

Adial Pharmaceuticals and BioLab Sciences **Enter into Distribution Agreement for** **COVID-19 Antibody Tests**

June 8, 2020

Antibody Testing Available for Landmark ONWARD(TM) Pivotal Phase 3 Trial Participants

BioLab Sciences Grants Adial Exclusive Rights to Sell and Distribute Rapid Result COVID-19 Antibody Tests to Designated Channel Partners

CHARLOTTESVILLE, VA / June 8, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW) (“Adial”), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, and BioLab Sciences, Inc. (“BioLab”), a regenerative biotechnology company, which manufactures and sells Rapid Result COVID-19 antibody test kits, announced that they have entered into a Distribution Agreement (the “Agreement”) by which Adial has purchased Rapid Result COVID-19 antibody test kits from BioLab for use in Adial’s landmark ONWARDÔ pivotal Phase 3 clinical trial of its lead drug candidate, AD04, for the treatment of Alcohol Use Disorder (AUD) and BioLab has granted Adial exclusive rights to sell Rapid Result COVID-19 antibody test kits to designated channel partners.

The Rapid Result COVID-19 test is a 10-minute, ‘instant’ point-of-care test device for the qualitative detection of IgG and IgM antibodies specific to 2019-nCoV in human whole blood, serum or plasma specimens. During testing, the specimen reacts with 2019-nCoV antigen coated particles in the test cassette after droplets of blood from the subject are placed on the cassette’s coated membrane.

- The Rapid Result COVID-19 antibody test kits have been registered with the U.S. Food and Drug Administration (“FDA”).

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=653267&lpd=QKO>

- The Rapid Result COVID-19 antibody test kits are marketed and may be used in accordance with FDA policy originally issued on February 29, 2020 and last updated on May 11, 2020.

<https://www.fda.gov/media/135659/download>

- The Rapid Result COVID-19 antibody test kits are 100% USA manufactured.
- The Rapid Result COVID-19 antibody test detects IgG antibodies at a 98.6% accuracy.

IgG antibodies develop in most patients within 7 to 10 days after COVID-19 symptoms begin. IgG antibodies remain in the blood after an infection has passed and indicate that the patient may have had COVID-19 in the recent past and may have developed protective antibodies.

- The Rapid Result COVID-19 antibody test detects IgM antibodies at a 92.9% accuracy.

The IgM antibody is usually the first antibody produced when the virus attacks. A positive IgM test indicates that you may have been infected with COVID-19 and that your immune system has started responding to the virus and you may still be infected or recently recovered from COVID-19.

- The Rapid Result COVID-19 antibody test kits are in wide use globally and are produced for use

by government and distributed for diagnostic use in laboratories or by healthcare workers at point-of-care facilities.

- Millions of Rapid Result COVID-19 antibody test kits have been manufactured and shipped worldwide including to New York City and other COVID-19 epicenters.
- The Rapid Result COVID-19 antibody test kits have received European CE mark Number 146198600 with an effective date of February 18, 2020.

Under the Agreement, Adial secured access to the Rapid Result COVID-19 antibody test kits manufactured by BioLab for use as an indicator of whether subjects participating in clinical trials conducted by Adial have developed the antibodies associated with an immune response to the SARS-Cov-2 virus (i.e., the virus that causes COVID-19). Adial initially purchased 500 Rapid Result COVID-19 antibody tests, which are intended to be used to test subjects enrolled in Adial's landmark ONWARD™ pivotal Phase 3 clinical trial. The Agreement also provides Adial exclusive rights to sell Rapid Result COVID-19 antibody test kits to designated channel partners.

William Stilley, Chief Executive Officer of Adial Pharmaceuticals, commented, "The safety of our clinical trial subjects is of the utmost importance to Adial. In addition to advancing our goal to protect the health of our study subjects, securing access to a large quantity of Rapid Result COVID-19 antibody test kits is expected to allow us to identify people in our studies that potentially have less or greater risk of a COVID-19 infection so that we may potentially tailor visits and other trial activities to maintain the safest environment reasonably possible for our participants. Our plan is to offer the test to each subject enrolled in our landmark ONWARD™ pivotal Phase 3 clinical trial four times during the trial to enhance both safety and trial retention rates. We believe the impact on retention rates due to providing this service to our trial participants could be material."

"BioLab Sciences is pleased to partner with Adial for the distribution of the Rapid Result COVID-19 antibody test kits we manufacture. Our high-quality tests are in high demand as our country continues to reopen and return to work. We are pleased to see the Rapid Result COVID-19 antibody test kits being utilized in such an important Phase 3 trial and we look forward to building a large and important distribution relationship to serve Adial's partners," said Jaime Leija, Co-Founder and Chief Commercialization Officer of BioLab Sciences.

"As part of securing distribution rights for BioLab's state-of-the-art Rapid Result COVID-19 antibody tests, Adial has also secured exclusive rights for the Rapid Result COVID-19 antibody test kits for sale to certain partners that have demand for these tests," continued Mr. Stilley. "While our ONWARDÔ pivotal Phase 3 clinical trial is Adial's primary focus for these antibody tests, in procuring the tests for our trial, we took the decision to leverage our expertise and sales capabilities to make these important tests for a safe return to the workplace and for understanding our community's exposure to the virus more widely available to Adial's channel partners and other qualified purchasers."

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

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.

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 maintaining the safest environment reasonably possible for our participants in our ONWARD™ pivotal Phase 3 clinical trial, offering the test to each subject enrolled in the ONWARD™ pivotal Phase 3 clinical trial four times during the trial, the impact on retention rates due to providing this service to our trial participants, 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 enhance both safety and trial retention rates in our ONWARD™ pivotal Phase 3 clinical trial, 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 Pharmaceutical, Inc.

View source version on accesswire.com:

<https://www.accesswire.com/593109/Adial-Pharmaceuticals-and-BioLab-Sciences-Enter-into-Distribution-Agreement-for-COVID-19-Antibody-Tests>

