Adial Pharmaceuticals Announces COVID-19 Point-of-Care Antibody Test Granted First Ever FDA Emergency Use Authorization for Use with Fingerstick Blood Samples

September 29, 2020

CHARLOTTESVILLE, VA / September 29, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addictions, today announced that the U.S. Food and Drug Administration (FDA) has issued an emergency use authorization (EUA) for the Assure/FaStep® COVID-19 IgG/IgM Rapid Test Device. This marks the first FDA EUA for a serology (antibody) point-of-care (POC) test for COVID-19 using fingerstick blood samples as compared with current approved tests that only utilize serum, plasma, or a venous blood draw. *See* the FDA news release ***here***.

As a result of the FDA's EUA, fingerstick blood samples can now be utilized with the FaStep COVID-19 IgG/IgM Rapid Test Device for the test in POC settings, including doctors' offices, hospitals, urgent care centers, emergency rooms, or other locations where there is a licensed healthcare professional. The FaStep COVID-19 IgG/IgM Rapid Test Device was initially authorized for emergency use in July 2020 to help identify individuals with antibodies to SARS-CoV-2, indicating recent or prior COVID-19 infection, but as with all competing rapid COVID-19 test kits, was not yet authorized for fingerstick blood sample use.

Adial has commenced sales of the FaStep COVID-19 IgG/IgM rapid antibody test kits to healthcare providers and hospitals through The iRemedy Healthcare Companies, Inc. (iRemedy) network and ecommerce platform. *See* ***here***. Antibody test kits distributed by Adial are lateral flow assay, 10-minute, 'instant' point-of-care test devices for the qualitative detection of lgG and lgM antibodies specific to SARS-CoV-2 virus in fingerstick whole blood, venous whole blood, serum, and plasma. During testing, the specimen reacts with antigen coated particles in the test cassette after droplets of blood from the subject are placed on the cassette's coated membrane.

William Stilley, Chief Executive Officer of Adial Pharmaceuticals, commented, "The issuance of the EUA for the first point-of-care antibody test for COVID-19 in the U.S. using fingerstick blood samples is expected to provide an important competitive advantage, which should support more widespread adoption of the Assure/FaStep COVID-19 IgG/IgM Rapid Test Device as a fast, convenient and reliable method for COVID-19 serology testing. We see a market demand for these instant and efficient antibody tests to help combat the international COVID-19 pandemic with the addressable global COVID-19 rapid test kits market expected to reach $3.52 billion by the end of 2020."

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 therapeutic agent for the treatment of Alcohol Use Disorder (AUD) and is currently being investigated in a Phase 3 clinical 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 issuance of the EUA for the first POC Antibody Test for COVID-19 using fingerstick blood providing an important competitive advantage and supporting more widespread adoption of the Assure/FaStep® COVID-19 IgG/IgM Rapid Test Device, the addressable global COVID-19 rapid test kits market reaching $3.52 billion by the end of 2020 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 use the issuance of the EUA for the first POC Antibody Test for COVID-19 using fingerstick blood for competitive advantage and support more widespread adoption of the Assure/FaStep® COVID-19 IgG/IgM Rapid Test Device, our ability to enroll patients and complete 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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