# Adial Pharmaceuticals Announces FDA Reactivation of its Investigational New Drug Application for AD04 in Alcohol Use Disorder

**CHARLOTTESVILLE, VA / October 21, 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 reactivated Adial's U.S. Investigational New Drug (IND) application and lifted the clinical hold from AD04, a genetically-targeted therapeutic agent for the treatment of Alcohol Use Disorder (AUD). The IND had been on clinical hold due to insufficient manufacturing information at the time the IND was inactivated by the Company, which was done while the Company exclusively focused its efforts on the Company's landmark ONWARD™ pivotal Phase 3 clinical trial in Europe. The manufacturing data was developed and submitted to the relevant European regulatory authorities prior to commencing the ONWARD™ trial. However, since the trial was not being conducted in the U.S., the data had not yet been submitted to the FDA.

Reactivation of Adial's IND allows the Company to continue its pursuit of U.S. expedited review programs for AD04 and for the initiation of a planned Phase 1 pharmacokinetics (PK) clinical study in the U.S., which is intended to be supportive of a New Drug Application (NDA) submission with the FDA.

William Stilley, Chief Executive Officer of Adial Pharmaceuticals, commented, "Given the prolonged nature of the COVID-19 pandemic, the AUD crisis continues to escalate. For this reason, we have filed for an expedited review of AD04 with the FDA. The acceptance of our manufacturing data, as well as our plan for the proposed clinical study, marks an important milestone as we progress towards evaluating AD04 clinically in the United States. We continue to enroll patients in our landmark ONWARD™ pivotal Phase 3 clinical trial of AD04 in Europe and look forward to providing further updates as our progress continues."

**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 the Company continuing its pursuit of U.S. expedited review programs for AD04, the initiation of a planned Phase 1 pharmacokinetics (PK) clinical study in the U.S., which is intended to be supportive of a New Drug Application (NDA) submission with the FDA, progression towards evaluating AD04 clinically in the United States 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 commence evaluating AD04 clinicaly in the United States, our ability to advance pursuit of U.S. expedited review programs for AD04 and to initiate a planned Phase 1 pharmacokinetics (PK) clinical study in the U.S, 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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