July 14, 2021

Adial Announces Positive Pre-Clinical Data for its Adenosine Pain Platform

Data merits further testing for pain reduction as a possible alternative to opioids

Validation of Purnovate acquisition

CHARLOTTESVILLE, Va., July 14, 2021 (GLOBE NEWSWIRE) -- **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)**, a clinical-stage biopharmaceutical company focused on the development of treatments for addictions, today announced advancements related to its adenosine analog development platform being developed by Purnovate, Inc., a division of Adial Pharmaceuticals, Inc.

Key highlights:

- Compounds have been developed that are potent against specifically targeted adenosine receptors while being selective over the adenosine A1 receptor, which is known to have cardiovascular and central nervous system effects that can be problematic for many therapeutic indications. Historically, when selectivity has been achieved over the A1 receptor, water solubility has decreased, making effective tissue distribution in the human body (made largely of water) difficult to achieve and the compounds difficult or impossible to develop as drugs.
- Solubility more than 50 times greater than other known selective adenosine compounds of the same class has been demonstrated.
- Testing to date indicates good oral bioavailability so that oral administration (e.g., tablets) is likely to be one of the options for dosing these compounds.
- Initial animal studies indicate the compounds to be pharmacologically active.
- Multiple compounds have demonstrated a meaningful *in vivo* reduction in pain (rodents).
- All tested compounds appear synergistic with morphine.
- Certain compounds with higher solubility appear synergistic with acetaminophen (Tylenol).
- *In vivo* studies suggest that certain compounds may have effects against insulin insensitivity, which makes them potential candidates for licensing or partnership.
- Purnovate is establishing relationships to test its compounds in models of asthma, cancer, and inflammation, also with the intent of licensing products that show initial success or advancing partnerships.

Dr. Robert D. Thompson, Adial's Vice President, Chemistry, commented, "We are highly encouraged by the latest preclinical data related to our adenosine platform as a potential therapy for pain relief. Based on these data, we are proceeding with development of our compounds to determine if they may have broad implications as a replacement therapy for opioids or, when used in combination, as a way to support lower dose administration of

opioids. Importantly, our latest solubility data may be the key to unlocking the potential of adenosine analogs as a therapy. Specifically, while adenosine analogs have been studied extensively over the past five decades, poor solubility has limited the usefulness of this class of compounds as drugs. We believe our proprietary chemistry and solubility technology may also allow for effective oral administration of these compounds, and that our assessment is further supported by the data. Also noteworthy, we studied our adenosine compounds in combination with Tylenol and demonstrated enhanced pain reduction and duration of pain relief *in vivo*."

William Stilley, Adial's Chief Executive Officer, commented, "We believe there may be a number of potential lead compounds in the current inventory of novel chemical entities further bolstered by patent applications. Our unique chemistry and solubility technology may provide a broad, novel and patentable approach that could firmly establish our position as a leader in the field of pain management. We have also identified other potential physiological benefits, including increased insulin sensitivity, which could result in licensing or partnership opportunities. We are excited to advance these programs and view this latest data as a strong validation of our Purnovate acquisition, which we believe helps further advance our goal of becoming the leading biopharmaceutical company in the addiction space. Our mission is not only treating addiction, but addressing the root causes of addiction, including the systemic overuse of opioids, which has contributed to the current addiction pandemic."

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. Purnovate, Inc., a division of Adial Pharmaceuticals, is developing adenosine analogs for the treatment of pain and other disorders. Additional information is available at www.adialpharma.com.

About the Landmark ONWARD™ Pivotal Phase 3 Clinical Trial

The ONWARD trial is a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel group, Phase 3 clinical study to evaluate the efficacy, safety and tolerability of AD04 in patients with Alcohol Use Disorder (AUD) and selected polymorphisms in the serotonin transporter and receptor genes. Patients are genetically screened prior to enrollment in the ONWARD trial so that only genetically positive patients are enrolled. The primary endpoint for analysis of efficacy is the change from baseline in the monthly number of heavy drinking days during the last 8 weeks of the 24-week treatment period. ONWARD is currently being conducted in 25 clinical sites in seven countries in Scandinavia and Central and Eastern Europe (Sweden, Finland, Poland, Latvia, Estonia, Bulgaria and Croatia). The principal investigator is Professor Hannu E.R. Alho, Emeritus Professor of Addiction Medicine at the

University of Helsinki.

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 establishing relationships to test Purnovate's adenosine compounds in models of asthma, cancer and inflammation, exploring if the compounds have broad implications as a replacement therapy for opioids or, when used in combination, as a way to support lower dose administration of opioids, the latest solubility data being the key to unlocking the potential of adenosine analogs as a therapy, Purnovate's proprietary chemistry and solubility technology allowing for effective oral administration of adenosine analog compounds, a number of potential lead compounds in the current inventory of novel chemical entities being further bolstered by patent applications, Purnovate's chemistry and solubility technology, together with the potential for combination therapies, providing a broad, novel and patentable approach and firmly establishing Purnovate's position in the field of pain management, other unique potential physiological benefits, including increased insulin sensitivity, resulting in licensing or partnership opportunities, the Purnovate acquisition further advancing the Company's goal of becoming the leading biopharmaceutical company in the addiction space 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 establish relationships to test Purnovate's adenosine compounds in models of asthma, cancer and inflammation, our ability to demonstrate that the compounds have broad implications as a replacement therapy for opioids or, when used in combination, as a way to support lower dose administration of opioids, our ability to unlock the potential of adenosine analogs as a therapy, our ability to provide for effective oral administration of adenosine analog compounds, our ability to further bolster potential lead compounds in the current inventory of novel chemical entities by patent applications, our ability to provide a broad, novel and patentable approach using Purnovate's chemistry and solubility technology, together with the potential for combination therapies, our ability to establish Purnovate's position in the field of pain management, our ability to create licensing or partnership opportunities for other unique potential physiological benefits, including increased insulin sensitivity, pur ability to advance the Company's goal of becoming the leading biopharmaceutical company in the addiction space, our ability to enroll patients within the timelines anticipated and 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 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 Annual Report on Form 10-K for the year ended December 31, 2020, 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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Source: Adial Pharmaceuticals, Inc