Adial Pharmaceuticals Submits Continuation Patent Application for Use of AD04 in Opioid Dependence and Abuse

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Continuation patent would allow for broader protection beyond claims protected under current patents

CHARLOTTESVILLE, Va., Feb. 15, 2019 — **Adial Pharmaceuticals, Inc. (NASDAQ:ADIL;ADILW)**, a clinical-stage biopharmaceutical company focused on the development of medicines for addiction, today announced that it has submitted a continuation patent application with U.S. Patent and Trademark Office to broaden the claims relating to the use of AD04 for opioid dependence and abuse, commonly referred to as Opioid Use Disorder (OUD). The continuation patent claims priority to and therefore retains the filing date of the original patent.

William Stilley, CEO of Adial Pharmaceuticals, stated, "Given the progress we are making advancing towards our Phase 3 trial for AD04 in Alcohol Use Disorder (AUD), we are now accelerating our efforts to expand into other indications. We believe this program has significant potential since the physiology and neuro-transmitters involved in opioid addiction are similar to alcohol and could be expected to be modulated by a serotonin-3 receptor antagonist. In the past, we have filed claims and received patents globally that broadly recite addictive related disorders. This is the first time we have filed a continuation patent application specifically drawn to OUD."

Mr. Stilley continued, "In addition to our continuation patent application, we are also exploring non-dilutive grant funding opportunities, as OUD represents an underserved market and is a high priority with significant backing among both governmental and non-governmental organizations. Since fentanyl is a synthetic opioid, we believe AD04 represents a potential treatment option for these patients as well."

According to the Centers for Disease control, in 2017 alone, more than 72,000 people in the US died of drug overdoses, at least two-thirds of which were linked to opioids. This marked the highest number of Americans that have died of drug overdoses in a single year-more than those killed by guns, car crashes, or HIV/AIDS-with alcohol being one of the only other causes responsible for more deaths.

According to the National Institute on Drug Abuse (NIDA), among opioids, fentanyl is the biggest driver of overdose deaths in America, as it is roughly 100 times more potent than morphine and 50 times stronger than heroin. In 2016, synthetic opioids (primarily illegal fentanyl) passed prescription opioids as the most common drugs involved in overdose deaths in the United States.

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.

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 the beliefs that the program may have significant potential since the physiology and neuro-transmitters involved in opioid addiction are similar to alcohol and could be expected to be modulated by a serotonin-3 receptor antagonist and that AD04 represents a potential treatment option for OUD patients, the plans to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes, and the belief that AD04 has the potential 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, the ability of a serotonin-3 receptor antagonist AD04 to modulate the physiology and neuro-transmitters involved in opioid addiction; the ability of AD04 to

provide a potential treatment option for OUD patients; 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 our SAB in 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 and our Current Report on Form 10-Q for the quarter ended September 30, 2018. 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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