Adial Pharmaceuticals Awarded U.S. and International Patents for the Treatment Of Alcohol and Opioid Use Disorders Using AD04

CHARLOTTESVILLE, Va., Aug. 10, 2021 — **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 provided an update on recently issued patents for the use of Adial's lead asset, AD04, for the treatment of both Alcohol Use Disorder (AUD) and Opioid Use Disorder (OUD). AD04 is currently being evaluated in the Company's ONWARD trial, a Phase 3 clinical study to evaluate the efficacy, safety and tolerability of AD04 in patients with AUD, which is being conducted in seven countries.

Recently issued patents:

- U.S. Patent Number 16,807,379 covering the use of AD04 as a treatment for OUD in patients with a specific genetic biomarker in the serotonin transporter gene.
- Canadian Patent Number 2716498 covering the use of AD04 for both OUD and AUD in patients with specific genetic biomarkers in the serotonin transporter gene.
- Israeli Patent Number 262874 covering the use of AD04 as a treatment for OUD in patients with specific genetic biomarkers in the serotonin transporter gene.
- Brazilian Patent Number PI09084258 covering the use of AD04 as a treatment for OUD in patients with specific genetic biomarkers in the serotonin transporter gene.

The Company believes AD04 may 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.

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

Commenting on the patents, William Stilley, Adial's Chief Executive Officer, stated, "We are encouraged by our recent patent activity, not only for obtaining patents for AD04 to treat AUD and OUD patients, but also for having recently obtained a Notice of Allowance on a patent for the use of our genetic diagnostic panel in combination with AD04 for both AUD and OUD, which represents another potentially significant business opportunity for the Company. As we have done with the rest of our patent estate, we continue our policy of pursuing patents internationally in any jurisdictions where we believe a robust and potentially profitable market exists, as demonstrated by not just the U.S. patent issuance, but recent issuances in Brazil, Canada and Israel. The use of AD04 for AUD is already covered by patents issued in over 45 jurisdictions."

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. Additional information is available at www.adialpharma.com.

About the Landmark ONWARD™ Pivotal Phase 3 Clinical Trial

The ONWARD trial is a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel group, Phase 3 clinical study to evaluate the efficacy, safety and tolerability of AD04 in patients with Alcohol Use Disorder (AUD) and selected polymorphisms in the serotonin transporter and receptor genes. Patients are genetically screened prior to enrollment in the ONWARD trial so that only genetically positive patients are enrolled. The primary endpoint for analysis of efficacy is the change from baseline in the monthly number of heavy drinking days during the last 8 weeks of the 24-week treatment period. ONWARD is currently being conducted in 25 clinical sites in seven countries in Scandinavia and Central and Eastern Europe (Sweden, Finland, Poland, Latvia, Estonia, Bulgaria and Croatia). The principal investigator is Professor Hannu E.R. Alho, Emeritus Professor of Addiction Medicine at the University of Helsinki.

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 AD04 holding 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, the potential treatment of AUD in subjects with certain target genotypes, the use of the Company's genetic diagnostic panel in combination with AD04 for both AUD and OUD, representing another potentially significant business opportunity for the Company 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 the ONWARD™ Phase 3 trial of AD04 as a genetically targeted treatment for Alcohol Use Disorder through data read-out as planned, our ability to achieve key milestones for our pre-clinical adenosine program for non-opiate pain relief, 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, 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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