

Adial Pharmaceuticals Receives Issue Notification for Patent Covering AD04 for the Treatment of Opioid Use Disorder

CHARLOTTESVILLE, VA / March 26, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL)(NASDAQ:ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced that it received an Issue Notification for the issuance of a patent by the United States Patent and Trademark Office (USPTO) for the treatment of Opioid Use Disorder (OUD) with its lead drug candidate, AD04, in people that are positive for select genotypes identified using the Company's proprietary companion genetic test.

The patent is scheduled to issue as U.S. Patent Number 10,603,307 on March 31, 2020. Including the patent term adjustment provided in the Issue Notification, the patent is expected to provide commercial exclusivity for AD04 until September 2031, plus potential Hatch-Waxman extensions. Claim 1 of the patent provides for a method of treating an OUD, comprising administering to a patient in need thereof a therapeutically effective amount of AD04, wherein the patient is known to have certain genetics related to the serotonin system; AD04's primary mechanism of action is through the blockage of the serotonin-3 receptor.

"We continue to expand our activities around AD04, which we believe represents a potentially attractive treatment option for patients with OUD, since the physiology and neuro-transmitters involved in opioid addiction are similar to alcohol and could be expected to be modulated by a serotonin-3 receptor antagonist," said William Stilley, Chief Executive Officer of Adial Pharmaceuticals. "Similar to alcohol use disorder, OUD is a massively underserved market. The NIH and CDC report that almost 50,000 people in the U.S. died of opioid overdose in 2017, and the President's Council of Economic Advisors report from 2017 estimates the cost of the opioid epidemic to be more than half a trillion dollars annually in the U.S. alone. Adding this patent to our patent estates continues to enhance and strengthen our patent portfolio around AD04 and is an important milestone since AD04 has the potential to treat a variety of addictive disorders, including OUD. It is also another important step in building Adial into a leading pharmaceutical company focused on treating the terrible affliction of addiction."

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 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 new

patent providing commercial exclusivity for AD04 until September 2031, plus potential Hatch-Waxman extensions, AD04 representing a potentially attractive treatment option for patients with OUD, the physiology and neuro-transmitters involved in opioid addiction being modulated by a serotonin-3 receptor antagonist 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 maintain commercial exclusivity for AD04 until September 2031, plus potential Hatch-Waxman extensions, the ability of AD04 to become attractive treatment option for patients with OUD, our ability to modulate the physiology and neuro-transmitters involved in opioid addiction with a serotonin-3 receptor antagonist, pour 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.

Contact:

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

SOURCE: Adial Pharmaceutical, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/582671/Adial-Pharmaceuticals-Receives-Issue-Notification-for-Patent-Covering-AD04-for-the-Treatment-of-Opioid-Use-Disorder>