Adial Completes Validation of Genetic Biomarker Test in Collaboration with Eurofins for Upcoming Phase 3 Trial

Reports regulatory progress in Europe and imminent commencement of clinical trial

CHARLOTTESVILLE, VA / December 13, 2019 / Adial Pharmaceuticals, Inc. ("Adial") (NASDAQ:ADIL; ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced that it has completed validation of its genetic biomarker test for its planned Phase 3 trial. The Phase 3 trial is designed to study AD04, a genetically targeted therapeutic agent for the treatment of Alcohol Use Disorder.

Eurofins Genomics ("Eurofins"), a division of Eurofins Biopharma Services, a global scientific leader in bioanalytical testing, performed the laboratory validation of Adial's companion diagnostic genetic test using double strand Sanger sequencing and Fragment length analysis of polymerase chain reaction (PCR) products. These assays will be used for the analysis of patients' blood samples for genetic variants in defined genes caused by Single Nucleotide Polymorphisms or Fragment Length Polymorphisms. The acceptability of the assay validation will be evaluated further by the local ethics committees and regulatory authorities during the clinical trial application (CTA) assessments.

William Stilley, Chief Executive Officer of Adial Pharmaceuticals, commented, "Completion of the genetic test validation is a key milestone as we finalize preparations for our planned Phase 3 trial. By genetically pre-screening subjects prior to enrollment, our companion diagnostic genetic test allows us to only enroll those patients that have the genetic biomarkers indicating that they are expected to respond to AD04. We believe this approach will enhance the efficacy rates of AD04 in the trial and reduce the time and costs associated with conducting the trial. At the same time, we are making progress towards finalizing the necessary regulatory approvals in Europe and look forward to providing near-term updates on commencement of our Phase 3 clinical trial."

Elena Logan, Senior VP, Eurofins Biopharma Services, noted, "The genetic test met or exceeded all the necessary criteria for use in the upcoming Phase 3 trial. Adial is at the forefront of precision medicine, developing a personalized approach using a genetic companion diagnostic test to identify patients likely to respond to treatment. We are delighted to support Adial in this important mission to advance AD04 as an attractive potential therapy addressing a significant unmet need among patients with Alcohol Use Disorder."

About Eurofins Scientific

Eurofins Scientific through its subsidiaries (hereinafter sometimes "Eurofins" or "the Group") believes it is a scientific leader in food, environment, pharmaceutical and cosmetics products testing and in agroscience CRO services. It is also one of the global independent market leaders in certain testing and laboratory services for genomics, discovery pharmacology, forensics, CDMO, advanced material sciences and for supporting clinical studies. With about 45,000 staff in more than 800 laboratories across 47 countries, Eurofins offers a portfolio of over 200,000 analytical methods for evaluating the safety, identity, composition, authenticity, origin and purity of biological substances and products, as well as for innovative clinical diagnostics. The Group objective is to provide its customers with high-quality services, accurate results on time and expert advice by its highly qualified staff.

About Eurofins BioPharma Services

Reliable, high quality laboratory data is pivotal to the success of clinical trials. Since laboratory testing is our sole focus, we go above and beyond to provide an array of services to ensure that any clinical trial sample is collected, transported, managed, analyzed, reported and stored to meet the objectives and purpose of your study. We are dedicated to providing the most cost effective and efficient solutions to pharmaceutical, biotech companies and CROs alike.

Eurofins BioPharma Services supports our customers with Central Laboratory (U.S., Netherlands, Singapore, China),

Large and Small Bioanalytical (U.S., U.K., France), Phase 1/Early Development (France) and Immunology/Virology (U.S.) specialization laboratories globally. This provides our client base with true end-to-end laboratory solutions for your entire clinical phase development activity.

https://eurofinscentrallaboratory.com/biopharma-services

About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of treatments for addictions. The Company's lead investigational new drug product, AD04, is a genetically targeted therapeutic agent for the treatment of Alcohol Use Disorder (AUD). A Phase 2b clinical trial of AD04 for the treatment of AUD showed promising results in reducing frequency of drinking, quantity of drinking and heavy drinking (all with statistical significance), and no overt safety concerns (there were no statistically significant serious adverse events reported). The Company plans to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes, which are to be identified using the Company's proprietary companion diagnostic genetic test. AD04 is also believed to have the potential to treat other addictive disorders such as opioid use disorder, gambling, and obesity. www.adialpharma.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 plans to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes, genetically pre-screening subjects prior to enrollment allowing us to enhance the efficacy rates of AD04 in the trial and reducing the time and costs associated with conducting the trial, and the potential of AD04 to treat AUD 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 commence the Phase 3 clinical trials and enroll subjects as expected, our ability to enhance the efficacy rates of AD04 in the trial and reduce the time and costs associated with conducting the trial, our ability to expand the use of AD04 for use in patients with opioid use disorder, gambling and obesity, the ability of AD04 therapy to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, regulatory limitations relating to our ability to promote or commercialize our product candidates for specific indications, acceptance of its product candidates in the marketplace and the successful development, marketing or sale of products, our ability to maintain our license agreements, the continued maintenance and growth of our patent estate, our ability to establish and maintain collaborations, our ability to obtain or maintain the capital or grants necessary to fund its research and development activities, 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, 2018, 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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