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# Adial Pharmaceuticals Announces Amendment to License Agreement with the University of Virginia Licensing & Ventures Group

CHARLOTTESVILLE, Va., Dec. 19, 2018 (GLOBE NEWSWIRE) -- **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)**, [www.adialpharma.com](http://www.adialpharma.com), a clinical-stage biopharmaceutical company focused on the development of medicines for addiction, today announced that it has amended its license agreement with the University of Virginia Patent Foundation, d/b/a the University of Virginia Licensing & Ventures Group (UVA LVG). Pursuant to the amendment, Adial must commence its Phase 3 clinical trial of AD04 for the treatment of Alcohol Use Disorder (AUD) in 2019. Adial has previously announced that it plans to begin its Phase 3 clinical trial of AD04 in the first half of 2019.

The University of Virginia Licensing & Ventures Group partners with faculty, entrepreneurs, and investors to bring innovations discovered at the University of Virginia (UVA) into the marketplace.

When Adial Chairman Dr. Bankole A. Johnson, internationally recognized for his addiction research, was the Chairman of the University of Virginia's Department of Psychiatry and Neurobehavioral Sciences, 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). There were no overt safety concerns with the trial (there were no statistically significant serious adverse events reported).

The license agreement with the UVA LVG grants Adial exclusive, worldwide and perpetual rights to the intellectual property underlying and protecting AD04, including without limitation, patents issued in 44 jurisdictions that are expected to provide market exclusivity for AD04. Under the license agreement, Adial will pay a total of \$1,450,000 in development and approval milestones (\$175,000 in development milestones, \$275,000 upon acceptance by the FDA of a new drug application, and \$1,000,000 upon approval for sale of AD04 in the U.S., Europe or Japan), a royalty on sales of AD04 of up to 2% with a minimum annual royalty of \$40,000, and 15% of any sub-licensing revenue received from third-party sublicensees.

"We appreciate the continued support of the University of Virginia Licensing & Ventures Group, which is part of a premier university and technology innovation center," commented William Stille, CEO of Adial Pharmaceuticals. "This latest amendment follows a series of important milestones leading up to the formal launch of our Phase 3 trial, including selection of a leading contract research organization (CRO), appointment of renowned Professor Alho as Principal Investigator, and the launch of our Scientific Advisory Board."

## **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). 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.

## **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 3 clinical trials in the first half of 2019, the expected benefit AD04 will bring to patients, the continued support of the UVA LVG, the expected exclusivity to be provided by the licensed patents and the belief that AD04 has the potential 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, the ability to commence the Phase 3 clinical trials in the first half of 2019, 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 registration statement on Form S-1 that we have filed with the SEC and the final prospectus and our Current Report on Form 10-Q for the quarter ended September 30, 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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