Adial Pharmaceuticals Verifies Proprietary Genetic Test in Landmark ONWARD(TM) Pivotal Phase 3 Clinical Trial

Adial Expects to Expand Use of Test to Planned Opioid Use Disorder Clinical Trials

CHARLOTTESVILLE, VA / April 16, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, announced that the functionality of its proprietary companion diagnostic genetic test has been verified as clinically effective through its utilization in the landmark ONWARD™ pivotal Phase 3 clinical trial of the Company's lead drug candidate, ultra-low dose ondansetron (AD04), for the treatment of Alcohol Use Disorder (AUD). The Company expects to expand the use of the genetic test into clinical trials of AD04 in the future for the treatment of other indications such as Opioid Use Disorder (OUD) and is working to establish testing capacity in the United States for future studies.

Adial's genetic test uses double-strand Sanger sequencing and fragment length analysis of polymerase chain reaction (PCR) products. These assays are being used for the analysis of subjects' blood samples for genetic variants in defined genes caused by Single Nucleotide Polymorphisms or Fragment Length Polymorphisms in order to identify subjects likely to respond to AD04 in the ONWARD™ trial. By segmenting the trial population so that only patients genetically predisposed to treatment with a drug are included as trial subjects (sometimes called, "Responders"), there is a greater likelihood that the effect can be distinguishable from placebo.

AD04 is the first drug candidate known to us to target addiction treatment using a genetic segmentation approach. This approach appears to have been successfully demonstrated in a 283 subject, Phase 2b trial of AD04 in subjects with AUD in that those who tested positive for the targeted genetics had a statistically significant response ($P = 0.004$) when compared with placebo. Adial seeks to confirm this result in the ONWARD™ Phase 3 trial by only including subjects that are identified as likely Responders based on testing using the Company's proprietary companion diagnostic genetic test.

"The potential for using ondansetron, the active ingredient in AD04 and a serotonin-3 (5-HT3) antagonist, to treat alcohol addiction was hypothesized decades ago since the 5-HT3 receptor was understood to modulate dopamine, a neurotransmitter known to affect rewards and craving," said Dr. Bankole A. Johnson, Chief Medical Officer of Adial Pharmaceuticals and inventor of AD04. "At the turn of this century, we were able to show that individuals with a biological predisposition to AUD were those that responded best to ultra-low dose ondansetron treatment. With advances in knowledge about human genetics at about the same time, I was able to theorize that targeting specific genotypes in the serotonin system would enable us to use more empirical methods to categorize likely responders to ultra-low dose ondansetron for the treatment of AUD. Indeed, in a follow up Phase 2b trial of ultra-low dose ondansetron, we confirmed that, among individuals with AUD with our predicted target genotypes, ultra-low dose ondansetron was significantly more efficacious than placebo. Now, we have designed and validated a proprietary, targeted genetic test, with very high levels of specificity and accuracy, which is currently being used to identify our target genotypes in the ongoing ONWARD™ Phase 3 trial. The ONWARD™ trial will only include patients with the target genotypes hypothesized to respond to Adial's formulation of ultra-low dose ondansetron, AD04, which should increase the prospect of demonstrating a clinically significant therapeutic effect compared to placebo.

As previously reported, prior to Adial's commencement of its landmark ONWARD™ pivotal Phase 3 clinical trial of AD04, Adial Pharmaceuticals' proprietary companion genetic test was validated for use in ONWARD™ by its genetic testing partner Eurofins Genomics, a division of Eurofins Biopharma Services, a global scientific leader in bioanalytical testing. Adial developed the genetic test with the selectivity and sensitivity it believes will allow approval for the test as a "Companion Diagnostic" as defined by the U.S. Food and Drug Administration (FDA), meaning that the test would be approved by the FDA for use in combination with AD04 to indicate treatment with AD04.

"We have filed patents covering the administration of our proprietary companion diagnostic genetic test to identify people

with AUD and Opioid Use Disorder and possibly other addictions who will likely respond favorably to treatment with AD04 based on their genetics," added William Stilley, Chief Executive Officer of Adial Pharmaceuticals. "Adial's patents in combination with FDA regulations would be expected to prohibit a competitor from marketing or using their own genetic test to identify patients for treatment with AD04."

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™ Phase 3 Pivotal 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. 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 expansion of our proprietary companion diagnostic genetic test to planned Opioid Use Disorder clinical trials, expanding the use of the genetic test into clinical trials of AD04 in the future for the treatment of other indications, the potential for using ondansetron, the active ingredient in AD04 and a serotonin-3 (5-HT3) antagonist, increasing the prospect of demonstrating a clinically significant therapeutic effect compared to placebo to treat addictions by including patients with the target genotypes hypothesized to respond to AD04, the genetic test having the selectivity and sensitivity to allow approval for the test as a "Companion Diagnostic" as defined by the U.S. Food and Drug Administration, our patents in combination with FDA regulations prohibiting a competitor from marketing or using their own genetic test to identify patients for treatment with AD04, 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 expand our proprietary companion diagnostic genetic test to other clinical trials including the planned Opioid Use Disorder clinical trials, our ability to obtain FDA approval of the test as a companion diagnostic, our ability to prohibit competitors from marketing or using their own genetic test to identify patients for treatment with AD04, our ability to continue enrollment and mitigate delays during the COVID-19 pandemic, our ability to expand the use of AD04 for use in patients with Opioid Use Disorder, gambling and obesity, the ability of AD04 therapy to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, 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, 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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