Adial Pharmaceuticals Advances Toward Phase 3 Development for AD04

Engages with Cytel's Machine Learning Technology on Data Analysis and Phase 3 Trial Design

GLEN ALLEN, Va., June 11, 2025 (GLOBE NEWSWIRE) -- Adial Pharmaceuticals, Inc. (NASDAQ: ADIL) ("Adial" or the "Company"), a clinical-stage biopharmaceutical company focused on developing precision treatments for addiction and related disorders, today announced progress in the design and planning of its upcoming Phase 3 trial evaluating AD04, its lead investigational therapy for Alcohol Use Disorder (AUD).

As part of its Phase 3 trial preparation, Adial engaged Cytel Inc., a global leader in data science and advanced statistical methodologies for clinical trials, to provide expert support on trial design and data interrogation. Cytel's contributions have helped inform key design elements of Adial's upcoming trial, with the goal of maximizing efficiency, cost-effectiveness, and the likelihood of success. In part, Cytel's efforts identified specific genetic subpopulations potentially more responsive to AD04, thereby enabling a refined Phase 3 strategy that aligns with both clinical and regulatory expectations.

Highlights:

- **Precision Phase 3 Planning:** Post-hoc analyses of historical clinical trial data identified genotype-defined patient subgroups likely to benefit most from AD04. This supports Adial's precision medicine approach in the upcoming Phase 3 trial-targeting higher efficacy and commercial differentiation.
- **Data-Driven, Adaptive Trial Design:** Adial partnered with Cytel to apply advanced statistical analytics and simulation modelling to support a more efficient and targeted Phase 3 strategy, including machine learning and proprietary tools such as East®, to optimize the trial design, enable adaptive enrichment, and align with regulatory expectations.
- **Upcoming Milestones**: The precision-focused Phase 3 trial is expected to begin in late 2025, with potential for interim analysis-driven readouts, supporting a streamlined path to potential regulatory submission.

"Adial's collaboration with Cytel reinforces our commitment to disciplined capital deployment and data-driven execution," said Cary Claiborne, CEO at Adial. "By leveraging advanced analytics and adaptive design, we are in a strong position to generate meaningful clinical data while minimizing time and spend. We believe this strategy materially increases the probability of success for AD04 and creates significant value for patients and shareholders alike."

Adial's platform is focused on developing genetically targeted therapies for addiction-an area of high unmet need and growing public health urgency. The Company believes AD04 represents a first-in-class opportunity in a multi-billion-dollar global AUD market, and that its refined clinical strategy will accelerate value realization.

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 maximizing efficiency, cost-effectiveness, and the likelihood of success of Adial's upcoming trial, enabling a refined Phase 3 strategy that aligns with both clinical and regulatory expectations, targeting higher efficacy and commercial differentiation in the upcoming Phase 3 trial, applying advanced statistical analytics and simulation modelling to support a more efficient and targeted Phase 3 strategy to optimize the trial design, enable adaptive enrichment, and align with regulatory expectations, beginning the Phase 3 trial later this year, the study design supporting a streamlined path to potential regulatory submission, being in a strong position to generate meaningful clinical data while minimizing time and spend by leveraging advanced analytics and adaptive design, the strategy materially increasing the probability of success for AD04 and creating significant value for patients and shareholders, developing genetically targeted therapies for addiction for Adial's platform, AD04 representing a first-in-class opportunity in a multi-billion-dollar global AUD market, accelerating value realization through the Company's refined clinical strategy 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, 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.

Investor Contact:

Crescendo Communications, LLC

David Waldman / Alexandra Schilt

Tel: 212-671-1020

Email: adil@crescendo-ir.com