# Adial Pharmaceuticals Establishes Scientific Advisory Board and Appoints Global Thought Leader in the Field of Alcohol Use Disorder

CHARLOTTESVILLE, Va., Nov. 29, 2018 — Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW), <a href="https://www.adialpharma.com">www.adialpharma.com</a>, a clinical-stage biopharmaceutical company focused on the development of a therapeutic agent for the treatment of alcohol use disorder, today announced that it has established a Scientific Advisory Board (SAB) and has appointed Dr. Giovanni Addolorato, a leading global expert in the field of alcohol use disorder (AUD), as its first member and Chairperson. The SAB will help to guide the Company's strategy and advance AD04, its lead therapeutic agent for AUD, with Phase 3 trials expected to commence in the first half of 2019.

Dr. Addolorato is a professor of Gastroenterology and Hepatology at the Department of Gastroenterology and Endocrino-Metabolic Sciences at the Catholic University of Rome. He is also the Director of the "Alcohol Use Disorder and Alcohol Related Disease" Unit at the Catholic University of Rome, and is a senior consultant of Internal Medicine, Gastroenterology and Liver Diseases at the Catholic University of Rome. He has published more than 600 publications on pharmacology and neurobiology of alcohol use disorders including therapeutics and treatment, and alcohol liver disease. More than 220 of his publications have been included in peer reviewed journals and have been featured in Lancet, Molecular Psychiatry, Journal of Hepatology, American Journal of Medicine, American Journal of Clinical Nutrition, American Journal of Gastroenterology, Journal of Internal Medicine, Alcoholism: Clinical and Experimental Research. He is an associate Editor of "Alcologia: European Journal of Alcohol Studies" and a is member of several Editorial Boards including, "World Journal of Gastroenterology", "Alcohol & Alcoholism", "European Addiction Research", "Journal of Addiction", "Journal of Alcoholism and Drug Dependence" and "World Journal of Hepatology." He has lectured at numerous international meetings and has received several prizes for his work. Since 2006, Dr. Addolorato has been a member of the European Research Advisory Board (ERAB). Since 2009, he has also been a member of the National Anti-Drugs Commission of the Department for Anti-Drug Policies, Office of the Government of Italy.

Dr. Addolorato commented, "I am delighted to join Adial Pharmaceuticals' SAB given the overwhelming market need for effective alcohol use disorder treatment and Adial's encouraging Phase 2b data, which also showed a strong safety profile without the negative side effects of current drugs on the market. I look forward to supporting the ongoing development AD04, which is designed to reduce cravings without the requirement of abstinence prior to or during treatment."

William Stilley, CEO of Adial Pharmaceuticals, stated, "We are pleased to officially launch our new Scientific Advisory Board to support the development efforts of AD04, our lead product candidate. We welcome Dr. Addolorato as the first member of our SAB, as he brings tremendous knowledge and experience in AUD and is expected to play an integral role as we prepare to begin our Phase 3 clinical trial."

#### 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.

### **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 forwardlooking 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 and the expected role Dr. Addolorato will play in connection with the Phase 3 clinical trial. 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, 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 contribution of Dr. Addolorato to advancing our Phase 3 clinical trial of AD04, 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. 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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