Adial Pharmaceuticals Plans to Enter Genetic Testing Market Following Allowance of U.S. Patent for Genetic Diagnostic Test

The Company believes the genetic companion diagnostic test for AD04 for Alcohol Use Disorder represents a multi-billion dollar potential market opportunity

CHARLOTTESVILLE, Va., June 22, 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 plans to enter the genetic testing market after it received a Notice of Allowance from the U.S. Patent and Trademark Office related to 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). The patent covered by the Notice of Allowance also pertains to the Company's use of its genetic diagnostic panel in combination with AD04 for the treatment of Opioid Use Disorder (OUD).

"This new patent related to the use of our genetic diagnostic panel in combination with AD04 for the treatment of AUD and OUD is a major milestone as we believe genetic evaluation of patients can be used to identify individuals that may benefit from AD04. We have been utilizing the genetic panel covered by this patent in our ongoing ONWARD™ Phase 3 trial, and, given this patent allowance, we anticipate that genetic diagnostics are expected to be an important segment of our commercial strategy going forward," said William Stilley, Chief Executive Officer of Adial Pharmaceuticals. "Our view that AUD has a solid nexus in genetics is fundamental to the premise of the successful Phase 2B trial of AD04 conducted at the University of Virginia and our ONWARD™ Phase 3 trial of AD04 currently underway in Europe. And, it is consistent with Adial's premise that the presence of certain genetics is expected to substantially influence whether an individual suffering from AUD or OUD would likely respond to treatment with AD04."

The recently allowed patent, once issued, is expected to provide market exclusivity for the AD04 genetic diagnostic test, creating a possibly significant profit center for the Company. Therefore, assuming approval by either the U.S. or European regulatory authorities, Adial plans to enter the genetic testing market as a stand-alone commercial business line and develop and market the genetic diagnostic panel as a Companion Diagnostic Test to AD04 for identification of the approximately one-third (33%) of AUD patients expected to respond to treatment with AD04. The Company also sees a future opportunity to commercialize a companion diagnostic test to AD04 for OUD, if an OUD approval is also received for AD04.

Commenting on the potential market for Adial's genetic companion diagnostic test for AD04 for the treatment of AUD, Mr. Stilley stated, "Market research conducted by Adial indicates a willingness among payors to reimburse a genetic companion diagnostic test, and this may allow Adial to provide patients personalized, precision medicine and also potentially provide dramatic cost savings to payors. Our models estimate the payback period for payors would be under 12 months at expected pricing, and, with 35 million people in the United States estimated to have AUD, we believe the total potential market for our companion diagnostic genetic test could be a multi-billion dollar opportunity in the United States alone."

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.

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 plans to enter the genetic diagnostic testing market as a stand-alone commercial business line, using genetic evaluation to identify the approximately one-third (33%) of AUD patients that may benefit from AD04, genetic diagnostics becoming an important segment of our commercial strategy going forward, AUD having a solid nexus in genetics, the presence of certain genetics influencing whether an individual suffering from AUD or OUD would likely respond to treatment with AD04, the recently allowed patent, once issued, providing market exclusivity for the AD04 genetic diagnostic test and creating a possibly significant profit center, plans to commercialize a companion diagnostic test to AD04 for OUD, providing to patients personalized, precision medicine and to payors cost savings, the payback period for payors being under 12 months, the total potential market for our companion diagnostic genetic test being a multi-billion dollar opportunity and the potential of AD04 to treat other addictive disorders such as alcohol 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 enter the genetic diagnostic testing market as a stand-alone commercial business line as planned, our ability to use genetic evaluation to identify the approximately one-third (33%) of AUD patients that may benefit from AD04, our ability to establish genetic diagnostics as an important segment of our commercial strategy going forward, our ability to demonstrate that AUD has a solid nexus in genetics, our ability to demonstrate that the presence of certain genetics influences whether an individual suffering from AUD or OUD would likely respond to treatment with AD04, our ability to obtain market exclusivity for the AD04 genetic diagnostic test and create a significant profit center once the recently allowed patent is issued, our ability to commercialize a companion diagnostic test to AD04 for OUD, our ability to provide to patients personalized, precision medicine and provide to payors cost savings, our ability to provide a payback period for payors of under 12 months, the total potential market for our companion diagnostic genetic representing a multi-billion dollar opportunity in the United States, 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, 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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