atai Life Sciences Increases its Ownership Position in COMPASS Pathways

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Demonstrates atai's confidence in COMPASS' Phase 2b data and its potential for patients with treatment-resistant depression

Reinforces COMPASS as highly complementary to atai's diversified approach to innovation in mental health

NEW YORK, Nov. 29, 2021 (GLOBE NEWSWIRE) -- atai Life Sciences (Nasdaq: ATAI) ("atai"), a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today announced that it has increased its ownership interest in COMPASS Pathways ("COMPASS"), from 19.4% to 20.8%.

This equity stake increase is a demonstration of atai's confidence in COMPASS Pathways and in the potential of COMP360 in mental health care, following the recent COMP360 data in treatment-resistant depression (TRD). This solidifies atai's position as COMPASS' largest shareholder.

"We've supported COMPASS Pathways since the early days, when they were our very first psychedelic initiative, as part of our quest for more effective solutions for mental health patients. We believe this month's Phase 2b data was a true milestone for innovation in mental health and COMP360 shows strong potential as a future treatment for patients with TRD," said Florian Brand, Co-Founder and Chief Executive Officer of atai Life Sciences. "This further confirms our belief in COMPASS' psilocybin-assisted psychotherapy as a valued part of our diversified approach to develop novel solutions for patients with unmet needs in mental health."

"Today's announcement underscores our belief in the potential of COMPASS and COMP360 in the future of mental health care. In my personal opinion, the market doesn't seem to appreciate the full upside potential given these impressive COMP360 data, the size of the unmet patient need and the potential of COMPASS' broad patent portfolio," said Christian Angermayer, Founder and Chairman of atai Life Sciences.

Over 300 million people worldwide live with depression and, of these, a third struggle with TRD that cannot be managed by currently available options.[1,2]

COMPASS's Phase 2b trial of COMP360 psilocybin in TRD is the largest and most robust trial ever to be conducted with psilocybin. Participants in this COMPASS trial had previously failed on two to four antidepressants. The 233-patient, 22-site, randomized, controlled, double-blind dose-controlled trial with COMP360 reported rapid and durable results in reducing depression, when combined with psychological support, and was generally well tolerated. A single 25mg dose achieved a 6.6 point reduction (vs 1mg), from baseline to week three, on the Montgomery-Åsberg Depression Rating Scale (MADRS) ($p<0.001$), successfully meeting the primary endpoint.

Most standard selective serotonin reuptake inhibitor (SSRI) antidepressants were approved on just a 2-3 MADRS point reduction in a general major depressive disorder patient population, and several weeks are typically required to show a significant benefit. Another comparable, intranasal esketamine has demonstrated only a 4 MADRS point reduction at 28 days vs. placebo in TRD (in third party studies), thus highlighting the potential of COMP360 in this challenging patient population.[3-5]

Despite the mounting problem of mental health in recent years, further compounded by the pandemic, innovation has been sorely lacking; only seven new treatments have been approved by the FDA for psychiatric disorders since 2015.[6,7]

In 2018, COMP360 received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) for TRD.[8] COMPASS has recently expanded the indications of interest to post-traumatic stress disorder and initiated an additional Phase 2 study. COMPASS also reported positive signals from an open-label investigator-initiated study in the U.S. of COMP360 for depression in cancer.[9,10] COMPASS' Phase 3 study of psilocybin in TRD is anticipated to launch in 2022. Furthermore, COMPASS is exploring the potential of COMP360 towards several further potential indications including type 2 bipolar disorder depression, anorexia nervosa, body dysmorphia, suicidal ideation and autism.

As we ultimately believe there is no one-size-fits-all solution in the treatment of mental health conditions, atai is progressing a pharmacologically-diverse array of programs, spanning psychedelics, non-psychedelics, and is developing innovative digital therapeutics to address the areas of highest unmet need in mental health. By developing COMP360 and other novel 5-HT2a agonists, COMPASS is highly complementary to our diversified platform and fully aligns with our vision to heal mental health disorders, so that everyone, everywhere can live a more fulfilled life.

References

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About atai Life Sciences

atai is a clinical-stage biopharmaceutical company aiming to transform the treatment of mental health disorders. atai was 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.

atai's business model combines funding, technology, scientific and regulatory expertise with a focus on psychedelic therapy and other drugs with differentiated safety profiles and therapeutic potential. By pooling resources and best practices, atai aims to responsibly accelerate the development of new medicines across its companies, seeking to effectively treat and ultimately heal mental health disorders.

atai's mission is to bridge the gap between what the mental healthcare system currently provides and what patients need. atai has offices in New York, London, and Berlin. 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, 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: the success, cost and timing of development of our product candidates and COMPASS Pathways' COMP360, including the progress of preclinical and clinical trials and related milestones; our business strategy and plans; potential acquisitions; and the plans and objectives of management for future operations and capital expenditures. The forward-looking statements in this press release are neither promises nor guarantees, and you should not place undue reliance on these forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, many of which are beyond our control and which could cause actual results, levels of activity, performance or achievements to differ materially from those expressed or implied by these forward-looking statements.

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 subject to a number of risks, uncertainties, and assumptions, 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 candidates; 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; 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. Other risk factors include the important factors described in the section titled "Risk Factors" in our final prospectus, dated June 17, 2021, filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424(b) under the Securities Act, and in our other filings with the SEC, that may cause our actual results, performance or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements.

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.

Contact Information

For atai:

Media Contact:
Camilla Dormer
VP, Communications, atai Life Sciences

Email: camilla@atai.life

Investor Contact:
Chad Messer
VP, Investor Relations, atai Life Sciences
Email: chad@atai.life