The Phase 3 ONWARD™ Trial Meets its Screening Target and Nears Enrollment Completion

Study Drug Continues to Appear to be Well-Tolerated

Patient Retention Currently Exceeds Expectations

CHARLOTTESVILLE, Va., July 06, 2021 — Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addictions, today announced that the Company has made significant progress on its pivotal ONWARD Phase 3 clinical trial having met 100% of its patient screening target and having achieved 90% of its patient enrollment target. The ONWARD trial is 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 Recent highlights:

- **100% of the number of patients expected to fully enroll ONWARD have been screened**
  - 1254 subjects have been screened which represents 100% of anticipated subjects required to be screened based on the trial's historical screening-to-enrollment rates
- **90% of the number of patients projected for full enrollment have been enrolled**
  - 261 of 290 (90%) subjects expected to be enrolled in ONWARD have been enrolled
- **33% of evaluated patients tested positive for the AD04-associated genotype**
  - This genetic data is consistent with Adial's expectations for U.S. prevalence of the target genotype and supports current addressable market forecasts for AD04, estimated at $36 billion and growing
- **AD04 appears to be well-tolerated**
  - While the trial is still blinded so it is not known which patients are taking AD04 or placebo, the vast majority of adverse events reported across all study subjects are mild in intensity
  - *No trial study drug-related serious adverse events have been observed to date*
- **Study retention rate of 84% continues to exceed expectations**
  - The 84% study retention rate continues to outpace the projected 70% retention rate
  - The high retention rate is consistent with the encouraging safety data observed and the Company believes retention is correlated with AD04's tolerance.

"We are on track to deliver trial data in the first quarter of 2022," said Schuyler Vinzant, Adial's Vice President of Development.

William Stilley, Adial's Chief Executive Officer, commented, "Full trial enrollment is expected in the coming weeks as we drive toward generating data from ONWARD as we advance our science with the goal of bringing help to those with addiction. The ramifications for all addictions, and even other mental health disorders, could be powerful and significant."

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.

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.

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 there being a correlation between the high retention rate and the AD04's tolerance, the projected timeline for the provision of data in the first quarter of 2022, having the ONWARD™ trial fully enrolled in the coming weeks, the ramifications of the trial being powerful and significant for all addictions, and even other mental health disorders 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 continue to enroll patients within the timelines anticipated and complete clinical trials on time, provide data when anticipated 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 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, 2019, 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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