Dyadic Announces Initiation of Dosing of First-In-Human Phase 1 Trial to Demonstrate Clinical Safety and Antibody Response in Humans for DYAI-100 COVID-19 Recombinant Protein RBD Booster Vaccine Candidate

JUPITER, Fla., Jan. 24, 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 today announced that, in line with the timing announced during management’s Q3 earnings call, it has initiated dosing in its Phase 1 clinical trial to demonstrate clinical safety and antibody response in humans for the DYAI-100 COVID-19 recombinant protein receptor binding domain (RBD) booster vaccine candidate.

The 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 RBD vaccine, produced using the C1 platform, administered as a booster vaccine at two single dose levels in healthy volunteers. Following the regulatory approval from the South African Health Products Regulatory Authority (SAHPRA) in late 2022, site preparations and patient recruitment was commenced in South Africa for initiation of the Phase 1 clinical trial and the first dosing for eligible patients began during the week of January 9th.

The trial will include healthy patients ages 18-55 in a randomization scheme of 4:1 with 15 subjects per cohort. Following the screening period there are 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 will be collected throughout the trial and immunogenicity assessments are scheduled on patient visits 1, 4, 5, 6 and the two follow up visits on Days 90 and 180. Dosing for the trial is expected to be completed within the first quarter of 2023, with a full study report being available later this year.

“Dyadic and our South African partner, Rubic One Health, are very pleased that dosing has begun for the DYAI-100 COVID-19 booster vaccine candidate,” commented Mark Emalfarb, President and Chief Executive Officer of Dyadic. “With the initiation of the Phase 1 clinical trial, this is the first time a vaccine or treatment manufactured from our C1 protein production platform is being tested in humans. Importantly, this study is expected to demonstrate clinical safety and antibody response in humans to help further combat the COVID-19 pandemic. The results from this first in human clinical trial are expected to accelerate the adoption of the C-1 protein production platform for both vaccine and therapeutic candidates. We continue to believe that the use of our industrially proven, highly productive C1 protein production platform to manufacture the recombinant protein antigen used in DYAI-100 represents a novel, highly efficient and economical approach to rapidly manufacture large quantities of vaccines,” Mr. Emalfarb concluded.

About Dyadic International, Inc.

Dyadic International, Inc. is a global biotechnology company committed to 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, 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 https://www.dyadic.com.

Contact:

Dyadic International, Inc.
Ping W. Rawson
Chief Financial Officer
Phone: (561) 743-8333
Email:_mailto:ir@dyadic.com