# Adial Pharmaceuticals Announces Positive In-Vivo Non-clinical Data with Purnovate's PNV-6005 as a Potential Treatment for Ulcerative Colitis

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PNV-6005 significantly reduced both weight loss and colon damage in ulcerative colitis animal model

CHARLOTTESVILLE, Va., Sept. 06, 2022 — **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)** ("Adial" or the "Company"), today announced that Purnovate, Inc., a subsidiary of Adial focused on developing novel molecules targeting the adenosine receptors for the treatment of major unmet medical needs, achieved positive in-vivo data from its study with mice treated with Purnovate's PNV-6005 as a potential treatment for inflammatory bowel diseases.

PNV-6005 is a selective adenosine 2A receptor agonist designed to have anti-inflammatory properties and protective effects against colitis and other inflammatory bowel diseases (IBD). In the study, PNV-6005 demonstrated statistically significant effect against both primary study endpoints, which are pre-clinical endpoints expected to indicate potential efficacy against ulcerative colitis in humans. Specially, PNV-6005 (i) significantly prevented weight loss as compared to the control group (greater than 50% inhibition of weight loss) and (ii) significantly prevented colon damage as evidenced by reduction of shortening of colon lengths in the PNV-6005 treated group (almost total prevention), as well as a decrease in inflammation as assessed histologically.

The study was conducted by Dr. Peter Ernst, DVM, PhD, Professor of Pathology at the University of California San Diego (UC San Diego), an expert in the fields of immunology, inflammation and infectious diseases.

A photo accompanying this announcement is available at
https://www.globenewswire.com/NewsRoom/AttachmentNg/1664150a-b1eb-4bc6-874a-e7462f47b19d

**Study Design**

- The study utilized a DSS- induced colitis model, which is widely used because of its simplicity and similarities with human ulcerative colitis
- PNV-6005 was administered intraperitoneally twice a day at 6µg/kg dose for 7 days
- DSS was administrated at 4% concentration via drinking water
- The study included four groups of 5 mice: (i) one group with normal drinking water; (ii) one group with DSS 4% volume concentration in drinking water; and (iii) two treated groups receiving PNV6005 intraperitoneal injections

The positive results follow a recent research collaboration agreement between Purnovate and UC San Diego, a leading education and research university, to evaluate the Company's proprietary adenosine analogs as a potential treatment for inflammatory diseases, including IBD and infectious diseases where a large immune response (i.e., cytokine storm) plays a significant role.

Dr. Ernst stated, "We are encouraged by these results, which demonstrate both *in-vivo* efficacy and the ability of Purnovate's adenosine compounds to effectively address the historical challenges of solubility and biodistribution. We look forward to further advancing this research in ulcerative colitis

as well as broader IBD indications and other inflammatory conditions."

William Stilley, CEO of Purnovate, stated, "We appreciate the support of Dr. Ernst and UC San Diego in supporting this important study, and look forward to advancing PNV-6005 towards first-in-human clinical trials. Ulcerative colitis is the most common form of IBD and causes inflammation and ulcers in the digestive tract, affecting an estimated 1 million people in the U.S. alone. According to QY Research Medical, the ulcerative colitis market was valued at $6.2 billion in 2020 and it is expected to reach $10.8 billion by 2030. In addition to advancing PNV-6005 for ulcerative colitis and IBD, we believe this research reinforces the broad potential of our Purnovate adenosine platform for other inflammatory conditions."

"These additional data strengthen our belief in the potential for our Purnovate platform and diverse opportunities," said Cary Claiborne, CEO of Adial. "We will continue to provide updates on our progress with Purnovate as we advance the first drug candidates from this program toward clinical development. Furthermore, we see good synergies between Adial's work in bringing AD04 toward the market and that of Purnovate, with a focus on building upon our addiction and pain treatment pipeline."

**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 drug candidates targeting the adenosine receptors to treat diseases and disorders such as pain, asthma, cancer, diabetes, non-alcoholic steatohepatitis (NASH), and inflammatory diseases and disorders such as burn/wound healing, inflammatory bowel disorder and infectious disease. For more information, visit www.adial.com/purnovate/.

**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) in heavy drinking patients and was recently investigated in the Company's ONWARD™ pivotal Phase 3 clinical trial for the potential treatment of AUD in subjects with certain target genotypes (estimated to be approximately one-third of the AUD population) identified using the Company's proprietary companion diagnostic genetic test. ONWARD showed promising results in reducing heavy drinking in heavy drinking patients, and no overt safety or tolerability concerns. 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.adial.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 Purnovate's PNV-6005 as a potential treatment for inflammatory bowel diseases, PNV-6005 having anti-inflammatory properties and protective effects against colitis and other inflammatory bowel diseases, advancing this research in ulcerative colitis as well as broader IBD indications and other inflammatory conditions, advancing PNV-6005 towards first-in-human clinical trials, the ulcerative colitis market reaching $10.8 billion by 2030, the broad potential of Purnovate's adenosine platform for other inflammatory conditions and diverse opportunities 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 PNV-6005 to have anti-inflammatory properties and protection against colitis and other inflammatory bowel diseases in human clinical trials, our ability to validate the potential of adenosine compounds as an alternative or adjunct therapy, 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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