Adial Pharmaceuticals Announces Positive Topline Results from the AD04-103 Pharmacokinetics Study of AD04 for the Treatment of Alcohol Use Disorder

Confirmed relative bioavailability to the reference standard, dose proportional increases in pharmacokinetic exposure, and no food effect

Marks final study needed for the upcoming FDA meeting for the Phase 3 study design and ongoing partnership discussions

Continued excellent safety and tolerability findings, consistent with extensive human use experience with ondansetron

GLEN ALLEN, Va., Nov. 14, 2024 (GLOBE NEWSWIRE) -- Adial Pharmaceuticals, Inc. (NASDAQ: ADIL) ("Adial" or the "Company"), a clinical-stage biopharmaceutical company focused on developing therapies for the treatment and prevention of addiction and related disorders, announced that it has completed a pharmacokinetics (PK) study of AD04, the Company's lead investigational genetically targeted, serotonin-3 receptor antagonist, and therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in heavy drinking patients (defined as less than 10 drinks/drinking day). This data will help the Company optimize study design elements needed for the upcoming Phase 3 clinical trial of AD04. Completion of this study also satisfied an FDA requirement for the upcoming Phase 3 clinical trials of AD04.

The study, a single-center, relative bioavailability, open label study, enrolled a total of 30 healthy adult volunteers in two cohorts. Cohort 1 (n=6) was a randomized, open-label, 2-sequence, 2-period crossover study to evaluate the PK variability of ondansetron from AD04 0.33 and 0.99mg. Cohort 2 (n=24) was a randomized, open-label, 6-sequence, 4-period crossover study to evaluate the relative bioavailability of the AD04 0.33mg tablet to a marketed ondansetron 4mg tablet, dose proportionality of ondansetron PK between AD04 0.33 and 0.99mg, and the effect of food on the bioavailability of ondansetron administered as the AD04 0.33mg tablet. The results of this study showed that, as a result of the lower dose, AD04 0.33mg delivered lower ondansetron PK exposure than the marketed reference standard ondansetron 4mg tablet; ondansetron pharmacokinetic exposure increased in proportion to dose across a 3-fold AD04 dose range; and AD04 can be taken in fed or fasted states.

Cary Claiborne, President and Chief Executive Officer of Adial commented, "Completion of this study achieves our goal to obtain the data we needed to design a more precise and informed Phase 3 trial protocol, including evaluating the optimal dosing regimen to maximize the efficacy and safety of AD04 in patients with AUD. Its completion is in accord with previous guidance provided by the FDA and is intended to enhance the likelihood of success in our upcoming Phase 3 trial. This relatively short and low-cost study was a key element of our strategy to advance ongoing partnership discussions. Additionally, the study will provide data necessary to support an application for approval of AD04 under a 505(b)(2) regulatory pathway with the FDA. We plan to engage with the FDA during Q4 2024 with the results of this pharmacokinetics study and obtain feedback which will assist with the AD04 Phase 3 study program. This meeting is an important next step to further advancing AD04 towards regulatory approval."

About AD04

AD04 (0.33mg ondansetron taken orally twice daily) acts upon the 5HT3 pathway and is thought to reduce alcohol craving. This mode of action is distinct from, but complimentary to, the currently approved therapies for AUD. Post-hoc analyses of Adial's prior clinical studies have indicated that patients with mutations in the 5HT3 receptor experience substantial and clinically meaningful reductions in alcohol consumption. The specific mutations that appear to respond to AD04 are single nucleotide polymorphisms (SNPs) on rs1150226-AG ("AG") or rs1176713-GG ("GG") genotypes in the gene that encodes the 5-HT3A receptor subunit. These genes are thought to affect the binding of AD04 to the 5HT3 receptor and its function. Furthermore, in both previous clinical trials, AD04 had similar adverse events to placebo, which further supports that it is likely to be extremely safe and tolerable. Adial has already developed a companion diagnostic test (CDx) to identify the specific genotypes that benefit from AD04. This test was used in its Phase 3 ONWARD study, will be used in future clinical studies, and will be commercially available at the time of AD04's launch.

About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of treatments for addictions and related disorders. The Company's lead investigational new drug product, AD04, is a genetically targeted, serotonin-3 receptor antagonist, therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in heavy drinking patients and was recently investigated in the Company's ONWARD™ pivotal Phase 3 clinical trial for the potential treatment of AUD in subjects with certain target genotypes identified using the Company's companion diagnostic genetic test. ONWARD showed promising results in reducing drinking in heavy drinking patients, and no overt safety or tolerability concerns. AD04 is also believed to have the potential to treat other addictive disorders such as Opioid Use Disorder, gambling, and obesity. Additional information is available at www.adial.com.

Forward-Looking Statements

This communication contains certain "forward-looking statements" within the meaning of the U.S. federal securities laws. Such statements are based upon various facts and derived utilizing numerous important assumptions and are subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Statements preceded by, followed by or that otherwise include the words "believes," "expects," "anticipates," "intends," "projects," "estimates," "plans" and similar expressions or future or conditional verbs such as "will," "should," "would," "may" and "could" are generally forward-looking in nature and not historical facts, although not all forward-looking statements include the foregoing. The forward-looking statements include statements regarding the pharmacokinetics study data helping the Company optimize study design elements needed for the upcoming Phase 3 clinical trial of AD04, designing a more precise and informed Phase 3 trial protocol, completion of the study providing the data needed to design a more precise and informed Phase 3 trial protocol, including evaluating the optimal dosing regimen to maximize the efficacy and safety of AD04 in patients with AUD, completion of the study enhancing the likelihood of success in the Company's upcoming Phase 3 trial, advancing ongoing partnership discussions, the study providing data necessary to support an application for approval of AD04 under a 505(b)(2) regulatory pathway with the FDA, plans to engage with the FDA during Q4 2024 with the results of the pharmacokinetics study and obtain feedback which will assist with the AD04 Phase 3 study program, further advancing AD04 towards regulatory approval and the potential of AD04 to treat other addictive disorders such as opioid use disorder, gambling, and obesity. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, our ability to pursue our regulatory strategy, our ability to advance ongoing partnering discussions, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, our ability to develop strategic partnership opportunities and maintain collaborations, our ability to obtain or maintain the capital or grants necessary to fund our research and development activities, our ability to complete clinical trials on time and achieve desired results and benefits as expected, regulatory limitations relating to our ability to promote or commercialize our product candidates for specific indications, acceptance of our product candidates in the marketplace and the successful development, marketing or sale of our products, our ability to maintain our license agreements, the continued maintenance and growth of our patent estate and our ability to retain our key employees or maintain our Nasdaq listing. These risks should not be construed as exhaustive and should be read together with the other cautionary statement included in our Annual Report on Form 10-K for the year ended December 31, 2023, subsequent Quarterly Reports on Form 10-Q and current reports on Form 8-K filed with the Securities and Exchange Commission. Any forward-looking statement speaks only as of the date on which it was initially made. We undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events, changed circumstances or otherwise, unless required by law.

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