Adial Pharmaceuticals Comments on Article in 'The Atlantic,' Highlighting the Second Pandemic of Addiction

CHARLOTTESVILLE, Va., June 07, 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, commends Kate Julian and *The Atlantic* for highlighting the major crisis facing our society in her article <u>America Has a Drinking Problem</u>. The article highlights the complexity of the factors driving alcohol use and its pervasiveness in human society and, particularly, in the United States.

William Stilley, Chief Executive Officer of Adial, commented, "We appreciate the spotlight that Ms. Julian and *The Atlantic* have put on the increase in Alcohol Use Disorder (AUD), which has been exacerbated by the COVID-19 induced lockdowns-the 'Second Pandemic of Addiction,' as further highlighted in my recent podcast interview with the <u>Wall Street</u> Resource."

Key statistics regarding Alcohol Use Disorder include:

- In the United States, approximately 35 million people each year suffer from AUD, resulting in significant health, social and financial costs according to the National Institute of Alcohol Abuse and Alcoholism ("NIAAA") and Journal of the American Medical Association ("JAMA").
- Excessive alcohol use is the third leading cause of preventable death and is responsible for 31% of driving fatalities in the United States (NIAAA Alcohol Facts & Statistics).
- AUD contributes to over 200 different diseases and 10% of children live with a person that has an alcohol problem (NIAAA Alcohol Facts & Statistics).
- 5-6% of new cancers and cancer deaths globally are directly attributable to alcohol (American Society of Clinical Oncologists).
- Alcohol is the leading cause of death in people ages 15-49 globally (The Lancet).
- AUD costs the United States economy about \$250 billion annually, with heavy drinking accounting for greater than 75% of the social and health related costs (The Centers for Disease Control).
- Only 7.7% of patients, or approximately 2.7 million people, with AUD are estimated to have been treated in any way and only 3.6% by a physician, or approximately 1.3 million people (JAMA).
- AUD in the United States appears to be growing with almost a 50% increase in prevalence between 2002 and 2013 (JAMA).

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, and the Company develops adenosine analogs for the treatment of pain and other disorders. Additional information is available at www.adialpharma.com.

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 forwardlooking 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 the potential of AD04 to treat other addictive disorders such as opioid use disorder, gambling, and obesity. Any forwardlooking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, our ability to leverage the acquisition of Purnovate and our other expansion plans to position ourself as a leader in the broader addiction market, our ability to enroll patients within the timelines anticipated and complete clinical trials on time and achieve desired results and benefits as expected, the ability of AD04 to treat other addictive disorders such as opioid use disorder, gambling, and obesity, 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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