# Adial Pharmaceuticals Announces Completion of Last Patient, Last Visit in its ONWARD™ Phase 3 Trial of AD04 for the Treatment of Patients with Alcohol Use Disorder

CHARLOTTESVILLE, Va., Feb. 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 that the final patient has completed the last dose and last clinical visit in the Company's ongoing ONWARD™ Phase 3 trial. ONWARD is evaluating the efficacy, safety and tolerability of 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, "Last patient, last visit in the ONWARD trial is a major milestone for the Company. As previously announced, we had enrolled 302 patients across 25 clinical sites, exceeding our prior enrollment targets and, therefore, enhancing the statistical power of the trial. The safety data and trial retention rate also suggest a well-tolerated therapy, in contrast to conventional therapies. We are now turning our attention to safety follow-up protocols and close-out activities with the expectation that topline results will be available in the second quarter."

"Patients suffering from AUD remains a significant yet underserved market, accounting for over 3 million deaths worldwide. Sadly, AUD is also the number one risk factor for death and disability in the U.S., and globally among men and women ages 15 to 49. Given the magnitude of this public health crisis, which has only increased since the start of the pandemic, it is more important than ever to bring AD04 to market for the patients. My sincerest gratitude goes to the patients and clinicians that participated in this important trial," continued Mr. Stilley. "While the last patient, last visit has occurred, the study will remain blinded until the completion of all safety protocol follow-up activities, site inspections, protocol review and other trial closing procedures and activities. Then the database will be locked and analysis of the data will take place. The goal is to show a statistically significant reduction in the number of days of heavy drinking over the course of the study in patients on active AD04 as compared to the placebo group."

**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.

**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.

**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 safety data and trial retention rate also suggesting a well-tolerated therapy, in contrast to conventional therapies, topline results being available in the second quarter, we expect, based the prior Phase 2 data, to show a statistically significant reduction in the number of days of heavy drinking over the course of the study in patients on active AD04 as compared to the placebo group, 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 provide topline results in the second quarter, the trial results showing a statistically significant reduction in the number of days of heavy drinking over the course of the study in patients on active AD04 as compared to the placebo group, 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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