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Adial Pharmaceuticals Engages CRO to Begin Phase 3 Clinical Trials of AD04 for the Treatment of Alcohol Use Disorder

CHARLOTTESVILLE, Va., Nov. 19, 2018 (GLOBE NEWSWIRE) -- **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)**, a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, and Crown CRO ("Crown"), a contract research organization based in Finland, today announced Crown's engagement to manage Adial's Phase 3 clinical trial for AD04 for the treatment of alcohol use disorder (AUD). The FDA approved protocol for this Phase 3 clinical trial is a 24-week trial with 290 patients in 30 clinical sites in 5 European countries.

William Stilley, CEO of Adial Pharmaceuticals, stated, "We are excited to begin our Phase 3 clinical trial of AD04 in the first half of 2019, and look forward to partnering with Crown following an extensive selection process and the completion of their feasibility studies. Partnering with Crown allows us to leverage their broad experience, as well as their understanding of local regulatory processes combined with a wide network of investigators and key opinion leaders. The strength of the Phase 2 results, which showed a reduction in frequency of drinking, quantity of drinking and heavy drinking (all with statistical significance) and no overt safety concerns, allows us to keep the trial at a manageable size and should reduce the time and costs associated with Phase 3 clinical trials."

Tarja Leikas, Chief Executive Officer of Crown CRO, further noted, "We are honored to have been selected by Adial to help oversee this important trial. The alcohol addiction market is dramatically underserved with very limited and often ineffective options for patients. Over 55 million people are afflicted with this disease in Europe alone. Given the prevalence of alcohol use disorder and the targeted genotype for AD04, we expect to be able to leverage our geographic expertise, especially within Scandinavia and Eastern Europe, to rapidly enroll patients while effectively managing costs."

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 candidate, 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.

About Crown CRO

Crown CRO is a privately owned Finnish contract research organization founded in 2005. Our headquarters is in Espoo, which is located in Finland's capital city region. Crown CRO provides full service clinical operations or any services related to clinical operations. Crown CRO provides services in the pharmaceutical, biotechnology, functional food and medical device sectors, as well as to other contract research organizations. Our services also cover quality assurance, pharmacovigilance, regulatory, and translation services. We have been involved in over 900 clinical studies in more than 18 countries in various therapeutic areas and in all phases of clinical development. We currently have 100 active clinical trials ongoing. Our vast experience enables us to serve our customers in coordinating trials from early phases up to late phase and real-world studies with high quality data and on time delivery within budget.

About Alcohol Use Disorder

According to an article in the widely respected publication *The Lancet*, alcohol is the number one cause of death globally among both men and women ages 15 to 49 years. In the United States alone, approximately 35 million people have AUD resulting in significant health, social and financial costs (NIAAA Alcohol Facts & Statistics). AUD contributes to over 200 different diseases, and 10% of children live with a person that has an alcohol problem. According to the American Society of Clinical Oncologists, 5-6% of new cancers and cancer deaths globally are directly attributable to alcohol. The Centers for Disease Control (CDC) has reported that AUD costs the U.S. economy about \$250 billion annually, with heavy drinking accounting for greater than 75% of the social and health related costs. In addition, according to the NIAAA, the problem in the United States appears to be growing with an approximately 50% increase in AUD prevalence between 2002 and 2013.

Despite the high prevalence and high costs, according to an article in the JAMA 2015 publication, only 7.7% of patients (i.e., approximately 2.7 million people) with AUD are estimated to have been treated in any way and only 3.6% by a physician (i.e., approximately 1.3 million people). The most common treatments for AUD are directed at achieving abstinence and typical treatments include psychological and social interventions. Most therapies require abstinence even prior to initiating therapy. Abstinence requires dramatic lifestyle changes often with serious work and social consequences. Significant side effects of current pharmacologic therapies include mental side effects such as psychiatric disorders and depressive symptoms and physical side effects such as nausea, dizziness, vomiting, abdominal pain, arthritis and joint fitness. These problems with the currently available therapies appear to limit the willingness of people with AUD to seek treatment and then to limit compliance with treatment requirements and, therefore, the ultimate results for many people attempting currently available therapies.

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 leveraging Crown CRO’s experience, as well as their understanding of local regulatory processes and network of investigators and key opinion leaders, the strength of the Phase 2 results allowing us to keep the Phase 3 trial at a manageable size reducing the time and costs associated with Phase 3 clinical trials, leveraging Crown CRO’s geographic expertise, especially within Scandinavia and Eastern Europe, in order to rapidly enroll patients while effectively managing costs and plans to commence a Phase 3 clinical trial in the first half of 2019 using AD04 for the potential treatment of AUD in subjects with certain target genotypes. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, our ability to leverage Crown CRO’s experience, understanding of local regulatory processes and network of investigators and key opinion leaders, our ability to commence the Phase 3 clinical trial in the first half of 2019 and reduce the time and costs associated with the Phase 3 clinical trial of AD04, our ability to leverage Crown CRO’s geographic expertise to rapidly enroll patients while effectively managing costs, the ability of AD04 therapy to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, our 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 manufacture AD04 through a process and at a scale to support a commercial product, 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 our 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 statements included in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 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 / Natalya Rudman

Tel: 212-671-1021

Email: dwaldman@crescendo-ir.com



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