AtaiBeckley's BPL-003 Shows Rapid, Durable Antidepressant Response in Treatment-Resistant Depression Patients on SSRIs; Phase 2a Data Published in CNS Drugs

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- 66.7% of participants achieved an antidepressant response by Day 2 following a single intranasal dose of BPL-003 in both the 10 mg (n=6) and 12 mg (n=6) cohorts
- Durable responses observed at Day 85: 83% (5/6) (10 mg) and 66.7% (4/6) (12 mg)
- BPL-003 received FDA Breakthrough Therapy Designation in October 2025
- Phase 3 initiation on track for Q2 2026

NEW YORK, April 08, 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 peer-reviewed Phase 2a results (NCT05660642) in *CNS Drugs* demonstrating that a single intranasal dose of BPL-003 (mebufotenin benzoate), which holds FDA Breakthrough Therapy Designation, achieved rapid and sustained reductions in MADRS scores from baseline in participants with treatment-resistant depression (TRD) who remained on stable SSRI therapy throughout the study (n=12). A 66.7% antidepressant response rate (≥50% reduction from baseline MADRS score) was observed at Day 2 in both the 10 mg (n=6) and 12 mg (n=6) cohorts, with 83% (5/6) of participants in the 10 mg cohort and 66.7% (4/6) of participants in the 12 mg cohort maintaining a response at Week 12. BPL-003 was generally well tolerated with no serious adverse events reported, and participants achieved a mean discharge approximately 100 minutes post-dose. Phase 3 studies are on track to initiate in Q2 2026 following recent FDA End-of-Phase 2 (EOP2) alignment.

Clinical Data Summary	
Drug	BPL-003 (mebufotenin benzoate intranasal spray)
Mechanism	5-HT1A and 5-HT2A agonist associated with rapid onset and treatment experience of ~2 hours
Indication	Treatment-resistant depression (TRD); failure to respond to ≥2 prior antidepressants at adequate dose and duration
Designations	U.S. FDA Breakthrough Therapy Designation granted October 2025
Trial	NCT05660642: four-part Phase 2a open-label study. Part 2 (SSRI-concomitant, n=12) reported here; Part 1 (monotherapy, single dose, n=12) published in Journal of Psychopharmacology in March 2026. Part 3 (8 mg + 12 mg, monotherapy, n = 12) topline announced September 2025. Part 4 (8 mg + 8 mg, adjunctive) ongoing; initial data expected Q4 2026.
Endpoint	Safety and tolerability; exploratory Montgomery-Asberg Depression Rating Scale (MADRS) total score change from baseline
Responder Rate (Day 2)	66.7% of participants achieved ≥50% MADRS reduction from a single dose
Durability (Day 85)	83% responders (10 mg cohort); 66.7% (12 mg cohort)
MADRS-6 Core Symptoms	19.2 → 6.2 (10 mg); 21.0 → 9.3 (12 mg); ≤10 = remission
Safety	No serious adverse events; majority of drug-related AEs transient and resolved on same day
Discharge Readiness	Mean ~100 minutes post-dose
Phase 3 Status	End-of-Phase 2 meeting with U.S. FDA completed; Phase 3 initiation on track for Q2 2026

Management Commentary

Srinivas Rao, Co-Founder and Chief Executive Officer of AtaiBeckley said: *"A 66.7% Day-2 response rate with a single intranasal dose of BPL-003, maintained through Week 12 in the 10 mg cohort, represents a compelling clinical signal in patients who remained on their baseline SSRI therapy. Combined with our statistically significant double-blind, randomized Phase 2b results in*

193 participants and our recent FDA End-of-Phase 2 alignment, these Phase 2a data reinforce the potential of BPL-003 to transform the treatment paradigm for TRD as we prepare to initiate Phase 3 in Q2 2026."

Dr. Kevin Craig, Chief Medical Officer at AtaiBeckley, added: *"This study provides the first Phase 2a evidence that BPL-003 can be administered alongside SSRIs without compromising efficacy or safety, a meaningful advance given that many TRD patients remain on chronic SSRI therapy. The rapid resolution of acute effects and ~100-minute discharge readiness further support the feasibility of integrating BPL-003 into existing interventional psychiatry settings."*

Study Details
The 12-week, open-label, single-center, ascending-dose trial enrolled 12 adults aged 18 to 75 years with moderate-to-severe major depressive disorder (baseline MADRS ≥24) and TRD. All participants had failed at least two prior antidepressants and remained on a stable dose of one of four SSRIs - citalopram, escitalopram, sertraline or fluoxetine - throughout the study. Six participants received a single intranasal 10 mg dose of BPL-003 and six received a single intranasal 12 mg dose of BPL-003, with psychological support before, during and after dosing. Participants were followed for 12 weeks.

This publication represents Part 2 of the four-part Phase 2a open-label study. Data from Part 1 (BPL-003 monotherapy, 10 mg single dose, n=12) was published in the Journal of Psychopharmacology in March 2026, reporting a mean 12.6-point MADRS reduction by Day 2, sustained through 12 weeks. Topline data from Part 3 (8 mg + 12 mg, BPL-003 monotherapy, n=12) were announced in September 2025, showing that a second dose of BPL-003 at Week 2 has the potential to induce additional reductions in MADRS scores without impact on the safety and tolerability profile of the treatment. Part 4 of the program - evaluating a two-dose induction regimen of BPL-003 (8 mg + 8 mg) in participants with TRD who are also receiving defined antidepressants – is ongoing. Initial data from that cohort is expected in Q4 2026.

About BPL-003
BPL-003 is a patent-protected, proprietary intranasal formulation of mebufotenin benzoate (5-MeO-DMT), administered via a nasal spray device used in a previously approved drug product. BPL-003 is designed to deliver rapid and durable effects from a single dose, with a short psychedelic duration, and is being investigated as a potential therapy for treatment-resistant depression (TRD) and alcohol use disorder (AUD). BPL-003 has been granted Breakthrough Therapy designation by the U.S. Food and Drug Administration and is covered by granted US, UK and European composition-of-matter patents, with multiple further claims pending in various jurisdictions.

About Treatment Resistant Depression
Treatment-resistant depression affects an estimated 30% of the nearly 300 million people living with depression around the globe, representing one of the largest areas of unmet need in psychiatry. TRD occurs when a patient does not achieve an adequate response following at least two courses of antidepressants.

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 TRD and EMP-01 ((R)-MDMA HCl) for social anxiety disorder. BPL-003 is in Phase 3 planning, 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 include express or implied statements relating to, among other things: our business strategy and plans; expectations regarding the outcome of regulatory discussions regarding the development of BPL-003; expectations regarding the advancement into Phase 3 studies in adults with TRD and related milestones; expectations regarding the design of the Phase 3 program; and the potential benefits of BPL-003 for patients with TRD.

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, 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"), as such factors may be updated from time to time in our quarterly reports and other filings with the SEC. AtaiBeckley disclaims any obligation to update or revise any forward-looking statements contained in this press release, other than to the extent required by applicable law.

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