Adial Pharmaceuticals Completes Key Regulatory Milestone Prior to Commencing European Phase 3 Clinical Trial of AD04 for the Treatment of Alcohol Use Disorder

Application for pediatric investigation plan waiver validated by European Medicines Agency

CHARLOTTESVILLE, VA / September 5, 2019 / Adial Pharmaceuticals, Inc. **(NASDAQ: ADIL; ADILW),** a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced that the European Medicines Agency (EMA) has validated the Pediatric Investigation Plan (PIP) waiver application for AD04, the Company's lead investigational new drug product for the treatment of Alcohol Use Disorder (AUD).

William Stilley, CEO of Adial Pharmaceuticals, stated, "We are pleased have our PIP waiver application validated by the European Medicines Agency, as it completes another important step in the process to advance AD04 and apply for marketing approval in Europe. AD04 is designed to reduce cravings for alcohol in subjects with certain target genotypes, without the requirement of abstinence prior to or during treatment. A Phase 2b clinical trial of our drug candidate showed promising results and we are making progress toward the start of our Phase 3 clinical 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 therapeutic agent for the treatment of Alcohol Use Disorder (AUD). 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). The Company plans to commence a Phase 3 clinical trial using AD04 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. 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 plans to commence the first Phase 3 trial of AD04 and the potential of AD04 to treat AUD and 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 commence the Phase 3 clinical trials as expected, the ability to expand the use of AD04 for use in patients with other addictive disorders such as 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, 2018, our subsequent quarterly reports on Form 10-Q and our other 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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