

July 6, 2020



Adial Pharmaceuticals Announces Approval to Commence Landmark ONWARD(TM) Pivotal Phase 3 Trial in Sweden and Estonia

CHARLOTTESVILLE, VA / ACCESSWIRE / July 6, 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 received approvals in Sweden and Estonia to commence the Company's landmark ONWARD™ pivotal Phase 3 clinical trial to investigate its lead drug candidate, 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. The Swedish Medical Products Agency and Swedish Ethical Review Authority have provided approval for ONWARD™ to commence in Sweden; and the Estonian State Agency of Medicines and Ethics Review Committee overseeing human trials granted approval to commence ONWARD™ in Estonia.

"We are pleased that the regulatory authorities and the ethics committees in Sweden and Estonia have recognized that AD04's safety and efficacy data profile support conducting the ONWARD™ trial in Sweden and Estonia," commented William Stilley, Chief Executive Officer of Adial Pharmaceuticals. "We intend to initiate sites in both countries in the coming weeks. With the relaxing of COVID-19 lockdown restrictions, Adial is working to achieve full operation of ONWARD™ clinical sites as rapidly as possible, with the trial goal to bring a meaningful new treatment for Alcohol Use Disorder to patients in Scandinavia, Eastern Europe and around the world. It is widely reported that the alcohol problem has grown worse during the COVID-19 lockdown, heightening the urgency for pharmacological interventions."

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 initiating sites in Sweden and Estonia to commence the Company's landmark ONWARD™ pivotal Phase 3 clinical trial in the coming weeks and working to achieve full operation of ONWARD™ clinical sites as rapidly as possible, 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 initiate sites in Sweden and Estonia to commence the Company's landmark ONWARD™ pivotal Phase 3 clinical trial as planned, our ability to achieve full operation of the ONWARD™ clinical sites, 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.

Contact:

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

SOURCE: Adial Pharmaceuticals, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/596360/Adial-Pharmaceuticals-Announces-Approval-to-Commence-Landmark-ONWARDTM-Pivotal-Phase-3-Trial-in-Sweden-and-Estonia>