Adial Pharmaceuticals Confirms Scheduling of Meetings with FDA and European Regulatory Agencies to Advance Clinical Development of AD04 for Alcohol Use Disorder

Type C meeting with FDA set for Second Quarter

Plans in Place to Meet with Multiple Regulatory Agencies Throughout Europe

CHARLOTTESVILLE, Va., Feb. 21, 2023 — 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 that it has secured meetings with regulatory authorities in the U.S. and Europe to discuss and develop plans for the clinical advancement of AD04 for alcohol use disorder toward potential approvals.

In the United States, Adial has secured a Type C meeting with the Food and Drug Administration (FDA) in the second quarter of this year. This meeting will allow Adial and the FDA to discuss the clinical development program for AD04 in the U.S. and the most appropriate path toward possible approval. In Europe, Adial has meetings scheduled or planned with five national regulatory authorities in France, Sweden, Finland, the United Kingdom and Germany. Adial intends to seek from the agencies a clear understanding and direction toward the most expeditious path to approval.

Cary Claiborne, Adial's President and Chief Executive Officer, said, "These meetings are the next step in our plan to complete clinical development of AD04 and bring to market a much-needed treatment for alcohol use disorder. In parallel, we are discussing opportunities with prospective pharmaceutical company partners that can help us to fund clinical development while also creating go-to market commercial strategies in the U.S. and Europe. We will provide an in-depth update on all AD04 program activities 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) in heavy drinking patients and was recently investigated in the Company's ONWARD™ pivotal Phase 3 clinical trial for the potential treatment of AUD in subjects with certain target genotypes (estimated to be approximately one-third of the AUD population) identified using the Company's companion diagnostic genetic test. ONWARD showed promising results in reducing heavy drinking in heavy drinking patients, and no overt safety or tolerability concerns. AD04 is also believed to have the potential to treat other addictive disorders such as Opioid Use Disorder, gambling, and obesity. Additional information is available at www.adial.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, meetings allowing Adial and the FDA to discuss the clinical development program for AD04 in the U.S. and the most appropriate path toward approval, scheduled or planned meetings with five national regulatory authorities in France, Sweden, Finland, the United Kingdom and Germany, discussing opportunities with prospective pharmaceutical company partners that can help us to fund clinical development while also creating go-to market commercial strategies in the U.S.

and Europe, AD04 being approved and brought to market, Adial partnering with another pharmaceutical company, Adial obtaining from agencies a clear understanding and direction toward the most expeditious path to regulatory approval, AD04 appearing to be well tolerated 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 develop plans for the clinical advancement of AD04 for alcohol use disorder toward potential approvals with regulatory authorities in the U.S. and Europe, our ability to partner with prospective pharmaceutical companies to help the Company to fund clinical development while also creating go-to-market commercial strategies in the U.S. and Europe, our ability to 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 our product candidates in the marketplace and the successful development, marketing or sale of our 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 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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