

Adial Pharmaceuticals and Tedor Pharma Announce Collaboration to Manufacture AD04 Through Commercialization

Adial Reaffirms on Track to Commence Phase 3 Trial in Q3 2019

CHARLOTTESVILLE, VA / June 6, 2019 / Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)

www.adialpharma.com, a clinical-stage biopharmaceutical company focused on the development of medicines for addiction, and Tedor Pharma, Inc., a full-service contract development and manufacturing organization (CDMO), today announced that they entered into a collaboration agreement to provide cGMP contract manufacturing services for AD04, a genetically targeted therapeutic agent for the treatment of Alcohol Use Disorder (AUD).

Adial is on track to commence its first Phase 3 trial of AD04 next quarter and plans to conduct that trial using its current inventory of drug product. The engagement with Tedor is expected to provide Adial with a qualified manufacturing partner for any further developmental requirements and for commercialization of AD04 upon approval.

William Stilley, President and Chief Executive Officer of Adial Pharmaceuticals, stated, "We are pleased to announce our collaboration with Tedor to manufacture AD04 tablets. This should allow us to continue performing against our strategic plan, and Tedor has the capabilities to support commercial sales of AD04 once it is approved. In the U.S. alone, we estimate there are over 10 million Americans with the target genotypes for AD04 and over 15 million Europeans. For this reason, we need a contract manufacturer with the resources and ability to rapidly scale manufacturing in order to meet the anticipated global demand, and Tedor is well-suited for this role."

"We are delighted to partner with Adial to provide CDMO services for AD04," commented Doug Drysdale, President and CEO of Tedor Pharma. "AD04 can be easily and efficiently manufactured at large scale to the U.S. Food and Drug Administration and the European Medicines Agency standards, with high consistency and a long-expected shelf life, which make it well suited for both the clinical trials and mass commercialization."

About Tedor Pharma, Inc.

Tedor Pharma is a specialized Contract Development and Manufacturing Organization with a strong track record of success in developing and manufacturing solid dose products, including DEA-scheduled products, for life science customers. Tedor is a full-service, end-to-end, contract development and manufacturing organization (CDMO) founded in 2001 that operates a 40,000 square foot cGMP solid dose production facility with 14 production ready manufacturing suites. Over the past 18 years, Tedor has helped customers meet their project timelines, achieve regulatory approvals and solve many formulation challenges from development through to large-scale manufacturing.

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 commencing the first Phase 3 trial of AD04 next quarter, the use of current inventory for the first Phase 3 trial, the ability to produce AD04 drug product that has high consistency and a long shelf life, performing against our strategic plan 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. 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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