Dyadic Announces Top-Line Results from its Successful Phase 1 Clinical Trial for a First-in-Human Filamentous Fungal-Based Vaccine Candidate

- ***Primary endpoint met***
- ***Demonstrated safety and reactogenicity of DYAI-100 recombinant protein***
- ***C1-cell produced antigen was both safe and well-tolerated***
- ***No Serious Adverse Events reported***
- ***Final Clinical Study Report available in the coming weeks***

JUPITER, Fla., Nov. 29, 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 announced successful top-line results for the Phase 1 clinical trial of its recombinant protein RBD vaccine candidate, DYAI-100. This marks the first-in-human use of a recombinant protein vaccine expressed by Dyadic's C1- cell expression platform.

The Phase 1 clinical trial was a double-blind placebo-controlled safety study of 30 healthy adults conducted in collaboration with Dyadic's South Africa licensee Rubic One Health ("Rubic"). In late 2022, Dyadic received regulatory approval of its Clinical Trial Application (CTA) from the South African Health Products Regulatory Authority (SAPHRA) to conduct the Phase I clinical trial for an antigen produced using its C1-cell protein expression platform. The primary endpoint of the study was to demonstrate the safety and reactogenicity of recombinant proteins. The C1 SARS-CoV-2 RBD single booster vaccine was administered at two dose levels. Top-line safety data confirmed that the study met its primary endpoint demonstrating that both dose levels are safe and well tolerated and that the vaccine produced immune responses at both dose levels.

"We are excited to share the top-line results from what we believe marks the first-in-human clinical trial for a vaccine antigen produced using a filamentous fungal cell line, such as our C1 platform," said Mark Emalfarb, CEO of Dyadic. "While vaccines and antibodies produced from our C1-cell protein production platform have previously demonstrated safety and efficacy in animal studies, this trial represents the initial evaluation of a C1-cell produced protein in humans and is clearly a key milestone for the Company. Notably, no Serious Adverse Events were reported, and the clinical study successfully met its primary endpoint demonstrating that a C1 produced antigen was both safe and well-tolerated in both the low and high dose groups."

Mr. Emalfarb continued, "The success of our phase 1 trial resulted in increased interest globally from academia, industry, government agencies, and non-profit vaccine development organizations that are considering leveraging our C1-cell expression platform for the

development of vaccine antigens and therapeutic proteins."

Dr. Julian Naidoo, Chief Executive Officer of Rubic One Health, Dyadic's African licensee, commented, "We believe Dyadic's C1 technology is a game changer in the vaccine manufacturing space for not only the African population but also patients in countries across all income levels worldwide." Dr. Naidoo continued, "Dyadic's successful DYAI-100 Phase 1 Clinical Trial results support our mission to bring much needed high demand vaccines that are safe, effective, and affordable to the African Continent. We believe that vaccines expressed from C1 are particularly well-suited for African conditions, as C1 produced recombinant vaccines do not need ultra-cold production or storage which can be distributed safely in remote and rural areas across the African continent."

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, visit www.dyadic.com.

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 Rubic One Health

Rubic One Health is made up of promoters of the project representing public health, medical, academia, vaccine technology, technology transfer and economics sectors. Development and the implementation of vaccine technologies is overseen by leading academics directed by the University of the Witwatersrand, Johannesburg (Wits) academic team, with the support of Wits Health Consortium (WHC), a wholly owned company of Wits. The Consortium collectively has a long track record in the fields of vaccinology, public health medicine, clinical trials, research, technology transfer, project management and health economics. This entity will coordinate the project, ensuring a synergistic outcome between the components of drug discovery/research and manufacture. It will also drive the strategic and operational direction. This will be accomplished by engaging with stakeholders and public health experts and academics to ensure that the company moves forward in a sustainable, Afro-centric manner, rooted in public good.

Visit Rubic's website at https://www.rubiconehealth.co.za for additional information.

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 third party interest in our C1-cell expression platform, the success of future clinical trial(s) of ours or our collaborators if any, 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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