Addiction Drug Developer Adial Pharmaceuticals Successfully Passes Patent Opposition Period in Europe for AD04 in Alcohol Use Disorder; Reports No Challenges to European Patent

Patent portfolio significantly enhanced and extended by this patent

CHARLOTTESVILLE, Va., Sept. 18, 2018 — **Adial Pharmaceuticals, Inc. (NASDAQ: ADIL; ADILW)**, a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced the strengthening of its intellectual property (IP) portfolio, as it has successfully passed the patent opposition period in Europe without any challenges to its patent for AD04, which was granted by the European Patent Office (EPO) as EP 2801625 B1 and validated in 2018 in 36 European countries .

William Stilley, CEO of Adial Pharmaceuticals, stated, "Following our recent patent award by the European Patent Office, we have now surpassed the opposition period for challenges, a key milestone in Europe, as it makes it much more difficult for potential competitors to challenge this patent in the future. The fact we were not only awarded the patent, but also faced no challenges, reinforces the strength of the patent. This patent should provide us patent protection for ADO4 for the treatment of alcohol use disorder through 2031. This patent is in addition to our already issued U.S. patents, which should provide us coverage through 2032, plus expected patent term extensions. The Company plans to continue to further expand its patent portfolio by pursuing additional patent applications related to its proprietary companion diagnostic genetic test and the use of AD04 in other addictive disorders such as opioid use disorder, gambling addiction and obesity."

With the opposition period having expired, a third party can no longer challenge the validity of EP 2801625 B1 in the EPO. This patent can now only be challenged in the individual national courts of the 36 European countries where it has been validated. This is a timely, costly, and uncertain approach to invalidating a patent. As a result, the Company believes the claims and scope of the patent are highly enforceable and provide broad protection.

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 candidate, AD04, is a genetically targeted therapeutic agent for the treatment of alcohol use disorder (AUD). 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). The Company plans to commence a Phase 3 clinical trial using AD04 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. AD04 is also believed to have the potential to treat other addictive disorders such as opioid use disorder, gambling, and obesity.

About Alcohol Use Disorder

According to an article in the widely respected publication *The Lancet,* alcohol is the number one cause of death globally among both men and women ages 15 to 49 years. In the United States alone, approximately 35 million people have AUD resulting in significant health, social and financial costs (NIAAA Alcohol Facts & Statistics). AUD contributes to over 200 different diseases, and 10% of children live with a person that has an alcohol problem. According to the American Society of Clinical Oncologists, 5-6% of new cancers and cancer deaths globally are directly attributable to alcohol. The Centers for Disease Control (CDC) has reported that AUD costs the U.S. economy about $250 billion annually, with heavy drinking accounting for greater than 75% of the social and health related costs. In addition, according to the NIAAA, the problem in the United States appears to be growing with an approximately 50% increase in AUD prevalence between 2002 and 2013.

Despite the high prevalence and high costs, according to an article in the JAMA 2015 publication, only 7.7% of patients (i.e., approximately 2.7 million people) with AUD are estimated to have been treated in any way and only 3.6% by a physician (i.e., approximately 1.3 million people). The most common treatments for AUD are directed at achieving abstinence and typical treatments include psychological and social interventions. Most therapies require abstinence even prior to initiating therapy. Abstinence requires dramatic lifestyle changes often with serious work and social consequences. Significant side effects of current pharmacologic therapies include mental side effects such as psychiatric disorders and depressive symptoms and physical side effects such as nausea, dizziness, vomiting, abdominal pain, arthritis and joint fitness. These problems with the currently available therapies appear to limit the willingness of people with AUD to seek treatment and then to limit compliance with treatment requirements and, therefore, the ultimate results for many people attempting currently available therapies.

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. These statements are based upon current beliefs, expectations and assumptions and include statements regarding the patent providing patent protection in Europe for ADO4 for the treatment of alcohol use disorder through 2031, already issued U.S. patents providing coverage through 2032, plus expected patent term extensions, plans to continue to further expand the Company’s patent portfolio by prosecuting patent applications related to its proprietary companion diagnostic genetic test and the use of AD04 in other addictive disorders, the claims and scope of the patent being highly enforceable and providing broad protection from competition and plans to commence a Phase 3 clinical trial using AD04 for the potential treatment of AUD in subjects with certain target genotypes. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, the ability of our patent portfolio to provide protection in Europe through 2031 and in the U.S. patents through 2032, plus expected patent term extensions, our ability to continue to further expand our patent portfolio by prosecuting patent applications related to our proprietary companion diagnostic genetic test and the use of AD04 in other addictive disorders, 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 our 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 statements included in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2018 that we have filed with the SEC. 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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