atai Life Sciences Announces Positive Initial Results for Phase 1 Trial of KUR-101, an Oral Formulation of Mitragynine for OUD

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– Initial results showed that single ascending oral dosing of KUR-101 produces dose-dependent analgesia (pain relief) with effects on respiration comparable to that of placebo.

– Topline results, including Part 2 comparing a single dose of KUR-101 to a single dose of oxycodone or placebo, are expected by the end of 2022.

– KUR-101 is an oral formulation of deuterated mitragynine, the major active alkaloid of the kratom plant, under development for the treatment of opioid use disorder (OUD).

– Nearly every 7 minutes, someone dies of an opioid-related overdose. Approximately 3 million people in the U.S. are diagnosed with OUD, and relapse occurs in up to 75% of patients.

NEW YORK and BERLIN, Oct. 12, 2022 (GLOBE NEWSWIRE) -- atai Life Sciences N.V. (Nasdaq: ATAI) (“atai”) announced today positive initial results for their Phase 1 clinical trial of KUR-101. KUR-101 is an oral formulation of deuterated mitragynine, the major active alkaloid of the kratom plant, under development for the treatment of opioid use disorder (OUD).

Initial results indicate that KUR-101 is safe and generally well-tolerated. Results also showed a dose-proportional pharmacokinetic (PK) profile that was unaffected by food. In the single ascending oral dose portion of the trial, no severe or serious adverse events were reported, with most treatment-related adverse events being mild. Changes in respiratory rate following treatment with KUR-101 were comparable to that of placebo-treated patients for the doses tested and comparable across doses.

“Exacerbated by the stresses of the pandemic, according to the CDC, the U.S. saw an approximate 30% increase in drug overdose deaths in 2020 and nearly 75% of those deaths involved opioids,” said Florian Brand, CEO of atai. “There are currently only three FDA-approved therapeutics for OUD; they produce side effects and about 75% of patients undergoing OUD therapy experience relapse within one year of treatment. New alternatives could improve the treatment landscape of addiction.”

According to Fortune Business Insights, the global OUD market is projected to grow from $2.68 billion in 2021 to $4.81 billion in 2028. The jump is driven partially by the surge in people suffering from opioid relapses and overdoses amid the pandemic.

The pharmacological therapies currently approved for OUD, buprenorphine, methadone, and naltrexone, carry several challenges, including limited efficacy for many patients, inconvenient treatment regimens, and access barriers due to inherent risks of abuse.

Compared with current options, KUR-101 is an atypical opioid receptor modulator with unique pharmacology that may make it safer for chronic use. The deuteration of mitragynine improves the PK and overall safety profile of KUR-101 while reducing dosing requirements. Topline results, including Part 2 of the trial comparing a single dose of KUR-101 to a single dose of oxycodone or placebo, are expected by the end of 2022.

“We’re pleased with the results of our initial Phase 1 findings of KUR-101,” said Dr. Chad Beyer, CEO of Kures, a subsidiary of atai Life Sciences leading the KUR-101 program. “These findings increase our confidence in KUR-101 as a potential treatment for patients battling addiction, experiencing pain, and debilitating mental health disorders.”

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

About Kures Therapeutics

Kures is a spinout from Columbia University and is developing KUR-101 for the treatment of OUD and acute pain. KUR-101 is a deuterated derivative of mitragynine, the major alkaloid in kratom that is a relatively low-potency mu-opioid receptor, or MOR, agonist. KUR-101 is a semi-synthetically produced drug substance designed to improve the safety profile and potential effectiveness of mitragynine. In results from our preclinical studies carried out to date, KUR-101 has shown dose-dependent analgesic effects without inducing significant respiratory depression at therapeutic doses in animal models.

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: statements regarding the trials by Kures, Inc. and future activities thereunder, the potential of KUR-101, the success, cost and timing of development of our product candidates, 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.

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. These forward-looking statements are subject to a number of risks, uncertainties, and assumptions that could cause actual results to differ materially from those 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; 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 cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized; 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; 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 and other important factors described in the section titled “Risk Factors” in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the Securities and Exchange Commission (“SEC”), our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K, as updated by our subsequent filings with the SEC, may cause our actual results, performance, or achievements to differ materially and adversely from those expressed or implied by the forward-looking statements. Any such forward-looking statements represent management’s estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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