Adial Pharmaceuticals Announces Partnership with Catalent to Package and Distribute Adial's AD04 for its Phase 3 Trial

Charlottesville, VA – February 20, 2019 –Adial Pharmaceuticals, Inc. (NASDAQ:ADIL;ADILW) www.adialpharma.com, a clinical-stage biopharmaceutical company focused on the development of medicines for addiction, today announced a partnership with Catalent Pharma Solutions, a leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products, to advance clinical activities related to AD04, Adial's genetically targeted, lead investigational new drug product for the treatment of alcohol use disorder ("AUD"). This partnership brings together critical capabilities to allow the commencement of Adial's planned initial Phase 3 trial, with Catalent providing packaging and distribution.

Based on the clinical experience to date and publicly available databases, Adial believes the genetic prevalence of genotype-positive AUD patients in the United States is about 33%, or about 11 million people, and that the prevalence in Scandinavia and in certain areas of Eastern Europe may be even higher, with possibly more than 50% being genetically positive for treatment with AD04. The U.S. Food and Drug Administration (FDA) has agreed that the Phase 3 trials of AD04 can proceed with enrolling patients that are genotype positive for this Phase 3 trial.

"The FDA's agreement to allow Adial to structure our Phase 3 trial of AD04 by inclusion of only genotype-positive patients significantly reduces the cost, time and risk as compared with having to enroll patients in the study that are genotype-negative for potential treatment with AD04," commented William Stilley, CEO of Adial Pharmaceuticals.

Adial plans to commence the initial Phase 3 trial of AD04 in Scandinavia and Eastern Europe during the first half of 2019. Adial selected these geographic areas premised on the expected higher prevalence of genotype positive patients, which will help to reduce the cost, time and risk to achieve Phase 3 results.

Catalent has a robust, global network, with the presence in Europe and the U.S. to provide flexible, integrated clinical supply services for investigational medicinal products. Catalent will be responsible for packaging and distributing AD04 to clinical sites. With additional facilities in the Asia/Pacific region and in Latin America, Catalent provides capabilities that should also be important in the future development of AD04, and for the eventual commercial launch of the product, once approved.

"We look forward to continuing our long-term relationship with Catalent, which will provide critical distribution and logistics support for AD04 in our upcoming Phase 3 trial," added Mr. Stilley. "With facilities and personnel servicing Scandinavia and Eastern Europe, Catalent is an ideal partner; we believe that its packaging and logistics expertise and GMP facilities are well equipped to support our planned clinical sites. In addition, Catalent brings broad capabilities in the U.S. and globally, which should be important as we seek to expand our clinical development activities and initiate commercialization promptly upon approval."

“Catalent is pleased to enter this partnership and we look forward to working with Adial as it drives to bring this new drug product to patients for the treatment of alcohol use disorder,” said Paul Hegwood, Catalent’s President of Clinical Supply Services.

About Catalent

Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products. With more than 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs over 11,000 people, including over 1,800 scientists, at more than 30 facilities across five continents, and in fiscal 2018 generated approximately $2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com.

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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. These statements are based upon current beliefs, expectations and assumptions and include statements regarding commencing Phase a 3 clinical trial in the first half of 2019, the expected reduction of cost, time and risk by conducting the Phase 3 trial in Scandinavia and Eastern Europe, the size of the market, the expected benefit AD04 will bring to patients and the expected contribution of Catalent. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, our ability commence the Phase 3 clinical trials in the first half of 2019, our ability to reduce the cost, time and risk to achieve Phase 3 results, the expected contribution of Catalent to helping us expand our clinical

development activities and seek to initiate commercialization, 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 that we have filed with the SEC. 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
Tel: +1 212-671-1021

Email: dwaldman@crescendo-ir.com

Catalent Pharma Solutions
Chris Halling
+44 (0)7580 041073

chris.halling@catalent.com

Richard Kerns
+44 (0)161 728 5880
richard@nepr.eu