

# **Adial Pharmaceuticals Announces Mark Howard Peikin, Esq. as Chief Strategy Officer and VP of Corporate Communications as Adial Advances Phase 3 Clinical Trial of AD04 for the Treatment of Alcohol Use Disorder**

**CHARLOTTESVILLE, VA / October 7, 2019 / Adial Pharmaceuticals, Inc. (NASDAQ:ADIL; ADILW)**

[www.adialpharma.com](http://www.adialpharma.com), a clinical-stage biopharmaceutical company focused on the development of treatments for addiction, today announced that Mark Howard Peikin, Esq., Chief Executive Officer of Bespoke Growth Partners (Bespoke), and a former General Partner of Aelius Healthcare Innovations Fund and partner within the corporate and securities group at the international law firm Brown Rudnick, was appointed as Chief Strategy Officer and Vice President of Corporate Communications. As Adial conducts its European Phase 3 clinical trial of AD04 for the treatment of Alcohol Use Disorder (AUD), which trial will study subjects for 24-weeks with 290 subjects projected to be enrolled in approximately 30 clinical sites in 7 European countries, Mr. Peikin will help oversee Adial's discussions with pharmaceutical companies, as well as strategic and institutional investors. The clinical trial itself will be managed by Crown CRO of Finland in conjunction with Company management.

For the past 10 years, as CEO of Bespoke, Mr. Peikin has successfully advised healthcare, biotechnology and pharmaceutical companies regarding business strategy, mergers and acquisitions, and fundamental investments. Mr. Peikin previously co-founded and co-managed Aelius Healthcare Innovations Fund, an equity fund focused on investment in private healthcare technology businesses serving the pharmaceutical industry. Aelius was sold in 2016 to Ridgetop Health. Mr. Peikin brings relationships with many of the leading healthcare funds, as well as premier hospital organizations and academic institutions.

Commenting on the appointment, William Stilley, CEO of Adial Pharmaceuticals, stated, "We are moving to advance our Phase 3 clinical trial of AD04. Just last week, we filed our Clinical Trial Application (CTA) in Sweden and we plan to file similar applications in 6 additional European countries in the coming weeks. We are honored that Mr. Peikin, whose company has been instrumental in advising Adial with respect to its business strategy, has agreed to accept the role of Chief Strategy Officer and Vice President of Corporate Communications. The timing is ideal in that Adial is moving forward with its Phase 3 study and we expect to begin dosing study subjects in the next few months. We look forward to leveraging Mr. Peikin's expertise, relationships and knowledge as we seek to aggressively increase awareness of Adial within both the pharmaceutical industry and the investment community."

"We believe Adial's commencement of its Phase 3 trial is a transformative event and an important step towards our goal of having AD04 approved for the treatment of AUD, first in Europe and then in the United States," said Mr. Peikin. "As the trial progresses, given Adial's unique position in the market with AD04 as a Phase 3 asset targeting a specific but prevalent genotype of patients with AUD, we expect pharmaceutical companies and investment managers to closely monitor our progress. We are confident in our innovative approach to target a therapeutic agent in patients with AUD, and along with the rest of the Adial management team, I will be advancing our market-driven strategy as our drug development team works towards the approval of effective treatments. I am honored to be involved with Adial and I would like to thank our CEO, William Stilley, and the entire Adial Board for the confidence they have placed in me."

"It is notable that Mr. Peikin has agreed to take this important position without salary," added Mr. Stilley. "Rather, Mr. Peikin has initially been awarded stock options that vest over 3 years and give him the right to purchase up to 225,000 shares of the Company's common stock. Of this amount, 75,000 options will have an exercise price of \$2.00 per share; 75,000 will have an exercise price of \$3.00 per share; and 75,000 will have an exercise price of \$4.00 per share. Given Mr. Peikin's vast experience, we are appreciative of his willingness to join Adial under this arrangement, which we believe is a clear vote of confidence in the future of our Company."

**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 commencing the Phase 3 clinical trials, the plan to file applications in 6 additional European countries in the coming weeks, the dosing of study subject within the next few months, leveraging Mr. Peikin's expertise, relationships and knowledge as the Company seeks to aggressively increase awareness of the Company within both the pharmaceutical industry and the investment community, the Company's commencement of its Phase 3 trial being a transformative event and an important step towards the Company's goal of having AD04 approved for the treatment of AUD, first in Europe and then in the United States, the monitoring of the Company's progress by pharmaceutical companies and investment managers, the expected benefit AD04 will bring to patients and Mr. Peikin's

expected contribution to the Company and confidence in the future of the Company. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, our ability to advance the Phase 3 clinical trials, 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 contribution of Mr. Peikin to advance our business objectives, 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 our filings 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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