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Adial Pharmaceuticals Announces Research Collaboration with the Medical College of Wisconsin to Advance Purnovate's Adenosine Compounds as Potential Treatments for Diabetes and NASH

CHARLOTTESVILLE, Va., May 19, 2022 (GLOBE NEWSWIRE) -- **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)** ("Adial" or the "Company"), today announced that Purnovate, Inc., an Adial company focused on developing novel molecules targeting the adenosine receptors for the treatment of major unmet medical needs, has entered into a research collaboration with the Medical College of Wisconsin, a leading medical school, and Dr. John Auchampach, PhD, Professor and Vice Chair of the Department of Pharmacology and Toxicology. The goal of the collaboration is to further evaluate the Company's proprietary adenosine analogs as potential treatments for diabetes and non-alcoholic steatohepatitis (NASH). NASH is the most severe form of non-alcoholic fatty liver disease involving liver inflammation (hepatitis) that can lead to life-threatening cardiovascular co-morbidities.

Under the agreement, Dr. Auchampach and his team will test Purnovate's adenosine compounds in preclinical models with the goal of further validating the potential of Purnovate's compounds as a treatment for diabetes and NASH.

Dr. Auchampach stated, "Based on our preliminary data in models of glucose control, we are optimistic that our study will demonstrate that animals receiving Purnovate's selective, potent, and soluble adenosine analogs will have reduced whole-body and hepatic fat content following high fat feeding, as well as more normalized glucose levels. We are excited to collaborate with Adial on this program to potentially develop breakthrough therapies."

Dr. Julien Dimastromatteo, Purnovate's Vice President, Research, commented, "We are honored to partner with the Medical College of Wisconsin and Dr. Auchampach, a leading researcher in the field of adenosine, purinergic pharmacology and G-Protein-Coupled receptors. Adenosine analogs have been studied extensively by Dr. Auchampach and others, demonstrating tremendous promise in animal models. However poor biodistribution of historical compounds, likely due to poor solubility, has limited their usefulness as human therapies. Our Purnovate adenosine analog compounds were specifically designed to overcome these solubility and biodistribution challenges, with strong supporting data thus far. As a result, we are encouraged by the therapeutic potential of these compounds and will work to rapidly identify a lead compound to bring forward as a drug candidate."

William Stilley, Adial's Chief Executive Officer, stated, "There is a significant unmet medical need for a safe, oral therapy to reduce overall body mass and liver fat content, as well as restore healthier glucose levels. The global NASH market alone is projected to reach over $54 billion by 2027 and is expected to grow at a 58.6% CAGR; and yet, there are currently no FDA-approved drugs that specifically target NASH. Moreover, we believe these compounds hold significant potential as an alternative or adjunct therapy for diabetics, pre-diabetics and overweight individuals."

About the Medical College of Wisconsin

With a history dating back to 1893, The Medical College of Wisconsin is dedicated to leadership and excellence in education, patient care, research and community engagement. More than 1,500 students are enrolled in MCW's medical school and graduate school programs in Milwaukee, Green Bay, and Central Wisconsin. MCW's School of Pharmacy opened in 2017. A major national research center, MCW is the largest research institution in the Milwaukee metro area and second largest in Wisconsin. In the last 10 years, faculty received more than $1.5 billion in external support for research, teaching, training and related purposes. This total includes highly competitive research and training awards from the National Institutes of Health (NIH). Annually, MCW faculty direct or collaborate on more than 3,100 research studies, including clinical trials. Additionally, more than 1,650 physicians provide care in virtually every specialty of medicine for more than 2.8 million patients annually.

About Purnovate, Inc.

Purnovate, Inc., a wholly owned subsidiary of Adial Pharmaceuticals, Inc., is a pharmaceutical development and chemistry company focused on inventing and developing selective, potent, stable, and soluble adenosine analogs to treat diseases and disorders such as pain, asthma, wound/burn healing, inflammation, infectious disease, cancer, diabetes and non-alcoholic steatohepatitis (NASH).

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, serotonin-3 receptor antagonist, therapeutic agent for the treatment of Alcohol Use Disorder (AUD) and is currently being investigated in the Company's landmark ONWARD™ pivotal Phase 3 clinical trial 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. 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). AD04 is also believed to have the potential to treat other addictive disorders such as Opioid Use Disorder, gambling, and obesity. The Company is also developing adenosine analogs for the treatment of pain and other disorders through its wholly owned subsidiary, Purnovate, Inc. Additional information is available at 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 testing Purnovate's adenosine compounds in non-clinical models further validating the potential of Purnovate's compounds as a treatment for diabetes and NASH, the study demonstrating that animals receiving Purnovate's adenosine analogs will have reduced whole-body and hepatic fat content following high fat feeding, as well as more normalized glucose levels, The Medical College of Wisconsin collaborating with the Company to develop breakthrough therapies, Purnovate's adenosine analog compounds overcoming solubility and biodistribution challenges, the Company identifying a lead compound to bring forward as a drug candidate, the global NASH market alone reaching over $54 billion by 2027 and growing at a 58.6% CAGR, the adenosine compounds holding significant potential as an alternative or adjunct therapy for diabetics, pre-diabetics and overweight individuals and the potential of AD04 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, our ability to further validate the potential of Purnovate's compounds as a treatment for diabetes and NASH, our ability to demonstrate that animals receiving Purnovate's adenosine analogs will have reduced whole-body and hepatic fat content following high fat feeding, as well as more normalized glucose levels, the ability of Purnovate's adenosine analog compounds to overcome solubility and biodistribution challenges, our ability to identify a lead compound to bring forward as a drug candidate, our ability to validate the potential of adenosine compounds as an alternative or adjunct therapy for diabetics, pre-diabetics and overweight individuals, our ability to complete clinical trials on time and achieve desired results and benefits as expected, 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 our product candidates in the marketplace and the successful development, marketing or sale of our 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, 2021, subsequent Quarterly Reports on Form 10-Q and current reports on Form 8-K filed with the Securities and Exchange Commission. 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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