Adial Pharmaceuticals Secures U.S.-Based Manufacturing Through Agreements with Cambrex and Thermo Fisher Scientific for Drug Substance and Drug Product Supply

Scope of Agreement with Cambrex to Provide Ondansetron HCL Drug Substance Under FDA Approved Drug Master File

Scope Of Agreement With Thermo Fisher to Provide Manufacturing Services Including Demonstration, Clinical, Registration And Validation Batches of AD04 for US Clinical Trials And NDA Submission

GLEN ALLEN, Va., June 25, 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 recent execution of agreements for the production of AD04 (0.33 mg ondansetron tablets), supporting both the completion of upcoming clinical trials and the planned New Drug Application (NDA) submission to the U.S. Food and Drug Administration (FDA) for the treatment of Alcohol Use Disorder (AUD) in the US. AD04 is the Company's lead investigational genetically targeted, serotonin-3 receptor antagonist, therapeutic agent for the treatment of AUD in heavy drinking patients.

The strategic collaboration with Thermo Fisher Scientific as the Contract Development and Manufacturing Organization (CDMO) for AD04 Drug Product, and Cambrex, a drug substance CDMO and supplier of Ondansetron API, has begun and is already seeing results in completion of the demonstration batches required prior to the conduct of the registration and clinical batches. The importance of choosing CDMOs with both drug substance development and manufacturing capabilities with successful track records was a key element to the signing of the agreements. The agreements include all phases of manufacturing for both the clinical supplies needed to conduct the upcoming clinical studies for AD04, as well as the Chemistry, Manufacturing, and Controls (CMC) module documentation required for the submission of the NDA to the FDA.

Cary Claiborne, President and Chief Executive Officer of Adial commented, "As our readiness in planning the future Phase 3 registrational study program for AD04 continues, these agreements with Thermo Fisher and Cambrex are another key component in our planning for the upcoming conduct of the AD04 clinical trial program and to meet our requirements for the FDA. The combination of Thermo Fisher and Cambrex makes for a strong collaboration for Adial in our quest to develop AD04 for the treatment of AUD. Choosing a contract manufacturer which can meet our timelines for starting the clinical program is paramount. It was important for the CDMOs to be on sound financial footing, but also to have drug substance manufacturing as well as drug product manufacturing in the US to meet the eventual commercial demands of AD04 given recent tariff implications for our industry. It is equally important to have confidence in the drug substance manufacturer and their ability to consistently supply the needs of Adial. We believe these relationships will be invaluable as we move forward with the initiation of our Phase 3 trials."

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.

About Cambrex Corporation

Cambrex is a leading global contract development and manufacturing organization (CDMO) that provides drug

substance development and manufacturing across the entire drug lifecycle, as well as comprehensive analytical and IND enabling services.

With over 40 years of experience and a team of 2,000 experts servicing global clients from North America and Europe, Cambrex offers a range of specialized drug substance technologies and capabilities, including continuous flow, controlled substances, liquid-phase peptide synthesis, solid-state science, material characterization, and highly potent APIs. For more information, please visit www.cambrex.com

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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 the upcoming clinical trials and the planned NDA submission to the FDA for the treatment of AUD in the US, developing AD04 for the treatment of AUD, meeting the eventual commercial demands of AD04, the relationships with CDMOs being invaluable the Company moves forward with the initiation of Phase 3 trials 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 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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