

# Adial Pharmaceuticals Announces Successful Product Retesting of AD04 for Phase 3 Clinical Trial

**CHARLOTTESVILLE, VA / September 11, 2019 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL) (NASDAQ:ADILW)**, a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced that its previously manufactured supply of clinical trial material (CTM), consisting of blister packaged tablets of AD04, was successfully retested. All criteria, including, without limitation, identity testing, content uniformity, assay, impurities, microbial limits, and other tests showed the clinical trial materials have passed review and are within the pre-specified acceptable limits for use in clinical trials. The CTM is intended to be used in the upcoming Phase 3 clinical trial of AD04 as a treatment for alcohol use disorder (AUD) in genetically targeted patients.

William Stilley, CEO of Adial Pharmaceuticals, stated, “We are approaching the start of our Phase 3 trial and are pleased to have completed this important step. Due to the successful retesting, we believe the approximately 52,000 blister packs of clinical trial material that we previously produced will be usable in our Phase 3 clinical trial of AD04 for AUD in biomarker positive patients. Importantly, we have already shipped drug product to Europe for the trial and it is in process for final packaging and labeling. Additionally, the retest data indicated that we have a very stable drug product that will likely achieve a commercial shelf life of five years when we take AD04 to market, assuming regulatory approval.”

## 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](http://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 that the CTM is intended to be used in the upcoming Phase 3 clinical trial of AD04 as a treatment for alcohol use disorder (AUD) in genetically targeted patients, the approximately 52,000 blister packs of clinical trial material that we previously produced will be usable in our Phase 3 clinical trial of AD04 for AUD in biomarker positive patients, the drug product will likely achieve a commercial shelf life of five years when we take AD04 to market, assuming regulatory approval plans to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes 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 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, 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](mailto:dwaldman@crescendo-ir.com)

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