Adial Pharmaceuticals Issued Second Patent Covering AD04 as a Treatment for Opioid Use Disorder

CHARLOTTESVILLE, VA / April 15, 2020 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced that U.S. Patent Number 10,619,209, titled "Serotonin Transporter Gene and Treatment of Opioid-Related Disorders" issued on April 14, 2020. This patent covers the treatment of Opioid Use Disorder by administering the Company's investigational new drug product, AD04, an antagonist of the serotonin-3 receptor (5-HT3), to patients with the LL and TT genotypes, which may be identified by Adial's proprietary genetic test.

The gene responsible for encoding the serotonin transporter (SERT), SLC6A4, located on the chromosome 17q11.1-q12, is the only known gene encoding the serotonin transporter and has a functional polymorphism at the 5′-regulatory promoter region, which results in two forms, long (L) or short (S). The LL-genotype is hypothesized to play a key role in the early onset of alcohol use. The issued patent discloses the differences in treatment and diagnosis based on the LL or SS genotypes as well as on a single nucleotide polymorphism of the SERT gene, the TT genotype of the 3′ UTR SNP rs1042173. It relates to the efficacy of using the drug ondansetron (AD04 is ondansetron repurposed at a lower dose than currently approved by the Food and Drug Administration for other indications) based on variations in the polymorphisms of the SERT gene as well as methods for diagnosing susceptibility to abuse of alcohol and other addiction-related diseases and disorders including Opioid Use Disorder.

"This is our second issued patent covering AD04 for the treatment of Opioid Use Disorder," said William Stilley, CEO of Adial Pharmaceuticals. "Importantly, as with the earlier issued patent, the author of this patent is Adial's Chief Medical Officer, Dr. Bankole Johnson. Adial's patent estate around AD04 is robust; we expect market exclusivity for AD04 through 2032, plus potential Hatch-Waxman extensions through 2037. This new patent reaffirms Adial's capacity to address Opioid Use Disorder if efficacy is demonstrated in clinical trials, which we expect to conduct in parallel with advancement of our landmark ONWARD™ Phase 3 pivotal clinical trial for the treatment of Alcohol Use Disorder."

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™ Phase 3 Pivotal 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. 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 the role

the LL-genotype is hypothesized to play in the early onset of alcohol use, market exclusivity for AD04 continuing through 2032, plus potential Hatch-Waxman extensions through 2037, conducting clinical trials in parallel with advancement of our landmark ONWARD™ Phase 3 pivotal clinical trial for the treatment of Alcohol Use Disorder*, 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 establish the role the LL-genotype plays in the early onset of alcohol use, our ability to maintain market exclusivity for AD04 through 2032, plus potential Hatch-Waxman extensions through 2037, our ability to conduct clinical trials in parallel with advancement of our landmark ONWARD™ Phase 3 pivotal clinical trial for the treatment of Alcohol Use Disorder, our ability to continue enrollment and mitigate delays during the COVID-19 pandemic, our ability to expand the use of AD04 for use in patients with Opioid Use Disorder, gambling and obesity, the ability of AD04 therapy to perform as designed, to demonstrate safety and efficacy, as well as results that are consistent with prior results, the ability to enroll patients and complete the clinical trials on time and achieve desired results and benefits, 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, 2019, 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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