atai Life Sciences Announces Key Clinical Pipeline and Corporate Updates

March 6, 2023

- *RL-007: First patient dosed in the on-going phase 2b study in cognitive impairment associated with schizophrenia*
- *GRX-917: Intention to progress GRX-917 into a phase 2 study in an anxiety disorder as the next step in clinical development*
- *COMP360: Recently announced acceleration of the Pivotal Trial 1 (COMP 005) part of the phase 3 program, with top line data now expected in the summer of 2024*
- *Corporate: As a result of our recent restructuring and pipeline updates, the company has extended its cash runway, which is now expected into 1H 2026*

NEW YORK and BERLIN, March 06, 2023 (GLOBE NEWSWIRE) -- atai Life Sciences (NASDAQ: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, provided key clinical pipeline and corporate updates.

"The dosing of the first patient in the phase 2b study of RL-007 in CIAS earlier this quarter exemplifies the execution capabilities of our team as we advance our programs into later-stage clinical studies," said Florian Brand, CEO and Co-Founder of atai. "Along these lines, we are excited to announce the updated clinical strategy for GRX-917. The compound will progress directly into a phase 2 study in patients living with an anxiety disorder to accelerate development and generate the robust clinical data needed to inform a potential future registration."

Mr. Brand continued, "As part of our efforts to further focus our capital allocation towards generating meaningful clinical readouts in the near-term and to optimize our operational efficiency, we reduced our team by approximately 30%. I am grateful for the dedication of the team members impacted by this decision and their contributions towards our mission."

Pipeline Updates

RL-007 (Pro-Cognitive Neuromodulator for Cognitive Impairment Associated with Schizophrenia (CIAS))

- The first patient was recently dosed in the phase 2b study of RL-007 in patients with CIAS. Initial results from this study are expected in the 2nd half of 2024.
- The phase 2b study is a randomized, placebo-controlled, double-blind, 3-arm study evaluating 20mg and 40mg of RL-007 vs placebo in approximately 230 patients with CIAS. The primary endpoint of the US-based study is the MATRICS Consensus Cognitive Battery neurocognitive composite score at 6-weeks.
- RL-007 is an orally available compound that modulates cholinergic, glutamatergic and GABA-B receptors, thereby putatively altering the excitatory/inhibitory balance in the brain to produce pro-cognitive effects. It has previously been evaluated in 10 clinical studies with over 500 unique participants dosed to-date and in which it was well tolerated at all doses tested.
- Notably, in four clinical studies that assessed cognition, including one in patients with CIAS, the compound consistently demonstrated pro-cognitive effects.

GRX-917 (Deuterated Etifoxine for Anxiety Disorders)

- The clinical development plan has been updated to now proceed with a phase 2 study in patients. The updated plan is anticipated to generate the robust clinical data needed to best support potential registration. More details on the clinical development plan will be provided upon initiation of the study.
- The updated plan follows the positive results from the phase 1 single and multiple ascending dose study of GRX-917. In this trial, GRX-917 was well-tolerated. Additionally, GRX-917 had an improved pharmacokinetic profile relative to etifoxine and provided pharmacodynamic evidence of GABA receptor target engagement through qEEG.
- GRX-917 is a deuterated version of etifoxine, a drug used for anxiety and first approved in France in 1979. Etifoxine has a rapid onset and efficacy comparable to leading benzodiazepines, like alprazolam and lorazepam, which are currently considered standard of care. In contrast to these benzodiazepines, however, and based on more than 40 years of the use of etifoxine in clinical practice, etifoxine appears to be non-addictive and does not seem to have the same sedation and other common adverse events. It is believed that etifoxine achieves its anxiolytic activity by increasing endogenous production of brain neurosteroids like allopregnanolone.

PCN-101 (R-Ketamine for Treatment-Resistant Depression)

- In January 2023, in conjunction with the phase 2a study results of PCN-101, atai announced it would further evaluate the data and work with its subsidiary Perception Neuroscience (“Perception”) to determine next steps for the program.
- atai will continue to support Perception’s development of PCN-101 through the IV-to-subcutaneous bridging study, which is currently on-track to be completed in the middle of 2023. In parallel, atai continues to work with Perception Neuroscience to explore strategic partnership options.
- PCN-101 is a single isomer of ketamine and belongs to a new generation of glutamate receptor modulators with the potential for rapid-acting antidepressant activity and anti-suicidal effects. Pharmacologically, PCN-101 is a non-competitive N-methyl-D-aspartate (NMDA) receptor antagonist. Both depression model studies in rodents and clinical data suggest that R-ketamine could possess more durable effects than S-ketamine despite a lower affinity to the NMDA receptor and potentially a more favorable safety and tolerability profile.

COMP360 (Psilocybin Therapy for Treatment-Resistant Depression)

- On February 28th, COMPASS Pathways (“COMPASS”) announced an acceleration of the Pivotal Trial 1 (COMP 005) part of the phase 3 program in treatment-resistant depression, with top line data now expected in the summer 2024.
- COMP360 is a proprietary formulation of synthetic psilocybin that is administered in conjunction with psychological support. Previously, COMPASS completed a phase 2b study with top line data showing a statistically significant ($p<0.001$) and clinically relevant improvement in depressive symptom severity after three weeks for patients who received a single high dose of COMP360 psilocybin with psychological support.

Corporate Updates

- As part of a strategic review of its pipeline and to enhance operational efficiency and focus, the Company has reduced its workforce by approximately 30%.
- The majority of the cost savings will result from a workforce reduction in general and administration and non-clinical development.
- The Company has extended its cash runway, which is now expected into 1H 2026.

About atai Life Sciences

atai Life Sciences is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. Founded in 2018 as a response to the significant unmet need and lack of innovation in the mental health treatment landscape, atai is dedicated to acquiring, incubating, and efficiently developing innovative therapeutics to treat depression, anxiety, addiction, and other mental health disorders.

By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines across its companies to achieve clinically meaningful and sustained behavioral change in mental health patients.

atai's vision is to heal mental health disorders so that everyone, everywhere can live a more fulfilled life. For more information, please visit www.atai.life.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. 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”). All statements contained in this press release other than statements of historical fact should be considered forward-looking statements, including without limitation statements regarding our future operating results and financial position; the success, cost, and timing of development of our product candidates, including the progress of preclinical studies and clinical trials and related milestones; the commercialization of our current product candidates and any other product candidates we may identify and pursue, if approved, including our ability to successfully build a specialty sales force and commercial infrastructure to market our current product candidates and any other product candidates we may identify and pursue; the timing of and our ability to obtain and maintain regulatory approvals; our business strategy and plans, including the benefits of our corporate restructuring; potential acquisitions, partnerships and other strategic arrangements; the sufficiency of our cash and cash equivalents to fund our operations; available funding under the Hercules Capital, Inc. loan facility; the plans and objectives of management for future operations and capital expenditures; and our participation in upcoming events and conferences.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and are subject to a number of important factors that could cause actual results, performance or achievements to differ materially from any future results, performance or achievements expressed or implied by the forward-looking statements, including without limitation: we are a clinical-stage biopharmaceutical company and have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future; we will require substantial additional funding to achieve our business goals, and if we are unable to obtain this funding when needed and on acceptable terms, we could be forced to delay, limit or terminate our product development efforts; our limited operating history may make it difficult to evaluate the success of our business and to assess our future viability; we have never generated revenue and may never be profitable; our product

candidates contain controlled substances, the use of which may generate public controversy; clinical and preclinical development is uncertain, and our preclinical programs may experience delays or may never advance to clinical trials; we rely on third parties to assist in conducting our clinical trials and some aspects of our research and preclinical testing, and those clinical trials, including progress and related milestones, may be impacted by several factors including the failure by such third parties to meet deadlines for the completion of such trials, research, or testing, changes to trial sites and other circumstances; we currently rely on qualified therapists working at third-party clinical trial sites to administer certain of our product candidates in our clinical trials and we expect this to continue upon approval, if any, of our current or future product candidate, and if third-party sites fail to recruit and retain a sufficient number of therapists or effectively manage their therapists, our business, financial condition and results of operations would be materially harmed; we cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized; research and development of drugs targeting the central nervous system, or CNS, is particularly difficult, and it can be difficult to predict and understand why a drug has a positive effect on some patients but not others; we face significant competition in an environment of rapid technological and scientific change; third parties may claim that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and may prevent or delay our development and commercialization efforts; as a result of covenants to our loan agreement with Hercules Capital, Inc., our operating activities may be restricted and we may be required to repay the outstanding indebtedness in the event of a breach by us, or an event of default thereunder, which could have a materially adverse effect on our business; a change in our effective place of management may increase our aggregate tax burden; we identified material weaknesses in connection with our internal control over financial reporting; and a pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital, our ability to conduct regular business and our financial results. These forward-looking statements are subject to a number of important factors that could cause actual results to differ materially from those in the forward-looking statements, including the risks, uncertainties, and assumptions described under “Risk Factors” in Item 1A of Part I, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in Item 7 of Part II and elsewhere in our Form 10-K for the year ended December 31, 2021 and under “Risk Factors” in Item 1A of Part II of our Form 10-Q for the quarters ended June 30, 2022 and September 30, 2022, respectively, filed with the Securities and Exchange Commission.

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. Except as required by applicable law, we undertake no obligation to update any of these forward-looking statements for any reason after the date of this press release or to conform these statements to actual results or revised expectations.

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