September 12, 2018

Alcohol Use Disorder Drug Candidate from Adial Pharmaceuticals Shows Positive Stability Results

Genetically targeted AD04 drug candidate indicates stability at four-year point as it moves toward Phase 3 clinical trial

CHARLOTTESVILLE, Va., Sept. 12, 2018 (GLOBE NEWSWIRE) -- **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)** , a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced successful results related to the stability testing of the clinical trial material for its lead drug candidate, AD04, a genetically targeted therapeutic agent being developed to treat alcohol use disorder (AUD). The program indicated stability at the four-year time point for both the active drug candidate and the placebo tablets that had been previously manufactured for use in clinical trials.

William Stilley, CEO of Adial Pharmaceuticals, stated, “We are pleased with the outcome of this independent drug stability testing, which demonstrated stability at four years. In fact, stability testing exceeded our expectations, and, because of these data, we believe there is a likelihood the product will remain stable through the 5th year. Given these results, we believe the clinical trial material we currently possess will be usable in the upcoming Phase 3 trial, once we update our CMC filings with the FDA. Moreover, the drug product was manufactured through a process and at a scale that we believe could be used to support a commercial product. This was an important step in moving toward commencing the Phase 3 trial on time, on budget and to eventual commercial launch.”

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 (the "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 the belief that the product will remain stable through the 5th year, that the clinical trial material will be usable in the upcoming Phase 3 clinical trial once we update our CMC filings with the FDA, and that the drug product was manufactured through a process and at a scale that could be used to support a commercial product and plans to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, the ability of AD04 to remain stable through the 5th year, our ability to use the clinical trial material in the planned Phase 3 clinical trial, the ability of the manufacturing process for the drug product to support a commercial product, the ability of AD04 therapy to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, our plan to

become a leading player in the war on addiction, 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, its 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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