

Adial Pharmaceuticals Awarded Additional U.S. Patent Combining the Use of the Company's Proprietary Genetic Diagnostic With AD04 to Treat Alcohol and Drug Dependence

New patent covers the use of the full genetic panel measuring all five genetic biomarkers

CHARLOTTESVILLE, Va., June 14, 2022 — **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 patent number 11,351,154 was issued on June 7, 2022, by the U.S. Patent and Trademark Office. The patent covers the use of the Company's genetic diagnostic panel in combination with the Company's lead product, AD04, for the treatment of alcohol use disorder (AUD) and Opioid Use Disorder (OUD). This patent expands coverage of previously issued patents to include the measurement of the genetic biomarkers for all of the targeted genotypes utilizing the Company's proprietary diagnostic test.

William Stilley, Adial's Chief Executive Officer, stated, "This latest patent covering the use of AD04 as a potential treatment for AUD and OUD, combining all five distinct genetic biomarkers, is a critical component of our broader strategy to build a robust moat of patents around AD04. Importantly, AD04 represents a potential breakthrough in the treatment of addiction as a genetically targeted therapy. Moreover, the pharmaceutical industry, insurers and regulators are increasingly focusing on precision medicine as a means to improve patient outcomes, while effectively managing healthcare costs by directing resources towards those patients most likely to respond. As a result of this latest patent, we have expanded our IP portfolio to over 90 patents and patents pending covering the use of both AUD and OUD in over 40 jurisdictions around the world. As a result, we believe we have built a robust patent estate providing us market protection through 2031, plus expected extensions until 2036.

"An estimated 35 million people in the United States alone, are estimated to have AUD. In addition to the market opportunity for AD04 as a therapy, we believe the total potential market for our companion diagnostic genetic test as a stand-alone commercial business line could represent another potentially significant business line for the Company. At the same time, we have completed our ONWARD™ Phase 3 pivotal trial, and look forward to reporting the results in the coming weeks."

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.

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 AD04 representing a potential breakthrough in the treatment of addiction as a genetically targeted therapy, the Company building a robust patent estate providing it market protection through 2031 plus expected extensions until 2036, an estimated 35 million people in the United States alone being estimated to have AUD, the total potential market for the Company’s companion diagnostic genetic test as a stand-alone commercial business line representing another potentially significant business line for the Company, reporting the ONWARD™ Phase 3 pivotal trial results in the coming weeks 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, the ability of AD04 to become a breakthrough in the treatment of addiction as a genetically targeted therapy, our ability to secure market protection from our patent estate through 2031 plus expected extensions until 2036, our ability to establish a significant stand-alone commercial business line for the Company’s companion diagnostic genetic test, our ability to report the ONWARD™ Phase 3 pivotal trial results as planned, 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, 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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