September 25, 2019

# Adial Provides Update on Clinical Activities; Filing to Commence Phase 3 Trial on Track for Q3 2019

**CHARLOTTESVILLE, VA / ACCESSWIRE / September 25, 2019 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW)**, a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today provided an update on its clinical activities. The Company reported that it is on track to complete its Clinical Trial Application (CTA) filing to commence the Phase 3 clinical trial of the Company's lead drug candidate, AD04, (the "Phase 3 Trial" or the "Trial") for the treatment of alcohol use disorder (AUD) in genetically targeted patients, on or before September 30, 2019.

The Phase 3 Trial is expected to enroll 290 subjects across approximately 30 selected clinical sites in Sweden, Finland, Estonia, Latvia, Poland, Bulgaria and Croatia. The Trial is a double-blind placebo-controlled trial with the primary objective to evaluate the efficacy of AD04 to reduce alcohol consumption in subjects with AUD that are positive for certain genetic biomarkers.

A number of key steps, some of which have been previously announced, have been accomplished, including: (a) Crown CRO based in Finland, which has extensive experience in the European markets where the Phase 3 Trial will be conducted, has been selected to manage the Phase 3 Trial; (b) Professor Hannu E.R. Alho, Emeritus Professor of Addiction Medicine at the University of Helsinki, Finland was appointed as Coordinating Principal Investigator; (c) clinical trial material has been delivered to Catalent (Germany), and is in the process of final packaging for use in the Trial; and (d) tablets and blister packaging have been tested to demonstrate long-term stability (5-year shelf life), which is expected to allow for use in the Trial. Additional information on the planned Phase 3 trial can now be found on ClinicalTrials.gov.

"Commencing a multinational, multicenter Phase 3 Trial is a complex undertaking, and we are pleased to report that we have completed most of the necessary steps, including selection of our CRO and principal investigator, site selection, testing of product materials and much more," stated Monika Rogozinska, Chief Development Officer of Adial Pharmaceuticals. "We look forward to commencing enrollment in the trial, which we believe will further demonstrate the safety and efficacy of AD04 as a treatment for AUD."

"I want to thank the entire Adial team for the incredible effort that has gone into making all of our accomplishments to date possible," commented William Stilley, Chief Executive Officer of Adial Pharmaceuticals. "In particular, I want to thank Monika Rogozinska for her strong leadership. Her past experience with European Phase 3 clinical trials, including leading the team that took Bavencio® to approval, has been invaluable in helping advance the AD04 program. I would also like to thank our esteemed Scientific Advisory Board for their active

involvement in this project. We look forward to reporting a number of key progress updates in the weeks and months ahead."

**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 therapeutic agent for the treatment of Alcohol Use Disorder (AUD). 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). The Company plans to commence a Phase 3 clinical trial using AD04 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. 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 that the CTA will be filed on or before September 30, 2019, the tablets and blister packaging of clinical trial material that we previously produced being be usable in our Phase 3 clinical trial of AD04 for AUD and the trial demonstrating the safety and efficacy of AD04 as a treatment for AUD, plans to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes and the potential of AD04 to treat AUD 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 commence the Phase 3 clinical trials as expected, the 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, 2018, 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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