Adial Pharmaceuticals Receives European Medicines Agency (EMA) Agreement on the Pediatric Investigation Plan (PIP) for AD04 in Alcohol Use Disorder

EMA Agreement paves the way for a marketing authorization in Europe after Phase 3

CHARLOTTESVILLE, VA / July 22, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW) ("Adial"), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, is pleased to report that the European Medicines Agency (EMA) has accepted its Pediatric Investigation Plan (PIP) for development of the Company's lead drug candidate, AD04, for the treatment of Alcohol Use Disorder (AUD) in the pediatric population, ages 12 to 17. The approved PIP does not require additional clinical trials, and all requirements can be accommodated in the current Phase 3 program.

AD04 is under development for the treatment of AUD in persons with certain target genotypes related to the serotonin transporter and receptor genes, and is currently the subject of the landmark ONWARD™ Phase 3 trial that initiated in early 2020. As part of the regulatory process for the registration of new medicines in Europe, pharmaceutical companies are required to provide a PIP outlining their strategy for investigation of the new medicinal product in the pediatric population. An approved PIP is a prerequisite for filing a Marketing Authorization Application (MAA) for a new medicinal product in the European Union.

"We are delighted by this outcome, which we regard as an important milestone for Adial and young patients suffering from AUD," stated Dr. Bankole Johnson, Adial's Chief Medical Officer. "Early alcohol use is associated with more regular and higher levels of alcohol use and dependence in adulthood, along with increased mental health issues and propensity to incur social harms. With a development plan in place for patients aged 12 to 17, Adial should be well-positioned to address this unmet medical need. The EMA's decision to allow Adial to use historical data to inform pediatric dose through modeling and simulation is notable as this mitigates practically any impact on cost and timeline. Acceptance of Adial's PIP paves the way for the Company's potential submission of an MAA in Europe following completion of AD04's ongoing Phase 3 program."

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

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 being well-positioned to address the unmet medical need for patients aged 12 to 17, acceptance of the PIP paving the way for the potential submission of an MAA in Europe following completion of the ongoing Phase 3 program for AD04 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 address the unmet medical need for patients aged 12 to 17, our ability to submit an MAA in Europe following completion of the ongoing Phase 3 program for AD04, 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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