression (TRD), VLS-01 (DMT buccal film) for MDD and GAD, and EMP-01 ((R)-MDMA HCl) for social anxiety disorder. BPL-003 was granted Breakthrough Therapy Designation from the U.S. Food and Drug Administration and is in Phase 3 clinical development; VLS-01 and EMP-01 are in Phase 2 clinical development. The Company is also advancing a drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for opioid use disorder and TRD. These programs aim to create breakthroughs in mental health through transformative interventional psychiatry therapies that can integrate seamlessly into healthcare systems.

For the latest updates and to learn more about the AtaiBeckley mission, visit www.ataibeckley.com or follow the Company on LinkedIn and on X.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "initiate," "could," "would," "project," "plan," "potentially," "preliminary," "likely," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Forward-looking statements in this press release include, among others, statements regarding: the timing and outcome of the Elumina Phase 2 trial of VLS-01, including the anticipated topline data readout in the fourth quarter of 2026; AtaiBeckley's plans to advance VLS-01 into a Phase 3 program in major depressive disorder, and the timing thereof, which is subject to positive Phase 2 results and regulatory alignment; the

Company's view of generalized anxiety disorder as a potential follow-on indication for VLS-01; the potential of VLS-01, alone or together with BPL-003, to address the broader spectrum of mood and anxiety disorders; and the Company's business strategy and plans for its product candidates generally.

Forward-looking statements are neither promises nor guarantees, but involve known and unknown risks and uncertainties that could cause actual results to differ materially from those projected, including, without limitation, results from the Elumina trial that differ from topline expectations, delays in completing the trial or reporting data, and the important factors described in the section titled "Risk Factors" in our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC") or Quarterly Reports on Form 10-Q filed with the SEC, as such factors may be updated from time to time in our other filings with the SEC. Any forward-looking statements made herein speak only as of the date of this press release, and you should not rely on forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, performance or achievements reflected in the forward-looking statements will be achieved or will occur. We disclaim any obligation to update or revise any forward-looking statements contained in this press release, other than to the extent required by applicable law.

Contact Information:

Investors:
Jason Awe, PhD
VP, Investor Relations
IR@ataibeckley.com

Media:
Charlotte Chorley
Associate Director, Communications
PR@ataibeckley.com