Adial Pharmaceuticals Provides Business Update and Reports Second Quarter 2022 Financial Results

August 16, 2022

Reported positive topline results for ONWARD™ Phase 3 trial of AD04 for the treatment of Alcohol Use Disorder

Pursuing submission of ONWARD™ results with both European and U.S. regulatory agencies

Actively exploring potential partnership opportunities for AD04

Ended second quarter with cash and cash equivalents of $9.2 million

CHARLOTTESVILLE, Va., Aug. 16, 2022 — **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 second quarter of 2022.

William Stilley, Adial's Chief Executive Officer, stated, "We recently reported successful results from the ONWARD trial, our Phase 3 clinical study evaluating the efficacy, safety and tolerability of AD04 in patients with Alcohol Use Disorder ("AUD") and selected polymorphisms in the serotonin transporter and receptor genes. The results showed that AD04 achieved a statistically significant mean reduction in heavy drinking days among the pre-specified group of "heavy drinkers" (avg. <10 drinks per drinking day at baseline), which accounted for approximately two-thirds of the trial population. We did not achieve statistical significance among "very heavy drinkers" (avg. 10 drinks per drinking day at baseline) due to the high placebo response among this particularly challenging patient population, which resulted in us not achieving the primary efficacy analysis among the combined population. Nevertheless, given the strength of the data, especially the statistical significance among heavy drinkers, as well as the safety and tolerability of AD04, we have consulted with both key opinion leaders and our regulatory advisors. Based on the feedback, we strongly believe there is a clear path forward to regulatory submission, and we are more encouraged than ever about the potential for commercialization."

Cary Claiborne, Chief Operating Officer of Adial, further noted, "Moving forward, we are working diligently to submit the ONWARD results to both the U.S. Food and Drug Administration ("FDA") and the European Medicines Authority ("EMA"). Moreover, we are actively exploring potential partnership opportunities in both the U.S. and Europe. Based on just the heavy drinking population alone, which constitutes the majority of AUD patients, we estimate the addressable U.S. market for AD04 to be in the multi-billion dollar range. Overall, we are very pleased with our progress and look forward to providing updates as additional developments unfold."

Other Recent Developments

Patents

Adial has been awarded key patents for AD04 in the United States, European Union and other jurisdictions, including its latest patent issued on June 7, 2022 that expands coverage of a previously issued patent to include the measurement of the genetic biomarkers for all of the targeted genotypes

utilizing our proprietary diagnostic test. This patent estate provides protection through 2031 with expected extensions until 2036.

Purnovate

The Company continues to advance programs developed using its adenosine platform, through its wholly-owned subsidiary, Purnovate, Inc. During the quarter, the Company announced research collaborations with leading adenosine experts to advance research and development of its compounds based on positive pre-clinical data. The Company announced research collaborations with the Medical College of Wisconsin related to the treatment of diabetes and non-alcoholic steatohepatitis (NASH), as well as UC San Diego related to the treatment of inflammatory diseases, including inflammatory bowel disease (IBD) and infectious diseases where a large immune response (i.e., cytokine storm) plays a significant role. The Company continues to advance its Purnovate compounds towards first-in-human clinical trials and has commenced cGMP manufacturing and IND enabling toxicology studies.

Second Quarter 2022 Financial Results

- Cash Position: As of June 30,2022, cash and cash equivalents were $9.2 million as compared to $6.1 million as of December 31, 2021, which the Company believes provides sufficient runway to advance ongoing regulatory and partnering activities related to AD04, as well as advancement of its Purnovate platform.
- Research and Development expenses decreased by $1.1 million to $1.2 million for second quarter of 2022, as compared to $2.3 million in the second quarter of 2021. The decrease was driven by lower costs related to the ONWARD Phase 3 trial as clinical activities were substantially complete by the second quarter of 2022.
- General and Administration expenses increased by $0.5 million to $2.6 million for the second quarter of 2022 as compared to $2.1 million in the second quarter of 2021, with $0.3 million of the increase related to non-cash items. General and administrative expenses held generally steady in the six months ended June 30, 2022, when compared to the six months ended June 30, 2021.
- Net Loss was $3.8 million for the second quarter of 2022 as compared to a net loss of $4.4 million in the second quarter of 2021. Net loss per share for the second quarter of 2022 was $0.16, compared to a net loss of $0.25 per share in the second quarter of 2021.

About Adial Pharmaceuticals, Inc.

Adial Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the development of treatments for addictions. 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. The Company is also developing adenosine analogs for the treatment of pain and other disorders. Additional information is available at www.adial.com.

About Purnovate, Inc.

Purnovate, Inc., a wholly owned subsidiary of Adial Pharmaceuticals, Inc., is a pharmaceutical

development and chemistry company focused on inventing and developing selective, potent, stable, and soluble drug candidates targeting the adenosine receptors to treat diseases and disorders such as pain, asthma, cancer, diabetes, non-alcoholic steatohepatitis (NASH), and inflammatory diseases and disorders such as burn/wound healing, inflammatory bowel disorder and infectious disease.

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 there being a clear path forward to regulatory submission, being more encouraged than ever about the potential for commercialization, submitting the ONWARD results to both the U.S. Food and Drug Administration ("FDA") and the European Medicines Authority ("EMA"),exploring potential partnership opportunities in both the U.S. and Europe, the addressable U.S. market for AD04 being in the multi-billion dollar range based on just the heavy drinking population alone, which constitutes the majority of AUD patients, providing updates as additional developments unfold, continuing to advance programs developed using Purnovate's adenosine platform, Purnovate, Inc. continuing to advance its compounds towards first-in-human clinical trials and cash and cash equivalents providing sufficient runway to advance ongoing regulatory and partnering activities related to AD04, as well as advancement of Purnovate's platform. Any forward-looking statements included herein reflect our current views, and they involve certain risks and uncertainties, including, among others, our ability to complete clinical trials on time and achieve desired results and benefits as expected, our ability to obtain regulatory approvals for commercialization of product candidates or to comply with ongoing regulatory requirements, 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, our ability to establish and maintain collaborations, our ability to obtain or maintain the capital or grants necessary to fund our research and development activities, our cash runway being sufficient to advance ongoing regulatory and partnering activities related to AD04, as well as advancement of Purnovate's platform, 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, 2021, 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.

Contact:
Crescendo Communications, LLC
David Waldman / Natalya Rudman
Tel: 212-671-1021
Email: adil@crescendo-ir.com


Adial
PHARMACEUTICALS