

Adial Pharmaceuticals to Announce Topline Results of ONWARD™ Phase 3 Trial for AD04 in Patients With Alcohol Use Disorder

July 18, 2022

Company to host conference call on Wednesday, July 20, 2022, at 1 PM ET

CHARLOTTESVILLE, Va., July 18, 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 it plans to report topline results from the Company’s ONWARD™ Phase 3 clinical trial on Wednesday, July 20, 2022. The Company plans to host a conference call at 1 PM Eastern Time on Wednesday (dial-in instructions to follow).

About the ONWARD™ Trial

The ONWARD Phase 3 clinical trial is a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel group, clinical study to evaluate the efficacy, safety and tolerability of AD04 in patients with Alcohol Use Disorder and selected polymorphisms in the serotonin transporter and receptor genes. Patients were genetically screened prior to enrollment in ONWARD so that only genetically positive patients were enrolled. Approximately one-third of the screened patients tested genetically positive for the targeted genetics, and patients were stratified by the severity of drinking into heavy drinkers and very heavy drinkers (determined by whether they averaged less than ten, or greater than or equal to ten drinks per drinking day, respectively, prior to enrollment). Approximately, two-thirds of the patients in the ONWARD trial were in the heavy drinking group and one-third in the very heavy drinker group.

ONWARD was conducted in 25 clinical sites in six countries in Scandinavia and Central and Eastern Europe (Sweden, Finland, Poland, Latvia, Bulgaria and Croatia). The 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 was recently investigated in the Company’s landmark ONWARD™ Phase 3 clinical trial for the potential treatment of AUD in subjects with certain target genotypes (estimated to be approximately one-third of the AUD population) 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.

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 plans to report topline results from the Company’s ONWARD™ Phase 3 clinical trial on Wednesday, July 20, 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 provide top-line results from the ONWARD™ Phase 3 clinical trial as planned, our ability to use the ONWARD trial as a basis for approval of AD04 for the treatment of Alcohol Use Disorder in patients identified as having the targeted genetics, our ability to enroll patients in future trials within the timelines anticipated and complete clinical trials on time, our ability to 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 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, 2021, 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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