# Adial Pharmaceuticals Reaches Full Enrollment Target for ONWARD™ Phase 3 Trial of AD04 for the Treatment of Patients With Alcohol Use Disorder

*On track for trial completion in the first quarter of 2022*

*Adial to host business update call at 11AM Eastern today*

CHARLOTTESVILLE, Va., Aug. 20, 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 reached its full enrollment target of 290 subjects in the Company's 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. ONWARD trial completion is expected in the first quarter of 2022.

William Stilley, Adial's Chief Executive Officer, stated, "Meeting our enrollment target is a major achievement in our ONWARD™ Phase 3 trial. I would like to thank all of the investigators involved in the trial that helped us reach this important milestone in spite of the ongoing pandemic. Trial engagement interest among patients continues to be strong, and consistent with what was seen in previous clinical testing; approximately 33% of those patients screened tested positive for the genetics expected to indicate responsiveness to AD04. Our confidence in the market potential of AD04 is bolstered by this apparent confirmation of the percentage of the population with the target genetics. We estimate the market potential for AD04 to be in excess of $36 billion in the U.S. alone, and we are evaluating marketing and distribution channel partners in the United States and abroad."

Mr. Stilley continued, "Due to increased demand for entry into the study near the end of our trial recruitment period, we still have additional patients that have been genetically screened as positive for enrollment in the study but have not yet been enrolled in ONWARD™. With this opportunity to rapidly enroll additional patients to increase the statistical power of the trial, and, we have determined to enroll these additional, already screened patients through the end of this month. This means total trial enrollment will exceed our enrollment goal of 290 patients."

"We are also encouraged by the high study retention rate with more patients than expected continuing to engage in the trial following enrollment. Moreover, no serious adverse events have been reported to date that have been determined to be study drug related, and the vast majority of adverse events have been mild and also unrelated. The retention rate and safety data are supportive of a well-tolerated therapy, differentiating AD04 from other marketed AUD therapies."

**Conference Call**

Adial will host a conference call at 11:00 A.M. Eastern Time today, on Friday, August 20, 2021. The conference call will be available via telephone by dialing toll free 844-369-8770 for U.S. callers or +1 862-298-0840 for international callers. A webcast of the call may be accessed at https://www.webcaster4.com/Webcast/Page/2463/42538 or on the Company's website at https://ir.adialpharma.com/.

An audio replay of the call will be available through September 3, 2021 and can be accessed by dialing 877-481-4010 for U.S callers or +1 919-882-2331 for international callers and by entering the access code: 42538.

**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 the ONWARD trial completion being expected in the first quarter of 2022, the target genetics expected to indicate responsiveness to AD04 the market potential for AD04 being in excess of $36 billion in the U.S. alone 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 achieve key milestones for our pre-clinical adenosine program for non-opiate pain relief, 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 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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