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Adial Pharmaceuticals Commences Phase 3 Trial of AD04 for Alcohol Use Disorder

CHARLOTTESVILLE, VA / ACCESSWIRE / February 6, 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 commenced a Phase 3 pivotal clinical trial to investigate AD04 as a genetically targeted therapeutic agent for the treatment of Alcohol Use Disorder (AUD). The trial has initially started in Finland, where Adial previously announced it had received approval to commence the trial. The trial is also expected to be conducted in Sweden, Poland, Latvia, Estonia, Croatia, and Bulgaria. Adial has filed clinical trial applications (CTAs) to also conduct the trial in each of these countries where additional trial sites will be initiated on a country-by-country basis following each CTA approval.

"We are pleased that the initial Phase 3 pivotal clinical trial of our drug AD04 for the treatment of Alcohol Use Disorder is underway, as we continue our progress toward bringing meaningful treatments for AUD and other addictions to market," declared William Stilley, Chief Executive Officer of Adial Pharmaceuticals. "In addition to testing AD04, the trial is designed to validate our proprietary companion diagnostic genetic test, which will identify biomarker positive patients for enrollment in the trial and, once validated in the trial, serve to identify patients for treatment in the commercial setting. By identifying patients expected to respond to the drug, we expect better response rates, which should improve the efficacy rates both in the trial and commercially. Deployment of our diagnostic genetic test should allow us to avoid treating patients for whom we would not expect the drug to be effective. This should save time and cost, and we believe will lead to reimbursement at premium pricing for both the drug and our proprietary companion diagnostic genetic test. We are conducting the trial in Scandinavia and Eastern Europe because, based on the publicly available genetic databases, we believe the prevalence of the people with the genetic biomarkers for treatment with AD04 is of higher in that part of the world, even higher than the 33% expected to have a responsive genotype in the United States."

"Advancing AD04 to a Phase 3 pivotal clinical trial is an exciting milestone for Adial. From the day these clinical studies began at the University of Virginia (UVA), we have been eager to see this discovery enrich and improve the lives of patients suffering from addiction," commented Michael Straightiff, Executive Director of the UVA Licensing & Ventures Group.

Dr. Bankole Johnson, Chief Medical Officer of Adial Pharmaceuticals, remarked, "For over thirty years, I have been treating patients with Alcohol Use Disorder. My experience working with AD04 during the Phase 2b clinical trial at UVA and the results of that trial have led me to believe that AD04 will be the most meaningful addiction treatment developed to date. The commencement of our Phase 3 pivotal trial is an emotional time for me since bringing AD04 to market will be the pinnacle accomplishment of my lifetime of work to help those afflicted with addiction."

"Finland is the first country that we have initiated, and we have filed in an additional six countries where we will commence operations as the respective regulatory approvals are received in the coming weeks," stated Päivi Itkonen, Chief Executive Officer of Crown CRO Oy, who has been contracted to conduct the Phase 3 clinical trial of AD04. "In total we expect to open twenty-four clinical sites in seven countries with a plan for six sites in Finland, three sites in Poland, three sites in Estonia, two sites in Latvia, one site in Sweden, six sites in Bulgaria and three sites in Croatia. Crown CRO is managing all aspects of the Phase 3 trial, including coordinating the genetic testing for the genetic biomarkers to identify patients for inclusion in the study through Adial's partnership with Eurofins, a global scientific leader in bio-analytical testing, and the trial randomization and the clinical drug product distribution that is being performed by Catalent, the world's leading clinical manufacturing and distribution company. With the clinical site plan and team in place, we believe the study can be rapidly enrolled."

"Since joining as the Principal Investigator for the Phase 3 pivotal trial of AD04, I have been working with Adial and the rest of their partners to ensure that we have completed all the regulatory requirements and developed a protocol that we believe can be successfully conducted," said Professor Hannu E.R. Alho, Emeritus Professor of Addiction Medicine at the University of Helsinki, Finland. "I have also now joined the trial as the head of the first clinical site initiated in the trial. The world needs a drug like AD04, and I am hopeful this trial will demonstrate that AD04 can be a safe and effective treatment for patients having Alcohol Use Disorder and the genetic biomarkers to indicate potential response to the drug."

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 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 identifying patients expected to

respond to the drug, to deliver response rates and improve the efficacy rates both in the trial and commercially, deployment of our diagnostic genetic test allowing us to avoid treating patients for whom we would not expect the drug to be effective, saving time and cost and leading to reimbursement at premium pricing for both the drug and our proprietary companion diagnostic genetic test, the prevalence of the people with the genetic biomarkers for treatment with AD04 being of higher prevalence in Scandinavia and Eastern Europe, the expectation of opening twenty-four sites in seven countries, the expectation that Phase 3 pivotal studies will confirm the results of the Phase 2b trial, the study being rapidly enrolled with the clinical team in place, having developed a protocol that can be successfully conducted, the trial demonstrating that AD04 can be a safe and effective treatment for patients having Alcohol Use Disorder and the genetic biomarkers to indicate potential response to the drug 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 identify patients expected to respond to the drug, to deliver response rates and improve the efficacy rates both in the trial and commercially, our ability to deploy our diagnostic genetic test to avoid treating patients for whom we would not expect the drug to be effective, saving time and cost and leading to reimbursement at premium pricing for both the drug and our proprietary companion diagnostic genetic test, our ability to confirm the prevalence of the people with the genetic biomarkers for treatment with AD04 being of higher prevalence in Scandinavia and Eastern Europe, 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 and open twenty-four sites in seven 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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