Adial Pharmaceuticals Announces Greater Than 50% of Patients Expected to Complete ONWARD™ Phase 3 Trial of AD04 for the Treatment of Alcohol Use Disorder Have Completed the Full 24-Week Treatment Period – Trial Completion Anticipated Q1 2022

CHARLOTTESVILLE, Va., Sept. 30, 2021 — **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, announces that greater than 50% of patients expected to complete the ONWARD™ Phase 3 trial evaluating AD04 as a therapeutic agent for the treatment of Alcohol Use Disorder (AUD) in persons with certain target genotypes related to the serotonin transporter and receptor genes have completed the full, 24-week, treatment period.

ONWARD is a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel group, pivotal Phase 3 clinical trial to evaluate the efficacy, safety and tolerability of AD04 in patients with AUD and selected polymorphisms in the serotonin transporter and receptor genes.

The intended primary endpoint for analysis of efficacy is the change from baseline in the monthly number of heavy drinking days (HDDs) during the last 8 weeks (weeks 16-24) of the 24-week treatment period, where heavy drinking is defined as the consumption of 5 or more drinks/day for men and 4 or more drinks/day for women.

Drinking levels are self-reported using the timeline follow-back (TLFB) method. The TLFB method is a daily calendar for alcohol consumption and employs memory aids to prompt recall. The TLFB has been used extensively in pharmacotherapy trials for AUD and other substance abuse disorders. Baseline is the 4-week period prior to the screening visit. For each subsequent clinic visit, alcohol consumption is recorded as the number of drinks per day.

Patients have been randomized based on a one-to-one (placebo-to-AD04) ratio, so that approximately 50% of enrolled patients will be in the placebo group and 50% in the AD04 group. Both placebo and active clinical trial material were manufactured in two batches of equal amounts and are light-yellow, oval tablets for oral administration with each tablet weighing approximately 80 mg. Placebo and active tablets are indistinguishable from each other. The active tablets have 0.33 mg of AD04's active ingredient, Ondansetron, in place of a similar volume of excipient (i.e., starch) in the placebo. They have been packaged in blister-packs of 18 tablets, which allows for 7-days of dosing plus 2-days extra to allow for flexibility in appointment scheduling. During packaging, the clinical trial material was coded so that neither the Company, the doctors, nor the patients can determine whether a package contains placebo or active tablets (i.e., double-blinding).

Adverse events are monitored by the Company's Chief Medical Officer; Crown CRO (the contract research organization running ONWARD), and the trial's Data Monitoring Committee. Clinical trial material can be unblinded in the event one of these safety reviewers determines unblinding is necessary to ensure the safety of any particular trial patient on a case-by case basis. To date, no situations have arisen where it was determined unblinding would be warranted, and therefore, no trial patients have had their dosing unblinded to determine if they were taking placebo or active tablets.

ONWARD is being conducted in 25 clinical sites in six countries in Scandinavia and Central and Eastern Europe: Sweden, Finland, Poland, Latvia, Bulgaria and Croatia. The Coordinating Principal Investigator is Professor Hannu E.R. Alho, Emeritus Professor of Addiction Medicine at the University of Helsinki.

Patients are genetically screened prior to enrollment in the ONWARD trial so that only genetically positive patients are enrolled. A total of 1216 people were genetically screened with 403 showing genetic positivity for the AD04 target genotypes (i.e., 33%).

Behavioral therapy (i.e., counseling) is administered to all trial patients so that the placebo or drug will be an adjunct therapy to behavioral therapy. This was required by the regulatory authorities because behavioral therapy is considered the standard of care. A successful approval would therefore likely result in a label stating that AD04 should be

administered in combination with behavioral therapy. This would be expected to be similar to psychiatric drugs, such as anti-depressants. The Company agreed that use of a standardized counseling protocol in the trial would be important and the Company's Chief Medical Officer provided training for all clinical sites to administer the behavioral therapy. All clinical sites have been certified for using this protocol.

In order to qualify for enrollment in ONWARD, in addition to having the genotype, patients had to meet the following additional requirements (i.e., inclusion criteria), among others:

- Male or female over the age of 18 years old;
- Qualify as having AUD under the Diagnostic and Statistical Manual of Mental Disorders, 5th Edition (DSM-5) [Criteria can be found here];
- Have experienced 6 or more heavy drinking days in the previous 4 weeks;
- Have not been abstinent for more than 14 days in the previous 4 weeks; and
- Expression of a desire to reduce or stop alcohol consumption (i.e., are treatment seeking).

Patients meeting the above inclusion criteria were rejected for enrollment in ONWARD based on the following key criteria (i.e., exclusion criteria), among others:

- Withdrawal symptoms requiring medical intervention at either the screening of baseline visit;
- Diagnosis of any of the following concomitant psychiatric disorders: non-treated, unstable schizophrenia, bipolar disorder, other psychotic disorder during the lifetime of the patient;
- Recent (within last 12 months) diagnosis of a major depressive disorder, post-traumatic stress disorder, panic disorder or eating disorder;
- Current or recent treatment with antipsychotics or antidepressants medications, which can have an effect on serotonin receptor or transporter actions, or opiate antagonists (e.g., naltrexone, Vivitrol®, Selincro®), glutamate antagonists (e.g., acamprosate), anticonvulsants (e.g., topiramate), serotonin reuptake inhibitors (e.g., fluoxetine), serotonin antagonists (e.g., buspirone), other antidepressants (e.g., tricyclic antidepressants or monoamine oxidase inhibitors), dopamine antagonists (e.g., haloperidol), and disulfiram (Antabuse®);
- Clinically significant untreated and unstable illness, for example, hepatic or renal insufficiency, or a cardiovascular, pulmonary, gastrointestinal, endocrine, neurological, infectious, neoplastic, or metabolic disturbance;
- Clinically abnormal ECG or significantly abnormal vital signs;
- Clinically significant hepatic disease; and
- Positive pregnancy test (females only).

The ONWARD Phase 3 clinical trial commenced with the opening of a site in Finland in February 2020, and 302 patients have been enrolled. Enrollment was closed on August 30, 2021 immediately after the 302nd patient was randomized for placebo or active treatment and completed the first treatment visit. Since each trial patient undergoes approximately 24 weeks of treatment, the last patient should complete dosing in February 2022. Each patient receives a follow-up call approximately 4 weeks after completing of the full treatment cycle to collect additional safety and tolerability information.

As of the week ending September 24th, 120 patients had successfully completed their participation in the trial, 60 patients had discontinued participation in the trial prior to completion, and 122 patients are still being dosed in the trial. As stated above, the last of these patients is expected to complete dosing in February 2022. Patient retention rates continue to exceed projections.

As each ONWARD trial site discharges its last patient, the Company will work expeditiously to resolve any outstanding data queries at each site so that it can be closed upon the last follow-up call 4 weeks later. Once the last patient completes his or her final dose, which is expected in February 2022, the Company anticipates closing the last site within 6 weeks. Following closure of the last site, the database containing all the information will be "locked," meaning it can no longer be changed; the trial will be unblinded so that it will be known for each patient whether the patient received placebo

or active tablets; and data analysis will commence by the Company's outside statisticians. Results will be released expeditiously, likely within a few weeks of the last site closure.

Dr. Bankole Johnson, Adial's Chief Medical Officer, commented, "Having overseen more than 20 AUD and other addiction related clinical trials during the course of my career, I am invigorated by the rapid progress of our ONWARD Phase 3 trial. Just last month we announced we had achieved full enrollment and now we have taken 50% of patients expected to complete the trial through their full trial dosing range of 24-weeks. We remain encouraged by the trial retention rate, which has exceeded our expectations. Importantly, we remain on target to complete all patient dosing in the first quarter of 2022. I would like to thank our team, our CRO and the clinical investigators for their hard work in efficiently advancing this important trial. I look forward with anticipation to trial data with great expectations."

William Stilley, Adial's Chief Executive Officer, stated, "Following years of research and clinical trials, as we move closer to completion of our ONWARD Phase 3 trial of AD04 for the treatment of AUD, we are highly confident that our genetically targeted approach may provide significant promise for those suffering from this devastating disease, which contributes to the annual deaths of more than 3 million people and costs the U.S. economy approximately $250 billion annually. This trial is especially timely given the dramatic increase in the number of persons suffering with this disorder, exacerbated in significant part due to the ongoing effects of the pandemic. In ONWARD, we anticipate demonstrating a favorable safety profile with AD04 with a low occurrence of any side effects and we are optimistic we will meet our primary endpoint. With the ease of oral administration by patients, we believe those suffering from AUD will be more likely to complete their treatment regimen in the real world as compared with current therapies, which are all known to have side effects that we believe, on balance, are more significant than those expected to be demonstrated by AD04. I extend a heartfelt thank you to our entire trial team and our patients that are bringing us closer to a new day in the treatment of alcohol use disorder."

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) and is currently being investigated in the Company's landmark pivotal ONWARD™ Phase 3 clinical trial for the potential treatment of AUD in patients with certain target genotypes, which are identified using the Company's proprietary companion diagnostic genetic test. A Phase 2b clinical trial of AD04 for the treatment of AUD showed promising results in reducing frequency of drinking, quantity of drinking and heavy drinking (all with statistical significance), and no overt safety concerns (there were no statistically significant serious adverse events reported). 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.adialpharma.com.

About the Landmark ONWARD™ Pivotal Phase 3 Clinical Trial

The ONWARD trial is a 24-week, multicenter, randomized, double-blind, placebo-controlled, parallel group, pivotal Phase 3 clinical trial to evaluate the efficacy, safety and tolerability of AD04 in patients with Alcohol Use Disorder (AUD) and selected polymorphisms in the serotonin transporter and receptor genes. Patients are genetically screened prior to enrollment in the ONWARD trial so that only genetically positive patients are enrolled. The primary endpoint for analysis of efficacy is the change from baseline in the monthly number of heavy drinking days during the last 8 weeks of the 24-week treatment period. ONWARD is currently being conducted in 25 clinical sites in six countries in Scandinavia and Central and Eastern Europe (Sweden, Finland, Poland, Latvia, Bulgaria and Croatia). The Coordinating Principal Investigator is Professor Hannu E.R. Alho, Emeritus Professor of Addiction Medicine at the University of Helsinki.

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 completion of the ONWARD Phase 3 trial in Q1 2022, the last patient dosing being completed in February 2022, the Company's genetically targeted approach providing significant promise for those suffering from AUD, demonstrating a favorable safety profile with AD04 with a low occurrence of any side effects, meeting the primary endpoint, patients suffering from AUD being more likely to complete their treatment regimen in the real world as compared with current therapies due to the ease of oral administration by patients, side effects of current treatments being more significant than those expected to be demonstrated by AD04, 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 complete the ONWARD Phase 3 trial in Q1 2022 and complete dosing of the last patient in February 20222, and achieve desired results and benefits as expected, including meeting the primary endpoint and a favorable safety and low-side effect profile, 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 product candidates in the marketplace and the successful development, marketing or sale of 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 its research and development activities, 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, 2020, 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