Adial Pharmaceuticals Reports Third Quarter 2023 Financial Results and Provides Business Update

Advancing Discussions with Potential Strategic Partners

Received Frost & Sullivan's 2023 North American Precision Medicine for Addiction Disorders Technology Innovation Leadership Award

Closed $4 Million Private Placement Priced At-The-Market Under Nasdaq Rules; Extends Cash Runway into Q4 2024

CHARLOTTESVILLE, Va., Nov. 14, 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 provided a business update and reported its financial results for the third quarter of 2023.

Cary Claiborne, President and Chief Executive Officer of Adial, stated, "We have made steady progress throughout the third quarter of 2023 including receiving favorable feedback from our U.S. and EU regulatory meetings, advancing strategic partner discussions, and improving our balance sheet. We are pursuing a highly focused regulatory strategy and are finalizing our clinical development plan which we anticipate will include conducting two phase 3 trials with AD04 in parallel to support potential approval in the shortest timeframe possible while minimizing risk. Our current plan includes focusing on approval in the U.S. as we intend to design the trials to satisfy both U.S. and EU submission requirements."

"We are also under confidentiality agreements and in discussions with companies that have expressed interest in supporting the development and commercial launch of AD04 in both the U.S. and EU. They are currently reviewing data and regulatory feedback from appropriate agencies. Securing quality partnerships would allow us to rapidly penetrate the appropriate markets given the expectation of AD04 being widely accessible, reasonably priced, and reimbursable. Moreover, we have improved our balance sheet as a result of the recent private placement which provided us with an additional $3.5 million of net proceeds, extending our cash runway beyond key upcoming milestones and into the fourth quarter of 2024. Overall, we are focused on a refined, well-researched, and commercially attractive plan for AD04 while having the capital resources to initiate the next phase of our development strategy."

"In addition, we were recently awarded the 2023 Best Practices Technology Innovation Leadership Award in the North American precision medicine for addiction disorders industry by Frost & Sullivan, a globally recognized business consulting firm that offers in-depth market research and analysis. We believe this acknowledgment validates our progress and innovative approach to treating Alcohol Use Disorder. We remain confident in AD04's ability to address the significant unmet need for patients suffering from alcohol use disorder, representing an addressable market of approximately $40 billion in the U.S. alone," concluded Mr. Claiborne.

The complete Frost & Sullivan award report is available at www.frost.com/Adial-Pharmaceuticals.

Third Quarter 2023 Financial Results

- Research and Development expenses decreased by $489 thousand (70%) in the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This decrease was driven partly by a reduction of approximately $383,000 in direct development costs of AD04 as trial activities, which were in their wind-down phase in the third quarter of 2022, were no longer taking place in the third quarter of 2023, replaced by less expensive regulatory consultations and data analysis.
- General and Administrative expenses decreased by $708 thousand (38%) in the three months ended September 30, 2023, compared to the three months ended September 30, 2022. This decrease was due to lower general and

administrative non-equity compensation expenses of approximately $137,000 and lower general and administrative equity compensation expenses of approximately $262,000, which were due to reduced bonus payments and headcount.

- Net Loss was $1.4 million for the three months ended September 30, 2023, compared to a net loss of $3.1 million for the three months ended September 30, 2022.
- Cash and cash equivalents were $315 thousand as of September 30, 2023, compared to $4.0 million as of December 31, 2022. Subsequent to the end of the quarter, the Company completed a private placement resulting in net proceeds of approximately $3.5 million, after deducting agent fees and expenses payable by the Company. The Company believes that the net proceeds from the private placement, together with the collection of the remaining $350 thousand in cost reimbursement related to the Purnovate sale, will fund its current operations into the fourth quarter of 2024.

About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of therapies for the treatment and prevention of addiction 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 (estimated to be approximately one-third of the AUD population) identified using the Company's proprietary 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 FDA approval translating to acceptance in other international markets, plans to conduct two Phase 3 trials with AD04 in parallel to support potential approval in the shortest timeframe possible, progressing with partnering discussions and providing further updates as appropriate, AD04's ability to address a significant unmet need for patients suffering from alcohol use disorder, representing an addressable market of approximately $40 billion in the U.S. alone, being well positioned to execute on the Company's development strategy and reach meaningful milestones that will drive significant value for shareholders 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 retain our key employees or maintain our Nasdaq listing, 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, 2022, 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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