Dyadic Provides Phase 1 Clinical Trial Update for its DYAI-100 COVID-19 Recombinant Protein RBD Booster Vaccine Candidate

- *Dosing of all patients was completed at the end of February*
- *No Serious Adverse Events (SAE's) have been reported*
- *Phase 1 clinical initial safety and antibody response update expected in Q2, 2023*

JUPITER, Fla., March 07, 2023 (GLOBE NEWSWIRE) -- Dyadic International, Inc. ("Dyadic", "we", "us", "our", or the "Company") (NASDAQ: DYAI), a global biotechnology company focused on building innovative microbial protein production platforms to address the growing demand for global protein bioproduction and unmet clinical needs for effective, affordable and accessible biopharmaceutical products for human and animal health, today provided an update regarding its Phase 1 Clinical Trial for its DYAI-100 COVID-19 recombinant protein receptor binding domain (RBD) booster vaccine candidate.

"We are pleased that patient dosing of both low and high dose groups has been completed. Thus far, the vaccine has been well tolerated with no Serious Adverse Events being reported to date," said Mark Emalfarb, CEO of Dyadic. "While our C1 protein production platform has shown safety and efficacy in multiple animal studies for vaccines and antibodies, this is the first time a vaccine or treatment manufactured from our C1-cell protein production platform has been tested in humans for clinical safety. The DYAI-100 recombinant protein antigen COVID-19 booster vaccine is an example of our highly efficient and economical approach to the rapid manufacture of large quantities of vaccines."

Mr. Emalfarb continued, "This study is also expected to demonstrate antibody responses in humans from C1 produced antigens and the success of this trial is expected to accelerate the adoption of Dyadic's C1-cell protein production platform for both vaccine and therapeutic candidates. We are already starting to see an increased level of interest from academia, industry, and government agencies."

About DYAI-100

DYAI-100, also known as C1-SARS-CoV-2 RBD vaccine, is a novel receptor binding domain (RBD) recombinant protein booster vaccine candidate, highly expressed in Dyadic's proprietary C1-cell protein production platform for the prevention of COVID-19. The C1-SARS-CoV-2 RBD vaccine drug product consists of the SARS-CoV-2 RBD adjuvanted with Alhydrogel 85® 2%.

About DYAI-100 Phase 1 Clinical Trial

Dyadic's Phase 1 randomized, double blind, placebo-controlled trial is designed as a first-in-human trial to assess the clinical safety and antibody response of DYAI-100, a C1-SARS-CoV-2 recombinant protein receptor binding domain (RBD) vaccine, produced using the C1-cell protein production platform, administered as a booster vaccine at two single dose levels (low dose and high dose cohorts) in healthy volunteers.

The trial included healthy patients ages 18-55 in a randomization scheme of 4:1 (active:placebo) with 15 subjects per cohort. Following the screening period there were 8 scheduled clinic visits with the first 6 visits occurring within the first 29 days and two follow-up visits on Days 90 and 180. Safety data was collected throughout the trial and immunogenicity assessments were scheduled on patient visits 1, 4, 5, 6 and the two follow up visits on Days 90 and 180. A full study report is expected to be available in the second half of 2023.

About Dyadic International, Inc.

Dyadic International, Inc. is a global biotechnology company focused on building innovative microbial platforms to address the growing demand for global protein bioproduction and unmet clinical needs for effective, affordable, and accessible biopharmaceutical products for human and animal health.

Dyadic's gene expression and protein production platforms are based on the highly productive and scalable fungus *Thermothelomyces heterothallica* (*formerly Myceliophthora thermophila*). Our lead technology, C1-cell protein production platform, is based on an industrially proven microorganism (named C1), which is currently used to speed development, lower production costs, and improve performance of biologic vaccines and drugs at flexible commercial scales for the human and animal health markets. Dyadic has also developed the Dapibus™ filamentous fungal based microbial protein production platform to enable the rapid development and large-scale manufacture of low-cost proteins, metabolites, and other biologic products for use in non-pharmaceutical applications, such as food, nutrition, and wellness.

With a passion to enable our partners and collaborators to develop effective preventative and therapeutic treatments in both developed and emerging countries, Dyadic is building an active pipeline by advancing its proprietary microbial platform technologies, including our lead asset DYAI-100 COVID-19 vaccine candidate, as well as other biologic vaccines, antibodies, and other biological products.

To learn more about Dyadic and our commitment to helping bring vaccines and other biologic products to market faster, in greater volumes and at lower cost, please visit https://www.dyadic.com.

Safe Harbor Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934, including those regarding Dyadic International's expectations, intentions, strategies, and beliefs pertaining to future events or future financial performance, such as the success of our clinical trial and interest in our protein production platforms, our research projects and third-party collaborations, as well as the availability of necessary funding. Actual events or results may differ materially from those in the forward-looking statements because of various important factors, including those described in the Company's most recent filings with the SEC. Dyadic assumes no obligation to update publicly any such forward-looking statements, whether because of new information, future events or otherwise. For a more complete description of the risks that could cause our actual results to differ from our current expectations, please see the section entitled "Risk Factors" in Dyadic's annual reports on Form 10-K and quarterly reports on Form 10-Q filed with the SEC, as such factors may be updated from time to time in Dyadic's periodic filings with the SEC, which are accessible on the SEC's website and at www.dyadic.com.

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