Dyadic Announces Successful Toxicology Data Published in “Toxicologic Pathology”

- ***Toxicology data published in the international peer-reviewed scientific journal “Toxicologic Pathology” demonstrates excellent safety profile and lasting immunogenic response from Dyadic’s DYAI-100, recombinant protein receptor binding domain (RBD) COVID-19 vaccine candidate***
- ***Data further supports Dyadic’s anticipated First-In-Human clinical trial designed to accelerate adoption of its C1-cell protein production platform for manufacturing biopharmaceuticals***
- ***3rd peer-reviewed publication in 2022 relating to antigens produced from C1-cells showing safety and efficacy in animal models***

JUPITER, Fla., May 09, 2022 (GLOBE NEWSWIRE) — Dyadic International, Inc. (“Dyadic”, “we”, “us”, “our”, or the “Company”) (NASDAQ: DYAI), a global biotechnology company focused on deploying its proprietary C1-cell protein production platform to accelerate development, lower production costs and improve the performance of biologic vaccines and therapeutics, announced today the successful results and data received from the toxicology study of its DYAI-100 COVID-19 vaccine candidate. ***“Toxicity and Local Tolerance of a Novel Spike Protein RBD Vaccine Against SARS-CoV-2, Produced Using the C1 Thermothelomyces Heterothallica Protein Expression Platform”*** has been published in “*Toxicologic Pathology”* 2022, Vol. 50(3) 1-14″, an international peer-reviewed scientific journal. The toxicology study was performed under GLP Tox conditions by Covance’s Envigo CRS Israel Ltd (“Envigo”).

The paper summarizes the successful toxicological evaluation of Dyadic’s DYAI-100, Recombinant Protein RBD (Receptor Binding Domain) COVID-19 vaccine candidate, which was conducted under GLP conditions in a standardized accepted animal model for New Zealand White (NZW) rabbits. The NZW rabbits were repeatedly administered intramuscularly for a total of four administrations 1 week apart supporting a three-shot vaccination. No signs of toxicity were observed, including no injection site reactions. Starting from day 13 post-injection, ELISA studies revealed SARS-CoV-2 specific IgG antibodies were further elevated in the sera of the animals vaccinated. Histopathology evaluation and IHC staining revealed follicular hyperplasia, consisting of B-cell type, in the spleen and inguinal lymph nodes of the treated animals that were sustained throughout the recovery phase. “The fact that these changes were present throughout the recovery phase as well, demonstrates that the reaction provides sustained immunogenic response against RBD,” said Dr. Abraham Nyska, DVM, Dipl. ECVP, Fellow IATP, expert in toxicologic pathology.

“This paper demonstrates an excellent safety profile and an important lasting immunogenic response against RBD elicited from Dyadic’s DYAI-100 vaccine candidate which further supports the development of DYAI-100 for use in humans,” said Ronen Tchelet, Dyadic’s

Chief Scientific Officer.

“We have repeatedly demonstrated our C1 protein production platform can be used to rapidly develop stable cell lines and produce large quantities of recombinant protein antigens at low cost. Dyadic has generated stable cell lines for Wuhan, Alpha, Beta, Gamma, Delta, and Omicron, providing an effective and affordable traditional vaccine manufacturing capability that can provide our partners with a very powerful tool in the global battle against emerging SARS-CoV-2 viruses as well as future zoonotic and other biological threats.” concluded Dr. Tchelet.

Mark Emalfarb, Dyadic’s Founder and CEO, also commented, “This study is an important milestone in our goal to advance Dyadic’s proprietary and patented Recombinant Protein (RBD) DYAI-100 COVID-19 vaccine candidate, towards the first-in-human Phase 1 clinical trial which we believe will also validate that C1 produced proteins are safe in humans and further accelerate adoption of our C1-cell protein production platform. We believe the C1 protein production platform can help address unmet global needs for access to large quantities of affordable novel vaccines and therapeutic treatments in timeframes that can impact the changing pandemic landscape and help to make healthcare accessible and affordable to patients globally.”

The article can be accessed through the *Toxicologic Pathology* website or in the Scientific Publications section of the Company’s website below:

https://www.dyadic.com/wp-content/uploads/2022/05/Sage-Journals-5-5-22.pdf

About Dyadic International, Inc.

Dyadic International, Inc. is a global biotechnology company which is developing what it believes will be a potentially significant biopharmaceutical gene expression platform based on the fungus *Thermothelomyces heterothallica* (formerly *Myceliophthora thermophila*), named C1. The C1 microorganism, which enables the development and large-scale manufacture of low-cost proteins, has the potential to be further developed into a safe and efficient expression system that may help speed up the development, lower production costs and improve the performance of biologic vaccines and drugs at flexible commercial scales. Dyadic is using the C1 technology and other technologies to conduct research, development and commercial activities for the development and manufacturing of human and animal vaccines and drugs, such as virus like particles (VLPs) and antigens, monoclonal antibodies, Fab antibody fragments, Fc-Fusion proteins, biosimilars and/or biobetters, and other therapeutic proteins. Certain other research activities are ongoing which include the exploration of using C1 and other technologies to develop and produce certain metabolites and other biologic products. Dyadic pursues research and development collaborations, licensing arrangements and other commercial opportunities with its partners and collaborators to leverage the value and benefits of these technologies in development and

manufacture of biopharmaceuticals. As the aging population grows in developed and undeveloped countries, Dyadic believes the company's technologies may help bring biologic vaccines, drugs, and other biologic products to market faster, in greater volumes, at lower cost, and with new properties to drug developers and manufacturers, and improve access and cost to patients and the healthcare system, but most importantly save lives.

Please visit Dyadic's website at https://www.dyadic.com for additional information, including details regarding Dyadic's plans for its biopharmaceutical business.

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. 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: ir@dyadic.com