

# **Adial Pharmaceuticals Announces Approval to Commence Landmark ONWARD(TM) Pivotal Phase 3 Trial in Poland**

June 11, 2020

***Achievement of Poland Approval an Important Milestone in Advancement of Trial***

***Trial Progress Accelerates as Host Countries Reopen Following COVID-19 Lockdowns***

**CHARLOTTESVILLE, VA / June 11, 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 all necessary approvals to commence 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. This includes the receipt of approvals from both the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products and the relevant regional Polish Ethics Committees overseeing the trial.

“Poland is one of the largest countries in Europe and we believe it is critical to the successful rapid recruitment of patients into our landmark ONWARD™ trial,” stated Schuyler Vinzant, Vice President of Development of Adial Pharmaceuticals. “Regulatory review in Poland was put on hold due to the COVID-19 pandemic. When regulatory reviews recently restarted, the speed of approval to commence the ONWARD™ trial was unexpectedly fast. We are excited by the prospect of opening sites in Poland in the next few weeks.”

“We are grateful the Polish authorities determined the ONWARD™ pivotal Phase 3 trial justified rapid approval,” commented William Stilley, Chief Executive Officer of Adial Pharmaceuticals. “We believe this further demonstrates that regulatory authorities recognize we are targeting an unmet medical need with a drug with the potential to be safe and effective. Today, there is no adequate treatment for Alcohol Use Disorder, and there are strong indications that the problem has only gotten worse during COVID-19 lockdowns. It is imperative that the world moves to bring additional treatments to those suffering with addiction. We are highly confident in our genetically-targeted approach with AD04 and our trial is designed to achieve statistical significance against placebo using endpoints correlated to improved quality of life and reduction in harm (e.g., less death, cancer, accidents, missed work, etc.). The approval to commence the trial in Poland is a landmark achievement in the advancement of our trial.”

## **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](http://www.adialpharma.com)

## **About BioLab Sciences, Inc.**

BioLab Sciences is a regenerative medicine company focused on creating new ways to regenerate the body for optimal performance. Headquartered in Scottsdale, Arizona, BioLab Sciences is expanding the human body's ability to regenerate by developing and manufacturing human cell and tissue therapies as an alternative to invasive, painful and expensive treatment protocols. Through research and innovation, BioLab Sciences is uncovering better ways to address orthopedic injuries, wound care, pain management, aesthetic medicine, respiratory ailments, cardiovascular indications, ophthalmic issues, and more. Learn more at [www.biolabsciences.net](http://www.biolabsciences.net).

## **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 Poland being critical to the successful rapid recruitment of patients into our landmark ONWARD™ trial, the prospect of opening sites in Poland in the next few weeks, the regulatory authorities recognizing we are targeting an unmet medical need with a drug with the potential to be safe and effective 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 open sites in Poland in the next few weeks, 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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