Adial Announces Positive Pre-Clinical Data for Purnovate's PNV-5030 as Drug Candidate for the Treatment of Pain

Results suggest potential of PNV-5030 as both a standalone and combination therapy to reduce or eliminate opioid use and achieve meaningful pain reduction

Clinical trial expected to commence in 2022

CHARLOTTESVILLE, Va., Oct. 21, 2021 — **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)**, a clinical-stage biopharmaceutical company focused on developing therapies for the treatment and prevention of addiction and related disorders, today announced positive data in a pre-clinical model of pain reduction. Based on this positive data, Purnovate, Inc., a wholly owned subsidiary of Adial Pharmaceuticals, Inc., has selected PNV-5030 as the lead compound for its program to develop a drug for the treatment of pain.

PNV-5030 has been tested to be more than 1000-fold selective over the adenosine A1 receptor, which is known to have cardiovascular and central nervous system effects across several 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. However, PNV-5030 has demonstrated solubility more than 50 times greater than other known selective adenosine compounds of the same class. Solubility is often an important characteristic of successful drug candidates, and Purnovate believes solubility is a particularly important characteristic in determining the drug development potential of molecules of this class.

In the most recent study, PNV-5030 was tested in a mouse model of somatic nociceptive pain where discomfort was initiated using a laser focused on the mouse's tail, with the time before the mouse flicked its tail away being measured by a sensor. Response groups of 12 mice were analyzed with a control group receiving vehicle alone (i.e., liquid dosing solution without any drug) and other groups receiving either 1mg/kg or 2mg/kg doses of morphine, a common opioid pain relief medication, alone; PNV-5030 alone; or morphine plus PNV-5030.

PNV-5030 alone exhibited a significant pain reduction as compared to the control group and a similar effect to 1mg/kg morphine. Importantly, PNV-5030 demonstrated a significant effect when administered with 1 mg/kg morphine as compared to administering 1 mg/kg morphine alone. Interestingly, when combined with 1 mg/kg morphine, PNV-5030 achieved a similar level of pain reduction to the reduction obtained with 2mg/kg morphine. These results could indicate the possibility of lowering the opioid dose to achieve a similar pain reduction level by combining an opioid with PNV-5030 or even eliminating the use of an opioid for pain relief in favor of a higher dose of PNV-5030.

Notably, certain mice in both the PNV-5030 plus morphine groups achieved results at the maximum time allowed under the study (15 seconds), and, therefore, may have shown even greater pain reduction results had the protocol allowed continuation of the test beyond the time limit. The data are shown in the following chart:

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/4ea7515c-ad4d-446b-9a51-52d0807c87fa

Dr. Julien Dimastromatteo, Purnovate's Vice President, Research, commented, "We are highly encouraged by what we consider to be robust pre-clinical data demonstrating that PNV-5030 should be advanced as a drug candidate for treating somatic nociceptive pain. We have conducted an additional battery of both *in vitro* and *in vivo* screening and believe that PNV-5030 has the characteristics to successfully complete the required toxicity and toxicology studies to allow us to proceed with testing in humans. With our lead compound selection made, we expect to efficiently advance PNV-5030 into clinical trials in 2022."

William Stilley, Adial's Chief Executive Officer, stated, "The Purnovate adenosine platform continues to exceed

expectations, and PNV-5030's success in an oral model of pain, after demonstrating pain reduction effects when administered interperitoneally, is a validation of our belief that the platform has the ability to underpin a drug development program addressing pain and a number of other prevalent ailments such as diabetes, asthma, cancer, Parkinson's Disease, inflammatory bowel disease, and infectious diseases where a cytokine storm is a significant contributing factor, including COVID-19. We are highly encouraged by this data, which suggests PNV-5030 may help reduce the need for morphine and perhaps other opioids when used as either a standalone or combination therapy or eliminate the need for the use of an opioid altogether."

About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on developing therapies for the treatment and prevention of addiction and related disorders. 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. Additional information is available at www.adialpharma.com.

About Purnovate, Inc.

Purnovate, Inc., a wholly owned subsidiary of Adial Pharmaceuticals, 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, cocaine addiction, inflammation, infectious disease, cancer, asthma, and diabetes. Additional information is available at www.purnovate.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 solubility being a particularly important characteristic in determining the drug development potential of this class of adenosine compounds, PNV-5030 having the characteristics to successfully complete the required toxicity and toxicology studies to allow the Company to proceed with testing in humans, advancing PNV-5030 into clinical testing in 2022, the Purnovate adenosine platform having the ability to underpin a drug development program addressing pain and a number of other prevalent ailments such as diabetes, asthma, cancer, Parkinson's Disease, inflammatory bowel disease, and infectious diseases where a cytokine storm is a significant contributing factor, including COVID-19 , 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 provide for effective oral administration of adenosine analog compounds, our ability to successfully complete the required toxicity and toxicology studies to allow us to proceed with testing in humans and, advancing PNV-5030 into

clinical trials in 2022 , our ability to demonstrate that PNV-5030 has 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 addressing pain and other prevalent ailments where a cytokine storm is a significant contributing factor, 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 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 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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