September 25, 2020

Adial Pharmaceuticals Files for Expedited Review of AD04 with the FDA

CHARLOTTESVILLE, VA / ACCESSWIRE / September 25, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addictions, today announced that it has submitted a formal request to the U.S. Food and Drug Administration (FDA) in support of Adial's position that AD04 should be considered eligible for an FDA expedited review program. Adial's lead drug candidate, AD04, is a therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in persons with certain target genotypes and the Company and regulatory advisors have concluded that AD04, which is being developed for a serious condition that is an unmet medical need, is a candidate for this FDA program.

William Stilley, Chief Executive Officer of Adial Pharmaceuticals, stated, "We are making rapid progress enrolling patients in our landmark ONWARD™ pivotal Phase 3 clinical trial of AD04. Sadly, now more than ever, the AUD crisis continues to escalate. As recently reported by the NIAAA, 'the COVID-19 pandemic has increased stress for people worldwide, with millions experiencing prolonged periods of fear, anxiety and social isolation - conditions that are known to increase craving, consumption, and risk of relapse in individuals with alcohol and substance use disorders.' AD04 is designed to address this serious condition for which existing treatment options have low retention rates and potentially inferior safety profiles. Given the significant results of our Phase 2 trial, the progress of our Phase 3 trial, and the gravity of the social and economic impacts of alcohol use disorder, exacerbated by this pandemic, we believe this is the appropriate time to seek FDA expedited review of AD04."

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 AD04 being considered eligible for an FDA expedited review program, this being the appropriate time to seek FDA expedited review of AD04and 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 be granted expedited review by the FDA, 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.

Contact:

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

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