# AtaiBeckley Announces Additional Phase 2a Results for EMP-01 (oral R-MDMA) Showing Large and Consistent Improvements in Social Anxiety Disorder

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- EMP-01 demonstrated a large, clinically meaningful reduction in patient-reported SAD symptoms at Day 43: placebo-adjusted LSMD -11.5 points (p=0.002) on SPIN; placebo-adjusted LSMD -15.6 points (p=0.004) on SAFE - a 38% and 32% reduction, respectively
- Patient-perceived global improvement: 49% PGI-C responders at Day 43 compared to 12% on placebo
- No severe or serious adverse events

NEW YORK, April 22, 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 expanded Phase 2a results for EMP-01 (oral R-MDMA) in adults with Social Anxiety Disorder (SAD) (n=70), demonstrating clinically meaningful and consistent improvements across clinician-rated symptoms, patient-reported experience, and real-world behavioral outcomes. At Day 43, EMP-01 achieved a 38% reduction vs 15% on placebo (Hedges’ g=0.84) on the patient-reported Social Phobia Inventory (SPIN), a 32% reduction vs 14% on placebo on the Subtle Avoidance Frequency Examination (SAFE), and a previously reported −11.9-point LS mean difference (LSMD) on the Liebowitz Social Anxiety Scale (LSAS) versus placebo (g=0.45), with 49% responder rates on both Clinical Global Impression-Improvement (CGI-I) (previously reported) and Patient Global Impressions of Change (PGI-C). EMP-01 was well tolerated, with no severe or serious adverse events.

| **Clinical Data Summary** | |
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| **Drug** | EMP-01 (oral R-MDMA) |
| **Indication** | Social Anxiety Disorder |
| **Trial** | NCT06693609: Phase 2a (Randomized 1:1, N=70). Two-dose regimen (Days 1 and 29) with no psychotherapy; last assessment Day 43. |
| **Endpoints** | Primary endpoints safety and tolerability; secondary endpoint change in LSAS total score at Day 43; exploratory endpoints SPIN, SAFE, CGI-I, PGI-C, PK/PD, 11D-ASC |
| **Primary Result** | Well tolerated; no SAEs; no severe TEAEs |
| **Secondary Results** | LSAS placebo-adjusted LSMD: -11.9 points, moderate effect size (g=0.45) at Day 43 (previously reported) |
| **Exploratory Results** | At Day 43:<br><br>SPIN: -18.3 points (38% reduction from baseline vs 15% on placebo), with a large between-group effect size (Hedges’ g=0.84); post hoc MMRM placebo-adjusted LSMD -11.5 points (p=0.002)<br><br>SAFE: -25.9 points (-32% reduction from baseline vs 14% on placebo); post hoc MMRM placebo-adjusted LSMD -15.6 points (p=0.004)<br><br>CGI-I responders: 49% vs 15% placebo (previously reported)<br><br>PGI-C responders: 49% vs 12% placebo |

**Efficacy Findings**
EMP-01 produced consistent and clinically meaningful improvements across all major symptom domains of SAD:

- LSAS: EMP-01 demonstrated a clinically meaningful LSMD of −11.9-points vs placebo (g=0.45) at Day 43 (previously reported), with both total and subscale improvements. Improvements were observed across both fear and avoidance subscales on the clinician-rated 24-item Liebowitz Social Anxiety Scale, indicating that patients experienced fewer social situations as distressing and were more able to engage in them. This degree of change is considered clinically meaningful and reflects broad symptom improvement across core features of social anxiety disorder including fear and anxiety of

social situations.

- SPIN: EMP-01 produced a large, clinically meaningful patient-reported improvement of -18.3-points (38% reduction vs 15% on placebo), which corresponded to a large between-group standardized effect size (g=0.84), in self-reported SAD symptoms from baseline to Day 43. Additional model-based analyses further supported treatment benefits at Day 43, showing statistically significant improvements with a placebo-adjusted LSMD of -11.5 points (95% CI: -18.5, -4.6; p=0.002) at Day 43. Patients treated with EMP-01 moved from severe baseline symptom severity to substantially lower symptom burden by Day 43. These results on the 17-item SPIN are equivalent to being able to initiate conversations, attend social events, and perform at work with substantially less fear and avoidance.
- SAFE: EMP-01 demonstrated a large, clinically meaningful improvement of −25.9-points (32% reduction vs 14% on placebo) in real-world behavioral avoidance at Day 43. Additional model-based analyses further supported treatment benefits at Day 43, showing statistically significant improvements with a placebo-adjusted LSMD of -15.6 points at Day 43 (95% CI: -26.0, -5.2; p=0.004). These results on the Subtle Avoidance Frequency Examination, a 32-item questionnaire that measures safety behaviors, suggest that participants were more willing to participate in everyday activities such as social interactions without engaging in avoidant coping behaviors.
- Clinical impression: 49% CGI-I responders (NNT=2.95) at Day 43 compared to 15% on placebo (previously reported). This measure reflects clinicians' overall judgment of meaningful improvement in a patient's condition, considering symptom severity, functioning, and overall clinical presentation.
- Patient perception: 49% PGI-C responders (NNT=2.72) at Day 43 compared to 12% on placebo. This result indicates that patients themselves perceived the treatment-associated improvements as noticeable and meaningful in their daily lives, reinforcing the clinical and functional outcomes observed on other measures.

**Safety & Tolerability**
EMP-01 was generally safe and well tolerated:

- No SAEs and no severe TEAEs in any participant
- 97% retention, with 0% study dropouts attributed to TEAEs
- TEAEs were expected and consistent with the class, transient, and predominantly mild-to-moderate

Professor Murray Stein, Distinguished Professor of Psychiatry and Public Health at the University of California San Diego (UCSD) and consultant to AtaiBeckley, said: "*I was particularly struck by the consistency of the findings across clinician-rated and patient-reported outcomes. The improvement on the SAFE is especially interesting because reductions in subtle avoidance behaviors are seen as an important goal of cognitive behavioral therapies and yet are seldom measured in medication trials for social anxiety disorder. Taken together, these findings provide strong support for continued development of EMP-01.*"

**Management Commentary**
Dr Srinivas Rao, Co-Founder and Chief Executive Officer at AtaiBeckley, said: *"In this Phase 2a trial of 70 patients, EMP-01 delivered a 49% clinician-rated and patient-reported responder rate alongside significant improvements across LSAS, SPIN, and real-world avoidance behavior. Unlike current standards of care, which require daily, chronic dosing, the durability observed in this study following just two administrations suggests that EMP-01 could be a differentiated treatment option that could meaningfully improve outcomes for people living with Social Anxiety Disorder."*

Dr Kevin Craig, Chief Medical Officer at AtaiBeckley said: "*Social Anxiety Disorder is a chronic and highly impairing condition for which many patients do not achieve adequate benefit from currently available treatments. The consistent improvements observed across clinician-rated symptoms, patient-reported experience, and avoidance behavior—alongside a favorable tolerability profile —provide encouraging evidence that EMP-01 may address multiple important dimensions of this disorder."*

**Study Design**
The multi-center study enrolled 71 adults with moderate-to-severe SAD across 7 clinical sites in the UK. Participants were randomized to receive two in-clinic administrations of EMP-01 (225 mg) or placebo, given 28 days apart, with no adjunctive psychotherapy. 70 participants received at least one dose of study drug, and 69 completed the Day 43 efficacy assessments, indicating high patient acceptability and retention. All clinician-rated assessments were conducted by blinded central raters. Topline results from this study were previously reported in February 2026.

**Frequently Asked Questions**

**Q1: What do the additional Phase 2a results for EMP-01 mean for patients with Social Anxiety Disorder?**
A1: AtaiBeckley today reported additional efficacy and safety dataset from its Phase 2a trial of EMP-01 (oral R-MDMA) in adults with Social Anxiety Disorder. The results show consistent, clinically meaningful improvements across every major symptom domain - clinician-rated anxiety (LSAS), patient-reported symptoms (SPIN), real-world avoidance behavior (SAFE), and global impression scales (CGI-I, PGI-C). Approximately 49% of EMP-01-treated patients were rated as much or very much improved by both their clinician and themselves, compared to roughly 15% and 12% on placebo, respectively. The full safety dataset also confirmed a favorable safety and tolerability profile and no serious adverse events.

**Q2: How does EMP-01's reduction in patient-reported social anxiety compare to standard-of-care treatments?**
A2: On the Social Phobia Inventory (SPIN), EMP-01 produced a placebo-adjusted LSMD of 11.5 points in a supportive post hoc MMRM analysis, with a large effect size (Hedges' g = 0.84) and a 38% reduction from baseline after two doses over six weeks. In

a cross-trial comparison, standard-of-care pharmacotherapies (venlafaxine, paroxetine) produced placebo-subtracted SPIN differences of approximately 6.7–7.8 points at comparable timepoints. On the SAFE behavioral avoidance measure, EMP-01 produced a 32% reduction (−25.9 points), exceeding the −17-point benchmark reported for cognitive behavioral therapy for SAD after 12–16 weeks. Cross-trial comparisons are inherently limited due to differences in study design, patient populations, endpoints, and duration.

**Q3: How does EMP-01 differ from existing pharmacotherapies for Social Anxiety Disorder?**
A3: Current first-line treatments for SAD - primarily SSRIs and SNRIs - require daily dosing and approximately 8–12 weeks to show meaningful effect, and roughly 50% of patients do not achieve adequate response. EMP-01 is designed as an intermittent, in-clinic oral treatment: in this trial, two administrations delivered over 28 days produced clinically meaningful improvements at Day 43, without adjunctive psychotherapy. EMP-01 is an investigational product and has not been approved by the U.S. Food and Drug Administration (FDA).

**Q4: What is Social Anxiety Disorder (SAD)?**
A4: Social Anxiety Disorder (SAD) is one of the most prevalent psychiatric conditions worldwide, affecting an estimated 400–800 million individuals with a lifetime prevalence of approximately 12%. The disorder is characterized by persistent and debilitating fear, self-consciousness, and heightened anxiety during social interactions. SAD is frequently co-morbid with major depressive disorder, generalized anxiety disorder, obsessive–compulsive disorder, attention deficit/hyperactivity disorder, bipolar disorder, and substance use disorders, contributing to substantial functional impairment and reduced quality of life. In the United States alone, roughly 30 million adults are affected by SAD; however, only about 50% of affected individuals receive treatment. Even among patients who access care, treatment adequacy remains suboptimal, and around 50% of SAD patients do not achieve adequate response to first line therapies and often deal with chronic medication side effects.

**Q5: What does post hoc MMRM mean**
A5: These were supportive statistical analyses conducted after topline results using a standard repeated-measures modelling approach. The results were consistent with the primary dataset and increase confidence in the robustness of treatment effects on SPIN and SAFE.

**About EMP-01 (Oral R-MDMA)**
EMP-01 is an oral, single-enantiomer R-MDMA candidate being developed as a potential treatment for people living with Social Anxiety Disorder (SAD). It has been designed to elicit entactogenic and psychedelic subjective effects, with reduced dopaminergic and noradrenergic activity compared with racemic MDMA in order to support safe, scalable outpatient administration for individuals with SAD, who currently have a high unmet medical treatment need. EMP-01 is an investigational product and has not been approved by the FDA.

**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," "anticipate," "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; progress and results of our EMP-01 trials; the timing of further data on EMP-01; the therapeutic potential of EMP-01; and the potential benefits of EMP-01 for patients with SAD.

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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