

Adial Pharmaceuticals Receives Notice of Allowance for Third U.S. Patent Covering AD04 for the Treatment for Opioid Use Disorder

CHARLOTTESVILLE, VA / January 11, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addictions, today announced receipt of a Notice of Allowance for its third U.S. patent relating to the use of AD04 for the treatment of opioid use disorder (OUD). The patent covers the use of the Company's lead product, AD04, as a treatment of Opioid Use Disorder in patients with a specific genetic biomarker in the serotonin transporter gene.

William Stilley, Chief Executive Officer of Adial Pharmaceuticals, commented, "We are pleased to announce our third patent for AD04 for the treatment of Opioid Use Disorder, which is both a large and an underserved market. As we continue to study AD04 in our landmark ONWARD™ Phase 3 pivotal clinical trial for the treatment of Alcohol Use Disorder, our goal is to confirm the findings of the Phase 2b trial, which demonstrated the efficacy of AD04 as a treatment for Alcohol Use Disorder. We believe the primary mechanism of action through which AD04 produces its pharmacological effect is through inhibiting activation of the serotonin-3 receptor in the brain, thereby blocking effects on the dopamine system. We see significant potential in AD04 for the treatment of Opioid Use Disorder since the physiology and neurotransmitters involved in opioid addiction are similar to alcohol and could be expected to be modulated by a serotonin-3 receptor antagonist."

According to the U.S. Centers for Disease Control and Prevention, an estimated 2 million people in the U.S. had an opioid use disorder in 2018 and nearly 70% of drug overdose deaths were attributed to opioids. "Sadly, we believe these numbers have grown significantly due to the ongoing pandemic, and we are hopeful that AD04 may provide a desperately needed treatment option for those suffering from opioid addiction," added Mr. Stilley.

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, serotonin-3 receptor antagonist, therapeutic agent for the treatment of Alcohol Use Disorder (AUD) and is currently being investigated in the Company's landmark ONWARD™ Phase 3 pivotal clinical trial 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. Additional information is available at 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 confirming the findings in the Phase 2b trial that the primary mechanism of action through which AD04 produces its pharmacological effect is through inhibiting activation of the serotonin-3 receptor in the brain and blocking effects on the dopamine system, the potential in AD04 for the treatment of Opioid Use Disorder and the potential of AD04 to treat other

addictive disorders such as alcohol 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 confirm the findings in the Phase 2b trial that the primary mechanism of action through which AD04 produces its pharmacological effect is through inhibiting activation of the serotonin-3 receptor in the brain, thereby blocking effects on the dopamine system, the ability of AD04 to be a treatment option for those suffering from opioid addiction and other addictive disorders, our ability to enroll patients within the timelines anticipated and complete clinical trials on time and achieve desired results and benefits as expected, 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, 2019, 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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