

## **Dyadic Provides Phase 1 Clinical Trial Update for its Recombinant Protein RBD Vaccine Candidate**

- *Dosing of patients completed at the end of February*
- *Data Safety Monitoring Board conducted analysis of Day 29 data*
- *No major vaccine-related safety concerns for either of the two dose levels*
- *No Serious Adverse Events (SAE's) or Adverse Events of Special Interest reported*
- *DYAI-100 RBD COVID-19 booster vaccine produced immune response at both dose levels*
- *Phase 1 full study report expected in Q4, 2023*

JUPITER, Fla., July 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 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.

An interim analysis of the Day 29 data for both the low and high dose groups by the Data Safety Monitoring Board (DSMB) determined there were no major vaccine-related safety concerns. As previously reported, no Serious Adverse Events or Adverse Events of Special Interest have been reported to date. Preliminary immunogenicity data has shown that DYAI-100 vaccine produced an immune response at both the low and high dosages.

“We are excited that the interim analysis of Day 29 data for a vaccine produced using our C1 platform has shown no major vaccine related safety concerns and that our vaccine candidate has been shown to produce an immune response in addition to being well tolerated,” said Mark Emalfarb, CEO of Dyadic. “This Phase I data demonstrates that a C1 produced protein is safe in humans which is a pivotal point in the evolution from our commercial success in industrial biotech to broadening our capability as a life-science biotechnology company. We believe this data will further accelerate the broadening interest and global adoption of our C1 platform which is already being embedded into a growing number of funded opportunities across industry, academia, and government in human and animal biopharmaceuticals,” concluded Mr. Emalfarb.

“We believe today’s announcement further demonstrates that the C1 platform is ready for broader adoption and commercialization, providing customers with the confidence that our C1-cell microbial protein production platform offers the speed, cost, and quality needed to gain market share in the competitive vaccine industry,” said Joe Hazelton, Dyadic’s Chief Business Officer. “As demonstrated by our recently announced fully funded project with a top five pharmaceutical company in a large infectious disease segment, Dyadic is expanding its

C1 licensing programs for strain engineering and production services with a focus on customers interested in creating high performance microbial strains for their vaccine antigens.”

### **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 was 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 fifteen subjects per cohort. Following the screening period there were eight scheduled clinic visits with the first six 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](http://www.dyadic.com).

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