Adial Pharmaceuticals Announces Positive Pre-Clinical Data for PNV2 as a Drug Candidate for Triple Negative Breast Cancer

PNV2 demonstrates reduction of metastases in animal model

CHARLOTTESVILLE, Va., Nov. 29, 2021 — **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)** ("Adial" or the "Company"), a clinical-stage biopharmaceutical company focused on developing therapies for the treatment and prevention of addiction and related disorders, today announced positive pre-clinical data for PNV2 in an animal model of triple negative breast cancer (TNBC). Based on the strength of this data, Purnovate, Inc., a wholly owned subsidiary of Adial Pharmaceuticals, Inc., plans to advance PNV2 as the lead compound for its cancer program.

PNV2 was tested in a metastatic breast cancer model with the primary endpoint being the amount of cancer metastases into the lungs after 28 days following orthotopic implantation of breast cancer.

Study highlights:

- Luciferase-engineered triple-negative breast cancer (TNBC) cells MDA-MB-231 were implanted in the mammary fat pad in female mice.
- Tumors grew over 28 days and were treated intratumorally three times a week.
- An active group (n=10) was treated with PNV2 in solution and a control group (n=10) was treated with only the solution.
- Metastasis into the lungs was then determined by measuring the amount of luciferase activity, which indicates the amount of cancer in the lungs.
- In the control group, 30% of the mice had large, well-established secondary tumors (i.e., metastatic, invasive tumors) in their lungs with luciferase activity of greater than 1585 AU in each mouse, while the PNV2 group appeared to have no large secondary tumors in the lungs of any mouse and luciferase activity of not more than 356 AU in any mouse.

Dr. Julien Dimastromatteo, Purnovate's Vice President, Research, commented, "This pre-clinical data is encouraging, as we seem to have demonstrated a reduction in metastases and cancer invasion into the lungs following treatment with PNV2. This data confirms prior research on the anti-cancer properties of adenosine analogs. However, historically, the solubility of these compounds has been a barrier to developing an effective therapy. This latest research around PNV2 is particularly exciting as we believe we have overcome the solubility challenges. We plan to conduct additional pre-clinical research with a goal of advancing PNV2 into clinical trials in 2022."

William Stilley, Adial's Chief Executive Officer, stated, "The Purnovate adenosine platform continues to demonstrate broad potential across a wide range of indications and is exceeding expectations. We are especially encouraged by this latest data in triple negative breast cancer following the recent pain data. We look forward to aggressively pursuing the full potential of the Purnovate Adenosine Platform and are evaluating the best strategy to achieve full value for our shareholders from the Platform, while we remain laser focused at Adial on obtaining our Phase 3 data on AD04 for treatment of Alcohol Use Disorder."

PNV2 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 that have limited the usefulness of adenosine analogs as treatments. 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, PNV2 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.

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, cocaine addiction, inflammation, infectious disease, cancer, asthma, and diabetes. Additional information is available at www.purnovate.com.

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. 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 plans to advance PNV2 as the lead compound for our cancer program, having overcome the solubility challenges of selective adenosine compounds and solubility being a particularly important characteristic in determining the drug development potential of molecules of this class, plans to conduct additional pre-clinical research with a goal of advancing PNV2 into clinical trials in 2022, aggressively pursuing the full potential of the Purnovate Adenosine Platform and the potential of AD04 to treat other addictive disorders such as Alcohol Use Disorder, 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 advance PNV2 into clinical trials and achieve similar results as those achieved in preclinical studies, our ability to commence clinical trials of PNV2 in 2022, 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 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 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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