Adial Pharmaceuticals Announces Planned Expansion of Lead Asset AD04 into Opioid Addiction Including Synthetic Opioids Such as Fentanyl

CHARLOTTESVILLE, Va., Dec. 13, 2018 — **Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW)**, www.adialpharma.com, a clinical-stage biopharmaceutical company focused on the development of medicines for addiction, today announced plans to expand activities around the Company's lead asset, AD04, beyond alcohol use disorder (AUD), to now include its potential use in patients with opioid use disorder.

William Stilley, CEO of Adial Pharmaceuticals, said, "We are expanding our activities around AD04 to include opioid use disorder (OUD) and 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."

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 who ever 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.

"OUD is a massively underserved market," continued Mr. Stilley. "Among opioids, fentanyl is the biggest driver of overdose deaths in America, according to the National Institute on Drug Abuse (NIDA). Fentanyl 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. Since fentanyl is a synthetic opioid, we believe AD04 represents a potential treatment option for these patients as well."

"We commend the White House's efforts to curtail the over prescription of opioids, as well as the flow of illegal synthetic opioids," concluded Mr. Stilley. "At the same time, it is crucial that we address the demand for these drugs, which is driven by addiction. This makes it imperative that we begin to treat addiction as a disease and recognize both the biological and genetic factors contributing to this epidemic."

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.

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 plans to expand activities around the Company's lead asset, AD04,

ADO4's potential use in patients with opioid use disorder, physiology and neuro-transmitters involved in opioid addiction being expected to be modulated by a serotonin-3 receptor antagonist, the belief that AD04 may represent a potential treatment option for patients with the targeted genotypes that are addicted to fentanyl and other synthetic opioids, commencing Phase 3 clinical trials in the first half of 2019, and the expected benefit AD04 will bring to patients. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, the ability commence the Phase 3 clinical trials in the first half of 2019, the ability to expand the use of AD04 for use in patients with opioid use disorder, 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 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, 2018Any 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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