

Adial Completes Final Packaging of AD04 for Shipment to Phase 3 Trial Clinical Sites

October 29, 2019

CHARLOTTESVILLE, VA / October 29, 2019 / Adial Pharmaceuticals, Inc. (“Adial”) (NASDAQ:ADIL)(NASDAQ:ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced that it has completed the final packaging of its lead investigational drug product, AD04 for the treatment of alcohol use disorder (“AUD”), for use in its planned Phase 3 trial of AD04 (the “Trial”). As previously announced, the Company has partnered with Catalent Pharma Solutions, a leading global provider of advanced delivery, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products, to advance clinical activities related to AD04, including packaging and distribution.

Adial recently filed its Clinical Trial Application (CTA) with the Swedish Medical Products Agency to commence the Trial in which Adial expects to enroll 290 subjects across approximately 30 selected clinical sites in Sweden, Finland, Estonia, Latvia, Poland, Bulgaria and Croatia. The Trial is a double-blind, placebo-controlled trial with the primary objective to evaluate the efficacy of AD04 to reduce alcohol consumption in subjects with AUD that are positive for certain genetic biomarkers.

William Stilley, Chief Executive Officer of Adial Pharmaceuticals, commented, “We continue to make steady progress towards commencing our Trial, including the recent submission of our CTA in Sweden, the successful testing of the clinical trial materials, and the contracting of vendors and qualification of clinical sites. Importantly, we now have over 12,000, fully packaged blister packs, including both the placebo and active drug, to supply the Trial. These materials are stored centrally at a Catalent facility in Germany for easy distribution to the clinical sites. Completion of the packaging is another milestone that brings us closer to dosing our first Trial subject.”

“Catalent is pleased to have successfully delivered the clinical trial material for the Phase 3 trial of AD04,” said Paul Hegwood, Catalent’s President of Clinical Supply Services. “We are excited by the prospect of an imminent start of the Trial.”

About Catalent

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable global clinical and commercial product supply. Catalent employs nearly 13,000 people, including approximately 2,400 scientists, at more than 35 facilities, and in fiscal year 2019 generated over \$2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com.

More products. Better treatments. Reliably supplied.™

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 a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes and enroll 290 subjects across approximately 30 selected clinical sites in Sweden, Finland, Estonia, Latvia, Poland, Bulgaria and Croatia, the potential of AD04 to treat AUD 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 and enroll subjects 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.

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