atai Life Sciences and Beckley Psytech Announce Positive Topline Results from the Phase 2b Study of BPL-003 in Patients with Treatment-Resistant Depression

July 1, 2025

- **Study met its primary and all key secondary endpoints, and BPL-003 demonstrated rapid, robust and durable antidepressant effects with a single dose**
- Both 8 mg and 12 mg single doses of BPL-003 showed statistically significant and clinically meaningful reductions in depressive symptoms at all time points of the study compared to a 0.3 mg low-dose active control out to Week 8
- BPL-003 was generally well-tolerated at all doses, with 99% of treatment-emergent adverse events being mild or moderate, and no drug-related serious adverse events or suicide-related safety signals
- Majority of patients deemed ready for discharge at the 90 minutes post-dose assessment, which suggests BPL-003 could fit within the existing 2-hour in-clinic interventional psychiatry treatment paradigm established by Spravato®
- The Phase 2b study is the largest ever controlled study of mebufotenin (n=193) and the only blinded Phase 2 study of mebufotenin to include the United States
- Safety and efficacy data support the selection of the 8 mg dose to advance into Phase 3 clinical development, pending consultation with regulatory authorities
- Strategic combination between atai Life Sciences and Beckley Psytech to create a global leader in short time in-clinic psychedelic-based mental health therapies is expected to progress to shareholder approval stage
- *Conference call scheduled for 8:00am EDT today, July 1, 2025*

NEW YORK, and AMSTERDAM and OXFORD, United Kingdom, July 01, 2025 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company on a mission to develop highly effective mental health treatments to transform patient outcomes, and Beckley Psytech Limited ("Beckley Psytech"), a private clinical-stage biopharmaceutical company pioneering the next generation of mental health treatments, today jointly announced positive topline results from the eight-week, quadruple-masked, dose-finding, core stage of the Phase 2b clinical trial evaluating the efficacy and safety of a single dose of BPL-003 (intranasal mebufotenin (5-MeO-DMT) benzoate) in patients with treatment-resistant depression (TRD). The study achieved its primary endpoint as well as all key secondary endpoints. At Day 29, a single 12 mg dose of BPL-003 demonstrated a statistically significant reduction in depressive symptoms, as measured by the Montgomery-Åsberg Depression Rating Scale (MADRS), with a mean decrease of 11.1 points from baseline compared to a 5.8 point reduction in the 0.3 mg comparator group ($p = 0.0038$). For the key secondary efficacy endpoints, a single 8 mg dose of BPL-003 also showed significant improvement at Day 29, with a mean MADRS score reduction of 12.1 points ($p=0.0025$ for change vs. 0.3 mg control). Notably, both the 8mg and 12mg doses of BPL-003 showed statistically significant improvements in MADRS scores as early as one day after dosing, with effects generally maintained out to Week 8.

Safety and efficacy results from this study support the selection of the 8 mg dose of BPL-003 for advancement into Phase 3 clinical studies. atai and Beckley Psytech plan to engage with the U.S. Food and Drug Administration (FDA) and other applicable agencies regarding the Phase 3 trial design for patients with treatment-resistant depression in the coming months.

With these positive Phase 2b results, the pre-agreed success criteria for the proposed strategic combination between atai and Beckley Psytech, which was announced in June 2025, has been achieved and the strategic combination is now expected to progress to atai shareholder approval stage. The atai Beckley combination is expected to create a global leader in short time in-clinic psychedelic-based mental health therapies.

Cosmo Feilding Mellen, Chief Executive Officer and Co-Founder of Beckley Psytech, said: *"The achievement of our primary and secondary endpoints in this study represents an important milestone in the development of BPL-003 and reinforces its potential to be a viable treatment option for patients and healthcare systems. We are particularly encouraged that a single 8 mg or 12 mg dose of BPL-003 showed rapid and durable efficacy results, favourable tolerability and a short time in-clinic, giving us important flexibility in optimising the design of future trials. Thank you to all of the patients and study partners who participated in this study - we now look forward to preparing for end-of-Phase 2 meetings with regulators and moving forward with our strategic*

combination with atai Life Sciences to form atai Beckley, a global leader in psychedelic-based mental health treatments."

The Phase 2b clinical study was conducted at 38 sites across six countries and enrolled a total of 193 patients with moderate-to-severe TRD (defined as non-response to two or more prior treatments in the current depressive episode) (NCT05870540). It is the largest controlled clinical study to investigate mebufotenin and the only blinded Phase 2b study of mebufotenin to include the United States. Patients were randomized to receive a single 12 mg (n=73), 8 mg (n=46), or 0.3 mg comparator (n=74) dose of BPL-003 and were followed for eight weeks with efficacy assessments conducted by centralised, blinded raters using the MADRS at Day 2, Day 8, Day 29 and Day 57.

Key efficacy findings:

- A single 12 mg dose of BPL-003 led to a mean reduction in MADRS score from baseline of 11.1 points compared with 5.8 points in the 0.3 mg comparator arm (p=0.0038) at Day 29, with the 8 mg dose arm showing a mean MADRS reduction from baseline of 12.1 points versus the 0.3mg comparator arm (p=0.0025) at that same timepoint.
- The 8 mg and 12 mg doses of BPL-003 demonstrated equivalent efficacy suggesting the 8 mg dose may be sufficient to achieve therapeutic benefit from a single dose.
- The difference in MADRS scores between the 8 mg and 12 mg doses versus the 0.3 mg dose were statistically significant in both active arms from as early as Day 2, with mean MADRS reductions from baseline of 8.8 points in the 8 mg group and 8.9 points in the 12 mg group observed at that timepoint, compared to a reduction from baseline of 3.9 points in the 0.3 mg group. These mean reductions from baseline increased to 11.1 points in the 8 mg group and 10.8 points in the 12 mg group at Day 8.
- A durable effect was also observed for both higher doses, with the 8 mg group showing a mean reduction of 10.8 points from baseline at Day 57 and the 12 mg group showing a mean reduction of 10.2 points from baseline compared with the 0.3 mg group (5.2 point reduction). These findings highlight the potential of BPL-003 to be a durable treatment for patients with TRD.

Key safety findings:

- BPL-003 was generally well-tolerated at all doses. More than 99% of treatment-emergent adverse events (TEAEs) were mild or moderate and there were no drug-related serious adverse events (SAEs).
- Dose related increases in administration site discomfort, nausea, headache, blood pressure and anxiety suggest the 8mg dose was better tolerated than the 12mg dose.
- No participants in the 8 mg nor 12 mg arms had any instance of treatment-emergent suicidal intent or behaviour, indicating no suicide-related safety signal observed to date.
- The average time to meet readiness for discharge criteria across all arms was within two hours of dosing, with the majority of patients deemed ready for discharge at the 90 minutes post-dose assessment. This, alongside the administration of BPL-003 via a previously approved nasal spray device, supports the potential of BPL-003 to fit within the existing interventional psychiatry treatment paradigm that has been successfully established by Spravato®.
- The study had a low drop-out rate with 90% of patients completing the core study.
- These findings suggest a favourable tolerability profile which are consistent with earlier Phase 1 and Phase 2a studies of BPL-003, as well as other psychedelic studies within the class.

Additional data from the core study is expected to be shared through publications and medical meetings in the future.

Dr David Feifel, Professor Emeritus of Psychiatry at the University of California, San Diego and Director of the Kadima Neuropsychiatry Institute said: *"What stands out in these results is that a single administration of BPL-003 in patients with treatment-resistant depression was generally well tolerated and produced a robust antidepressant effect that emerged rapidly and was solidly sustained for at least two months. Notably, the acute psychedelic effects were shorter than with most other psychedelics studied clinically, suggesting potential for a quicker functional recovery for patients and a reduced need for prolonged monitoring. If a treatment with this profile were available today, it would immediately become my treatment of choice for TRD."*

Follow-up in the eight-week open-label extension (OLE) stage of the study is ongoing. The OLE study is designed to evaluate the safety and efficacy of a second 12 mg dose of BPL-003 administered to patients eight weeks after dosing in the core study. 85% of eligible subjects from the core stage of the study have enrolled into the OLE. Data from the OLE study is expected in the third quarter of 2025 and will provide additional insights into the safety and tolerability of repeat dosing, as well as the durability of BPL-003's antidepressant effect.

Commenting on the news, Srinivas Rao, Chief Executive Officer and Co-Founder of atai, said: *"These findings strengthen our confidence in the potential of BPL-003 to be a transformative psychedelic therapy, offering rapid and durable antidepressive effects with minimal in-clinic time for patients with treatment-resistant depression. We look forward to engaging with the regulators*

later this year to advance this innovative treatment into Phase 3 clinical development."

Conference Call
atai and Beckley Psytech will host a conference call and live webcast today Tuesday, July 1, 2025, 2025 at 8:00 a.m. EDT. The conference call can be accessed by dialling 1-800-715-9871 for participants in the U.S. and 1-646-307-1963 for international callers, with the Conference ID: 1459387. The webcast can be accessed on the Investors section of atai's corporate website under Events. The presentation and an archived replay of the webcast will be available in the same section of the website for a minimum of 30 days following the event.

About BPL-003
BPL-003 is Beckley Psytech's patent-protected, proprietary intranasal formulation of mebufotenin 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 time in the clinic, and is being investigated as a potential therapy for treatment-resistant depression (TRD) and for alcohol use disorder (AUD). BPL-003 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.

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. atai's pipeline of psychedelic-based therapies includes VLS-01 (buccal film DMT) for treatment-resistant depression (TRD) and EMP-01 (oral R-MDMA) for social anxiety disorder, which are in Phase 2 clinical development. It is also advancing a drug discovery program to identify novel, non-hallucinogenic 5-HT2AR agonists for TRD. These programs aim to address the complex nature of mental health providing commercially scalable interventional psychiatry therapies that can integrate seamlessly into healthcare systems. For the latest updates and to learn more about atai's mission, visit www.atai.com or follow the Company on LinkedIn and on X.

About Beckley Psytech
Beckley Psytech Ltd is a private biopharmaceutical company dedicated to improving the lives of people living with neuropsychiatric disorders by developing rapid-acting psychedelic medicines. Founded in 2019, and underpinned by more than two decades of pioneering scientific research from the Beckley Foundation, Beckley Psytech combines world-leading psychedelic science with extensive drug development expertise in order to optimise patient outcomes, improve treatment opportunities and ease the burden neuropsychiatric conditions have on individuals, healthcare systems and society. For more information about Beckley Psytech, visit www.beckleypsytech.com or follow the Company on LinkedIn.

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 (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (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 closing of the acquisition of Beckley Psytech Limited (the "Proposed Transaction"), including timing and approvals; expectations regarding operations of the combined company, including strategic value of the clinical development programs for patients and shareholders as well as expectations regarding financial synergies; timing and results of Beckley Psytech's BPL-003 Phase 2b trial and related data readouts; expectations regarding Beckley Psytech's other clinical assets, including ELE-101; our business strategy and plans; and the potential, success, cost and timing of development of our product candidates, and the product candidates of those companies we invest in.

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 Proposed Transaction 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 Transaction; (iii) the possibility that any or all of the various conditions to the consummation of the Proposed Transaction 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; and (v) the effect of the announcement or pendency of the Proposed Transaction 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 (the "SEC"), 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 in this press release, other than to the extent required by applicable law.

Additional Information and Where to Find It
This press release is being made in respect of the Proposed Transaction. In connection with the Proposed Transaction, a

registration statement on Form S-4 will be filed (the "Registration Statement") which will include a proxy statement of the Company (the "Proxy Statement"), as well as other relevant documents regarding the Proposed Transaction. This press release is not a substitute for the Registration Statement, the Proxy Statement or any other document which the Company may file with the SEC. INVESTORS ARE URGED TO READ IN THEIR ENTIRETY THE REGISTRATION STATEMENT, INCLUDING THE PROXY STATEMENT REGARDING THE PROPOSED TRANSACTION, WHEN IT BECOMES AVAILABLE AND ANY OTHER RELEVANT DOCUMENTS FILED WITH THE SEC, AS WELL AS ANY AMENDMENTS OR SUPPLEMENTS TO THOSE DOCUMENTS, BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION.

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

Participants in the Solicitation

The Company and its directors and executive officers may be deemed to be participants in the solicitation of proxies from its shareholders in respect of the proposed transactions contemplated by the Registration Statement, including the Proxy Statement. Information regarding the persons who are, under the rules of the SEC, participants in the solicitation of the shareholders of the Company in connection with the proposed transactions, including a description of their direct or indirect interests, by security holdings or otherwise, will be set forth in the Registration Statement, including the Proxy Statement, when it is filed with the SEC. Information regarding the Company's directors and executive officers is contained in its Annual Report on Form 10-K for the year ended December 31, 2024 and its proxy statement on Schedule 14A, dated April 21, 2025, which are filed with the SEC.

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