

# Adial Pharmaceuticals Receives Notice of Allowance on U.S. Patent for the Treatment for Opioid Use Disorder Using AD04

Patent covers patients with a specific genetic biomarker for the serotonin-3 receptor

CHARLOTTESVILLE, Va., Jan. 24, 2022 — **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)** (“Adial” or the “Company”), a clinical-stage biopharmaceutical company focused on developing therapies for the treatment and prevention of addiction and related disorders, today announced the U.S. Patent and Trademark Office (USPTO) has mailed a Notice of Allowance for US Patent Application No. 16/784,051, a patent application for the treatment for opioid use disorder (OUD) using AD04. This patent application covers treatment of patients with a specific genetic biomarker for the serotonin-3 receptor.

AD04 is currently being evaluated in the Company’s ONWARD trial, which is designed as a Phase 3 clinical study to evaluate the efficacy, safety and tolerability of AD04 in patients with alcohol use disorder (AUD). The Company believes AD04 may also hold significant potential for the treatment of OUD 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.

William Stilley, Adial’s Chief Executive Officer, stated, “We continue to build the patent estate around AD04, and, including expected extensions, we believe AD04 will have robust, long-term patent protection of our intellectual property through 2036. Specifically, this represents our ninth U.S. patent, in addition to numerous international patents, covering AUD, OUD, or both. OUD remains a significant, yet underserved market. According to the CDC’s National Center for Health Statistics, there were an estimated 93,000 drug overdose deaths in the United States alone during 2020, an increase of nearly 30% from the prior year. The Centers for Disease Control and Prevention estimates that the total economic burden of prescription opioid misuse alone in the United States is \$78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.”

A Notice of Allowance is issued after the USPTO makes a determination that a patent can be granted from an application. The issued patent would have a term that expires no earlier than July 1, 2031.

## 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™ pivotal Phase 3 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. The Company is also developing adenosine analogs for the treatment of pain and other disorders through its wholly owned subsidiary, Purnovate, Inc. Additional information is available at [www.adialpharma.com](http://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 the potential of AD04 for the treatment of OUD 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, the patent estate around AD04 having robust, long-term patent protection of our intellectual property through 2036, the estimated total economic burden of prescription opioid misuse alone in the United States is \$78.5 billion a year, and the potential of AD04 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, our ability to 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 our product candidates in the marketplace and the successful development, marketing or sale of our 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, 2020, 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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