

Adial Pharmaceuticals Announces Database Lock for the ONWARD™ Phase 3 Clinical Trial

June 27, 2022

Expects Release of Top-Line Data in July

CHARLOTTESVILLE, Va., June 27, 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 database lock for the Company’s ONWARD Phase 3 clinical trial. The data sets have been transferred to the Company’s independent, external statistical consultants who have initiated the analysis of the data. Adial anticipates that it will provide top-line results in July 2022.

“We are excited that data analysis has commenced and we look forward to reporting the topline results of ONWARD this July,” said Dr. Bankole Johnson, Chief Medical Officer of Adial. “The primary endpoint of the ONWARD trial is reduction from baseline in the monthly number of heavy drinking days experienced by each patient during the last eight weeks of the 24-week treatment period. Secondary endpoints include reduction in total alcohol consumed and improvement as measured by the Patient Health Questionnaire-9, a widely accepted tool for assessment of depression. I am also pleased to reaffirm that no drug-related serious adverse events were reported during the 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 and selected polymorphisms in the serotonin transporter and receptor genes. Patients were genetically screened prior to enrollment in the ONWARD trial so that only genetically positive patients were enrolled. Approximately one-third of the screened patients tested genetically positive for the targeted genetics.

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.

The ONWARD trial is expected to serve as a basis for approval of AD04 for the treatment of Alcohol Use Disorder in patients identified as having the targeted genetics (i.e., a pivotal Phase 3 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 ONWARD™ pivotal 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.

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 providing top-line results in July 2022, the ONWARD trial serving as a basis for approval of AD04 for the treatment of Alcohol Use Disorder in patients identified as having the targeted genetics 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, the ability, our ability to provide top-line results as planned, the ability of the ONWARD trial to serve 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 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 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.

Contact:

Crescendo Communications, LLC
David Waldman / Natalya Rudman
Tel: 212-671-1021
Email: adil@crescendo-ir.com

