December 10, 2018

Adial Pharmaceuticals Announces Professor Hannu Alho, Emeritus Professor of Addiction Medicine at the University of Helsinki, Finland as Coordinating Principal Investigator for Phase 3 Clinical Trial of AD04 for the Treatment of Alcohol Use Disorder

CHARLOTTESVILLE, Va., Dec. 10, 2018 (GLOBE NEWSWIRE) -- **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)** www.adialpharma.com a clinical-stage biopharmaceutical company focused on the development of medicines for addiction, today announced that Professor Hannu E.R. Alho, Emeritus Professor of Addiction Medicine at the University of Helsinki, Finland was appointed as Coordinating Principal Investigator for the planned European Phase 3 clinical trial of AD04 for the treatment of Alcohol Use Disorder (AUD). This Phase 3 clinical trial will be a 24-week trial with 290 patients in 30 clinical sites in five European countries. Last month, Crown CRO of Finland was selected to manage the clinical trial.

Prof. Alho currently serves in several capacities in addition to his Professor of Addiction Medicine, University of Helsinki emeritus position. He is also Chief Physician, Unit of Substance Abuse Diseases, Department of Internal Medicine, Helsinki University Hospital and Research Professor, Unit of Prevention and Treatment of Addictions, National Institute of Health and Welfare, Helsinki. He has been the Principal Investigator of several non-sponsored, research oriented clinical studies, as well as national coordinator and principal investigator for several commercial research endeavors. He has published 219 original articles with 5440 citations and has been an invited speaker at more than 50 international scientific meetings, symposia and seminars in the field of addiction medicine and opiate dependence.

Commenting on the appointment, William Stilley, CEO of Adial Pharmaceuticals, said, “We are continuing to move toward commencing our Phase 3 clinical trial of AD04 in the first half of 2019. It is an honor that Professor Alho has agreed to accept the role of Coordinating Principal Investigator in our Phase 3 study, and we expect his oversight will help us to start and advance our study effectively and efficiently. We look forward to leveraging his expertise and knowledge to navigate the scientific and regulatory environments, and connect with additional respected thought leaders in the addiction space.”

“The Phase 3 trial will enroll adult patients with Alcohol Use Disorder and selected

polymorphisms in the serotonin transporter and receptor genes," said Prof. Hannu Alho, M.D. "This approach is an innovative way to target a therapeutic agent in patients with AUD as we work to develop effective treatments. I am honored to be involved in this important study."

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 candidate, 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.

About Alcohol Use Disorder

According to an article in the widely respected publication*The Lancet,* alcohol is the number one cause of death globally among both men and women ages 15 to 49 years. In the United States alone, approximately 35 million people have AUD resulting in significant health, social and financial costs (NIAAA Alcohol Facts & Statistics). AUD contributes to over 200 different diseases, and 10% of children live with a person that has an alcohol problem. According to the American Society of Clinical Oncologists, 5-6% of new cancers and cancer deaths globally are directly attributable to alcohol. The Centers for Disease Control (CDC) has reported that AUD costs the U.S. economy about $250 billion annually, with heavy drinking accounting for greater than 75% of the social and health related costs. In addition, according to the NIAAA, the problem in the United States appears to be growing with an approximately 50% increase in AUD prevalence between 2002 and 2013.

Despite the high prevalence and high costs, according to an article in the JAMA 2015 publication, only 7.7% of patients (i.e., approximately 2.7 million people) with AUD are estimated to have been treated in any way and only 3.6% by a physician (i.e., approximately 1.3 million people). The most common treatments for AUD are directed at achieving abstinence, and typical treatments include psychological and social interventions. Most therapies require abstinence even prior to initiating therapy. Abstinence requires dramatic lifestyle changes often with serious work and social consequences. Significant side effects of current pharmacologic therapies include mental side effects, such as psychiatric disorders and depressive symptoms and physical side effects, such as nausea, dizziness, vomiting, abdominal pain, arthritis and joint fitness. These problems with the currently available therapies appear to limit the willingness of people with AUD to seek treatment and then to limit compliance with treatment requirements and, therefore, the ultimate results for many people attempting currently available therapies.

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. These statements are based upon current beliefs, expectations and assumptions and include statements regarding commencing Phase 3 clinical trials of AD04 in the first half of 2019, the expected contribution of Professor Alho in connection with the Phase 3 clinical trial and the expected benefit AD04 will bring to subjects with certain target genotypes in the treatment of AUD. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, our ability commence the Phase 3 clinical trials in the first half of 2019, 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 contribution of Professor Alho to advancing our Phase 3 clinical trial of AD04, 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 registration statement on Form S-1 that we have filed with the SEC and the final prospectus. 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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Source: Adial Pharmaceuticals, Inc.