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Adial Pharmaceuticals Receives Approval to Commence Phase 3 Trial in Bulgaria

CHARLOTTESVILLE, VA / ACCESSWIRE / February 19, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced that it has received approval to commence its Phase 3 study to investigate AD04 as a therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in Bulgaria in persons with certain target genotypes related to the serotonin transporter and receptor genes. This includes receiving approvals from both the Bulgarian Drug Agency and the Bulgarian Ethics Committee for Clinical Trials overseeing the study.

"Bulgaria is expected to be an important country in our Phase 3 trial of AD04 in biomarker-positive study participants," stated William Stilley, Chief Executive Officer of Adial Pharmaceuticals. "Approximately one-half of our planned clinical sites are located in Finland and Bulgaria, and we have already opened the trial in Finland. The approval to commence the Phase 3 trial in Bulgaria was received ahead of schedule, which we anticipate will accelerate enrollment and reduce the cost of the trial."

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) and is currently being investigated in a Phase 3 clinical trial 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. 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). 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 Bulgaria being an important country in our Phase 3 trial of AD04 in biomarker positive study participants, approximately one-half of our planned clinical sites being located in Finland and Bulgaria, approval to commence the Phase 3 trial in Bulgaria should help accelerate enrollment and reduce the cost of the trial 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 open the Phase 3 trial in Bulgaria and recruit patients in Bulgaria, our ability to deploy our diagnostic genetic test to avoid treating patients for whom we would not expect the drug to be effective, our ability to confirm the results of the Phase 2b trial in the Phase 3 pivotal studies, our ability to rapidly enroll the study and develop a protocol that can be successfully conducted, the ability to obtain approvals in additional countries, the 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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