# Adial to File Fast Track Application for AD04 with the FDA

CHARLOTTESVILLE, Va., Feb. 23, 2021 — **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)** ("Adial" or the "Company"), a clinical-stage biopharmaceutical company focused on the development of treatments for addictions, today announced that it will be filing an application for "Fast Track" with the U.S. Food and Drug Administration (FDA) for its lead drug candidate, AD04, which is a therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in persons with certain target genotypes.

Adial previously announced on September 25, 2020, that the Company had submitted a formal request to the FDA in support of Adial's position that AD04 should be considered eligible for an FDA expedited review program. Adial and its regulatory advisors had previously concluded that AD04, which is being developed for a serious condition that is an unmet medical need, is a candidate for this FDA program.

"Adial's correspondence and consultation with the FDA following its expedited review filing in September 2020, leads us to believe that AD04 qualifies for Fast Track consideration," said Adial's Head of Regulatory, Dr. Jack Reich. "I am confident Alcohol Use Disorder qualifies as a serious condition and that there is an unmet medical need, based on our communication with the FDA and as set forth in the FDA's *Guidance for Industry Expedited Programs for Serious Conditions – Drugs and Biologics*."

"We are working with our regulatory counsel to prepare our Fast Track submission after consultation with the FDA," commented Adial's CEO, William Stilley. "Following our submission, the FDA is expected to review the request and make a decision within 60 days."

The FDA's Fast Track is a process designed to facilitate development and expedite the regulatory review of drugs that treat serious conditions and address unmet medical needs with the purpose of getting important drugs to patients earlier. While the FDA judges the seriousness of a condition on a case-by-case basis, the FDA generally considers whether the drug will have an impact on such factors as survival, day-to-day functioning, or the likelihood that the condition, left untreated, will progress to a more serious state. Depression is one such disease that is considered to be a serious condition for Fast Track purposes, and Adial believes that Alcohol Use Disorder will be treated similarly.

When reviewing a Fast Track application where there are available therapies, the Fast Track drug must demonstrate advantages over the available therapy currently approved for the indication in order to be considered as meeting an unmet medical need. Examples of advantages considered by the FDA that Adial believes are applicable to AD04 include: (1) has an effect on a serious outcome of the condition in patients who are unable to tolerate or failed to respond to available therapy; (2) decreases a clinical significant toxicity of an available therapy that is common and causes discontinuation of a treatment; (3) provides safety and efficacy comparable to those of available therapy but has a benefit that is expected to lead to an improvement in serious outcomes; and (4) has the ability to address emerging or anticipated public health need.

**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™ Phase 3 Pivotal 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, and the Company develops adenosine analogs for the treatment of

pain and other disorders. Additional information is available at 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 qualifying for Fast Track consideration, the FDA treating AD04 similarly to depression for Fast Track designation purposes, Alcohol Use Disorder qualifying as a serious condition and being an unmet medical need and the timing of the FDA review and decision process for the Company's Fast Track Designation request 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, to the FDA determining that AD04 qualifies for Fast Track Designation, our ability to enroll patients within the timelines anticipated and complete clinical trials on time and achieve desired results and benefits as expected, 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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