Adial Pharmaceuticals Submits Briefing Package to Guide Upcoming FDA Meeting

End of Phase 2 Meeting has been Rescheduled for July 29th

Meeting to Discuss Upcoming Clinical Development Plan and Protocol Designs

Strategic Partnership Discussions Expected to Accelerate Following a Positive FDA Meeting

GLEN ALLEN, Va., June 16, 2025 (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, today announced the submission of the required briefing package for the upcoming End of Phase 2 meeting (EOP2M) with the Food and Drug Administration (FDA). The FDA has rescheduled the meeting which will now be held on July 29th. The briefing package, a prerequisite for the EOP2M, must be submitted in advance to allow for FDA review and preparation ahead of the meeting.

AD04 is Adial's lead investigational drug, a serotonin-3 receptor antagonist, being developed for the treatment of Alcohol Use Disorder (AUD) in individuals with heavy drinking and select genotypes.

The objective for the EOP2M is to align with the FDA on the design of the Phase 3 Clinical Development program for AD04. This includes key elements of the planned adaptive study design elements, such as population, endpoints, inclusion/exclusion criteria, dose regime, and affirmation of the biomarker positive and biomarker negative groups. The briefing package is based on a comprehensive package, including legacy safety data, efficacy studies performed by Adial, and the data analysis conducted in collaboration with Cytel Inc. (Cytel). Adial worked together with Quantum Regulatory Solutions, LLC, a clinical and regulatory strategy advisor and Cytel, to develop the Phase 3 protocol, the statistical analysis plan, the briefing package, and related documents for the meeting.

A successful outcome from the EOP2M will not only provide critical regulatory alignment to advance AD04 into Phase 3 but is also expected to play a pivotal role in Adial's ongoing strategic partnering efforts. Clarity and validation from the FDA on the clinical development path are anticipated to significantly strengthen Adial's position in discussions with potential partners, who typically view regulatory momentum as a key de-risking milestone in the decision-making process.

Cary Claiborne, President and Chief Executive Officer of Adial commented, "We recently announced that the FDA had granted our request for an EOP2M. In parallel, we have been developing our future pivotal Phase 3 trial protocol. We are now prepared to engage with the FDA to align on the requirements needed to support a future marketing application for AD04. We are highly encouraged by the progress made over the past several months, which included a thorough analysis of our historical data and the integration of Cytel's advanced statistical analytics and simulation modeling incorporating machine learning and proprietary tools, such as East®. These efforts have been instrumental in refining the trial design to focus on the Alcohol Use Disorder (AUD) population most likely to benefit from AD04 treatment. We look forward to our meeting with the FDA and are optimistic about achieving a successful outcome at this critical development milestone. Importantly, we believe that a productive FDA meeting will also enhance our ability to advance ongoing partnership discussions, as regulatory clarity is a key consideration for potential collaborators."

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 accelerating strategic partnership discussions following a positive FDA meeting, developing AD04 for the treatment of AUD in individuals with heavy drinking and select genotypes, aligning with the FDA at the EOP2M on the design of the Phase 3 Clinical Development program for AD04, a successful outcome from the EOP2M providing critical regulatory alignment to advance AD04 into Phase 3 and playing a pivotal role in our ongoing strategic partnering efforts, clarity and validation from the FDA on the clinical development path significantly strengthening our position in discussions with potential partners, engaging with the FDA to align on the requirements to support the eventual marketing application for AD04, refining the trial design to focus on AUD population most likely to benefit from AD04 treatment, a productive FDA meeting enhancing our ability to advance ongoing partnership discussions, aand 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 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, 2024, 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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