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# Adial Pharmaceuticals Appoints Leading Addiction Specialist to its Scientific Advisory Board to Advance AD04 and Combat Alcohol Use Disorder

***Distinguished Professor Markus Heilig joins an accomplished assemblage of addiction specialists including Dr. Giovanni Addolorato and Professors Hannu Alho, Tomas Zima and Sebastian Mueller***

CHARLOTTESVILLE, Va., Feb. 12, 2019 (GLOBE NEWSWIRE) -- **Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW)** http://www.adialpharma.com/, a clinical-stage biopharmaceutical company focused on the development of medicines for addiction, today announced that it has appointed Professor Markus Heilig, MD, PhD as a Scientific Advisory Board (SAB) member. The SAB is charged with helping 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.

Professor Markus Heilig, MD, PhD, is a founding director of the Center for Social and Affective Neuroscience at Linköping Univ, in a joint initiative of the Swedish Research Council, the University and the Region. Professor Heilig received his MD and PhD from Lund University, Sweden, 1986 and 1989, respectively, and was a post-doc at The Scripps Research Institute, La Jolla, CA 1990 - 1992. Upon returning to Sweden and completing clinical training in psychiatry, he served at the Karolinska Institute, Stockholm, Sweden, in various clinical and academic leadership capacities until 2004. Between 2004 – 2015, he was the chief of intramural clinical and translational research at the U.S. National Institute on Alcohol Abuse and Alcoholism.

Heilig's research is centered on regulation of negative effect, as it applies to anxiety, addictive and affective disorders. He has published more than 250 peer reviewed papers, including in leading journals such as Science, Lancet, PNAS and others. Current efforts in the Heilig lab are focused on identifying novel mechanisms for pharmacotherapy of addiction, and developing these from target discovery and validation to human proof-of-concept trials. Currently pursued targets include systems involved in stress, and negative effect such as neurokinins, nociceptin, glutamate and cannabinoids. Recently, his laboratory has expanded the scope of its research to incorporate the neurobiology of choosing between alcohol and natural rewards, and how social factors influence these behaviors.

Professor Heilig commented, "I am honored to have the opportunity to join Adial Pharmaceuticals' Scientific Advisory Board. Alcohol use disorder is a global epidemic and I look forward to supporting the development of AD04 that should provide a viable option for patients with the targeted genotype, versus the limited and often ineffective options currently

available in the marketplace today. There is a pent-up demand for a therapeutic agent that can help patients reduce or perhaps eliminate cravings for alcohol altogether through a simple and tolerable oral formulation and I believe AD04 will be a safe and effective solution."

William Stilley, CEO of Adial Pharmaceuticals, stated, "We continue to assemble the strongest possible team of dedicated experts to help guide our efforts. We have world class doctors on our SAB and we intend to rely on their expertise and guidance to develop AD04 and take it through Phase 3 clinical trials."

**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 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, providing more viable options for patients with the targeted genotype, the expected benefit AD04 will bring to patients and the expected contribution of our SAB 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 our SAB in 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 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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