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Adial Pharmaceuticals Announces Commencement of Landmark ONWARD(TM) Pivotal Phase 3 Trial in Poland

Polish clinical sites initiated less than two weeks after regulatory approval

CHARLOTTESVILLE, VA / ACCESSWIRE / June 25, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW) ("Adial"), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced that it has commenced its landmark ONWARD™ pivotal Phase 3 clinical trial in Poland to investigate its lead drug candidate, AD04, as a therapeutic agent for the treatment of Alcohol Use Disorder in persons with certain target genotypes related to the serotonin transporter and receptor genes.

"We are pleased to announce we were able to begin the trial less than two weeks after we received approval from Poland's Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the relevant regional Polish ethics committees overseeing the trial," commented William Stilley, Chief Executive Officer of Adial Pharmaceuticals. "It is a particular honor to have the clinical group led by Dr. Dariusz Malicki at the prestigious Centrum Medyczne Luxmed in Lublin, Poland as part of the ONWARD™ team. We are excited to have initiated trial recruitment in Poland and expect the majority of the ONWARD™ trial sites to be fully operational this summer."

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. 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 majority of the ONWARD™ trial sites being fully operational this summer 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 have a majority of the ONWARD™ trial sites fully operational this summer, 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, our 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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