

Adial Pharmaceuticals Exceeds Enrollment Target in ONWARD™ Phase 3 Trial of AD04 for the Treatment of Patients with Alcohol Use Disorder

ONWARD trial enrollment closed; trial completion expected in Q1 2022

CHARLOTTESVILLE, Va., Aug. 31, 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, announces it has successfully enrolled 302 patients across 25 clinical sites and has now closed enrollment for its ONWARD™ Phase 3 trial evaluating AD04 as a therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in persons with certain target genotypes related to the serotonin transporter and receptor genes.

William Stilley, Adial’s Chief Executive Officer, stated, “I am pleased to report we have exceeded our enrollment target of 290 subjects. Given patient interest and because a larger patient population to evaluate AD04 enhances the statistical power of the trial and reduces the risk of not achieving the target number of fully completed patients in the trial, we extended our enrollment period by one month and now, with twelve additional patients enrolled, enrollment of ONWARD is now closed. Our appreciation goes out to the ONWARD clinical investigators across Scandinavia and Central and Eastern Europe, including clinical sites in Sweden, Finland, Poland, Latvia, Bulgaria and Croatia. Our team is highly encouraged by the trial retention rate and safety data to date. This data preliminarily suggests a well-tolerated therapy, which may place Adial’s AD04 at a significant advantage to other currently marketed AUD therapies. Importantly, we remain on target to complete patient dosing in the first quarter of 2022 and look forward to reporting our top line data as soon as practical.”

For more information regarding ONWARD, please visit the National Institute of Health’s [Clinical Trials website](#), which should be updated shortly to reflect full enrollment of the trial.

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 pivotal ONWARD™ Phase 3 clinical trial for the potential treatment of AUD in subjects with certain target genotypes, which are 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, pivotal 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 six countries in Scandinavia and Central and Eastern Europe (Sweden, Finland, Poland, Latvia, Bulgaria and Croatia). The Coordinating 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 the expectation that the ONWARD trial will be complete in the first quarter of 2022, 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 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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