atai Life Sciences and Beckley Psytech Announce U.S. FDA Breakthrough Therapy Designation Granted to BPL-003, Underscoring its Potential in Treatment-Resistant Depression

October 16, 2025

- Breakthrough Therapy designation recognizes the potential of BPL-003 to deliver substantial improvement over existing therapies for patients with treatment-resistant depression
- FDA designation follows previously announced Phase 2b topline data which showed rapid and durable antidepressant outcomes following a single dose of BPL-003
- Breakthrough Therapy designation provides intensive FDA guidance to support advancement of BPL-003

NEW YORK, AMSTERDAM and OXFORD, United Kingdom, Oct. 16, 2025 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) (“atai” or “Company”), and Beckley Psytech Limited (“Beckley Psytech”), who previously announced a planned strategic combination to create a global leader in transformative mental health therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy designation (BTD) to BPL-003 (mebufotenin benzoate) nasal spray for adult patients with treatment-resistant depression (TRD).

BTD is granted to expedite development of drugs targeting serious or life-threatening conditions where preliminary clinical evidence suggests that the drug may demonstrate substantial improvement on one or more clinically significant endpoints over existing therapies. The designation facilitates collaboration with the FDA and has the potential to expedite development timelines and regulatory reviews. BPL-003 is designed to deliver rapid and durable antidepressant effects from a single dose with a short therapeutic experience. The designation follows positive topline results from Beckley Psytech’s Phase 2b core, blinded study of BPL-003 in TRD which showed that a single administration of 8 mg or 12 mg of BPL-003 led to clinically meaningful and statistically significant reductions in depressive symptoms within 24 hours, with effects sustained through the eight-week trial period. Notably, the majority of patients were deemed ready for discharge at the 90-minute post-dose assessment, underscoring the potential scalability of the BPL-003 treatment model and its potential to fit into the established two-hour, in-clinic interventional psychiatry treatment paradigm.

Cosmo Feilding Mellen, Chief Executive Officer and Co-Founder of Beckley Psytech, said, “Receiving Breakthrough Therapy designation is a significant milestone which highlights the potential of BPL-003 to address the urgent unmet need of patients whose depression is not helped by existing therapies. We believe the Breakthrough Therapy designation supports the strength of our clinical data and, importantly, it will help to ensure the pivotal Phase 3 clinical program will be as expedited and efficient as possible, guided by the FDA.”

Srinivas Rao, M.D., Ph.D., Chief Executive Officer and Co-Founder of atai Life Sciences, said, “We are now among a select group of mental health companies with clinical programs that have been recognized by the FDA with Breakthrough Therapy designations. BPL-003 is well-positioned for Phase 3 trials which are expected to initiate in the second quarter of 2026, subject to alignment with the FDA. This is great news for patients.”

About BPL-003
BPL-003 is Beckley Psytech’s novel, patent-protected, proprietary intranasal formulation of mebufotenin (5-MeO-DMT) benzoate, 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 treatment window, and is being investigated as a potential therapy for treatment-resistant depression (TRD) and for 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
Depression is a debilitating and life-changing condition affecting nearly 300 million people across the globe, with around 52 million people affected by the condition in Europe and the US combined. Treatment-resistant depression occurs when an individual does not respond to two or more courses of antidepressants and some studies show that it may affect up to 50% of those living with depression, meaning there is a significant unmet need for more effective treatments. TRD is associated with higher rates of comorbid anxiety, sexual dysfunction, cognitive impairment, and reduced quality of life compared to non-resistant forms of depression. The condition places a significant burden on patients, caregivers, and healthcare systems, with elevated healthcare utilization and substantial societal costs.

About atai Life Sciences
atai is a clinical-stage biopharmaceutical company on a mission to develop highly effective mental health treatments to transform patient outcomes. Its pipeline of psychedelic-based therapies includes BPL-003 (intranasal mebufotenin benzoate) for treatment-resistant depression (TRD), which is being advanced through a strategic investment and planned strategic combination with Beckley Psytech Limited; VLS-01 (buccal film DMT) also for TRD; and EMP-01 (oral R-MDMA) for social anxiety disorder. All three programs are in Phase 2 clinical development. atai is also advancing a drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD and opioid use disorder. These programs aim to address the complex nature of mental health providing commercially scalable interventional psychiatry therapies that can integrate seamlessly into healthcare systems.

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, and Section 21E of the Exchange Act. 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, expectations regarding the potential benefits of the Breakthrough Therapy Designation; progress on and results of Beckley Psytech's BPL-003 trials, and the timing of development and regulatory review of BPL-003; 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, (i) the contemplated acquisition of Beckley Psytech and related transactions (collectively, the "Proposed Transactions") may not be completed in a timely manner or at all, including the risk that any required shareholder approvals are not obtained; (ii) the failure to realize the anticipated benefits of the Proposed Transactions; (iii) the possibility that any or all of the various conditions to the consummation of the Proposed Transactions may not be satisfied or waived; (iv) the occurrence of any event, change or other circumstance that could give rise to the termination of the share purchase agreement governing the Proposed Transactions; and (v) the effect of the announcement or pendency of the Proposed Transactions on atai's ability to retain and hire key personnel, or its operating results and business generally and other 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") and our Proxy Statement on Schedule 14A (the "Proxy Statement") that was filed with the SEC on September 24, 2025, in each case, as such factors may be updated from time to time in atai's other filings with the SEC. Atai disclaims any obligation or undertaking to update or revise any forward-looking statements contained herein, other than to the extent required by applicable law.

Additional Information and Where to Find It

This press release is being made in in respect of the Proposed Transactions. This communication is not a substitute for the Proxy Statement or any other document which the Company has or may file with the SEC. INVESTORS ARE URGED TO READ IN THEIR ENTIRETY THE PROXY STATEMENT REGARDING THE PROPOSED TRANSACTIONS AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THOSE DOCUMENTS, BECAUSE THEY CONTAIN IMPORTANT INFORMATION.

A free copy of the Proxy Statement, as well as other filings containing information about the Company, may be obtained at the SEC's website (http://www.sec.gov).

Contact Information
Investor Contact:
IR@atai.com

Media Contact:
PR@atai.com

Beckley Psytech Media Contact:
charlotte.chorley@beckleypsytech.com