

Adial Pharmaceuticals Announces Database Lock in Pharmacokinetics Study of AD04 for the Treatment of Alcohol Use Disorder

Topline results expected in fourth quarter of 2024

GLEN ALLEN, Va., Sept. 19, 2024 (GLOBE NEWSWIRE) -- Adial Pharmaceuticals, Inc. (**NASDAQ: ADIL**) ("Adial" or the "Company"), a clinical-stage biopharmaceutical company focused on developing therapies for the treatment and prevention of addiction and related disorders, announced database lock for the pharmacokinetics study of AD04, the Company's lead investigational genetically targeted, serotonin-3 receptor antagonist, therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in heavy drinking patients (defined as < 10 drinks/drinking day). Topline results are expected to be announced during the fourth quarter of 2024.

Cary Claiborne, President and Chief Executive Officer of Adial, said, "We are pleased to announce database lock for our pharmacokinetics study. The data has now been transferred to independent statisticians, who will begin the data analysis process for our next FDA interaction. As we prepare for the release of topline results in the fourth quarter, our attention turns to the next critical steps, including planning for re-engagement with the FDA. The insights gained from this study will be crucial in shaping our clinical strategy for the Phase 3 study. In addition, we believe the topline results, will strengthen our position for potential strategic collaborations as we finalize planning efforts for the future clinical development of AD04."

The single-center open-label relative bioavailability and dose proportionality study enrolled 30 healthy adult volunteers and compared the pharmacokinetic profile of AD04 when administered as an oral dose of 0.33 mg, with or without food, against a reference standard product.

About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of treatments for addictions 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) 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 identified using the Company's companion diagnostic genetic test. ONWARD showed promising results in reducing 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 announcing topline results during the fourth quarter of 2024, planning for re-engagement with the FDA, the insights gained from the study being crucial in shaping the Company's clinical strategy for the Phase 3 study, the topline results strengthening the Company's position for potential strategic collaborations, finalizing planning efforts for the future clinical development of AD04 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 release topline results for our

pharmacokinetics study of AD04 as planned, our ability to pursue our regulatory strategy, our ability to advance ongoing partnering discussions, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, our ability to develop strategic partnership opportunities and maintain collaborations, our ability to obtain or maintain the capital or grants necessary to fund our research and development activities, our ability to complete clinical trials on time and achieve desired results and benefits as expected, 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 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, 2023, 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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9/19/2024 8:30:00 AM