atai Life Sciences Announces Results from the Kures Therapeutics Phase 1 Trial of KUR-101

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- *This two-part phase 1 trial in healthy volunteers was designed to assess the safety, pharmacokinetics, and analgesic activity of KUR-101*
- *KUR-101 was well tolerated and demonstrated analgesic activity in two experimental pain models*
- *An assessment of the respiratory impact of KUR-101 was inconclusive as the positive control, oxycodone, failed to separate from placebo*
- *KUR-101, a deuterated derivative of mitragynine, is a low-potency, partial mu-opioid receptor (MOR) agonist designed to produce therapeutic effects without clinically significant respiratory depression*

NEW YORK and BERLIN, Dec. 23, 2022 (GLOBE NEWSWIRE) -- atai Life Sciences N.V. (Nasdaq: ATAI) (“atai” or “the Company”), a clinical stage biopharmaceutical company aiming to transform the treatment of mental health disorders, today announced additional clinical data from the Kures Therapeutics Phase 1 trial of KUR-101 in healthy volunteers. This two-part trial was designed to assess the safety, tolerability, pharmacokinetics, and analgesic activity of KUR-101.

Part 1 consisted of a double-blind, randomized, 5-cohort single-ascending dose study to evaluate the safety and analgesic activity of a single oral dose of KUR-101 (10mg, 20mg, 40mg, 60mg, 90mg) in a total of 42 healthy volunteers. Analgesic activity was assessed by the cold pressor test (CPT) and impact on respiration was evaluated by measuring respiration rate at multiple time points. As previously reported, KUR-101 was well tolerated and produced dose-dependent analgesic activity without clinically significant effects on respiration at any dose-level tested, including at the 90mg dose level selected for the Part 2 comparator study.

Part 2 consisted of a randomized, double-blind, crossover study to evaluate the safety and analgesic activity of KUR-101 compared to both oxycodone and placebo. 18 healthy volunteers were enrolled and randomized into one of three sequences (6 subjects each). Each subject received single oral doses of KUR-101 (90mg), oxycodone (20mg), and placebo separated by a 7-day washout. Analgesic activity was measured by both CPT and thermal testing. Respiratory rate was assessed at multiple time points.

Results from part 2 showed that a single dose of 90mg of KUR-101 was generally well tolerated and was observed to produce analgesic effects on CPT comparable to those seen in Part 1 of this trial. The analgesic effects of KUR-101 were less than those seen with oxycodone on both CPT and thermal testing. Further, both KUR-101 and oxycodone demonstrated effects on respiration comparable to placebo, thus precluding definitive conclusions of KUR-101’s respiratory impact.

“We are pleased that KUR-101 was both well tolerated and demonstrated clinical activity in healthy volunteers. As the data comparing the respiratory effects of KUR-101 to both oxycodone and placebo are inconclusive at this stage, additional research will be needed to further characterize the therapeutic potential of KUR-101,” said Florian Brand, CEO and Co-Founder of atai.

About KUR-101

Current OUD therapies like buprenorphine, methadone, and naltrexone show limited efficacy for many patients and come with inconvenient treatment regimens, side effects, and barriers to access due to abuse liability. In contrast, KUR-101 is an atypical opioid receptor modulator with a unique pharmacology that may make it safer for chronic use. Its deuteration improves its pharmacokinetic and overall safety profile while reducing dosing requirements.

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 Therapeutics, an atai Life Sciences Company, 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 leaves that is a relatively low-potency mu-opioid receptor (MOR) agonist. It 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 and results 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; available funding under the Hercules Capital, Inc. loan facility; the plans and objectives of management for future operations, capital expenditures and capital allocation; and our participation in future events and conferences. 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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