Dyadic Advancing Towards Human Clinical Trial of its SARS-CoV-2-S-RBD vaccine candidate, DYAI-100

- ***Israel Institute for Biological Research (IIBR) reports successful challenge studies using human ACE2 transgenic mice vaccinated with SARS-CoV-2-S-RBD vaccine candidate manufactured from C1-cells***
- ***DYAI-100 generated high levels of neutralizing antibodies in preclinical studies in mice, supporting its potential to promote excellent immunogenicity responses***
- ***DYAI-100 has been evaluated in ten animal trials by academic, industrial, and governmental R&D groups globally***
- ***Engaged CR2O, a contract research organization, to manage and support further preclinical and clinical development of DYAI-100***
    - ***Toxicology study expected to begin in Q2 2021***
    - ***First-in-human Phase 1 clinical trial expected to begin in 2H 2021***
- ***A successful Phase 1 clinical trial using DYAI-100 will help validate protein antigens manufactured from C1-cells are safe in humans***
- ***In parallel with advancing DYAI-100, Dyadic is engineering additional C1-cells to manufacture SARS-CoV-2 variant antigens for monovalent and multivalent vaccine candidates.***

JUPITER, Fla., March 18, 2021 (GLOBE NEWSWIRE) — Dyadic International, Inc. (“Dyadic”, “we”, “us”, “our”, or the “Company”) (NASDAQ: DYAI), a global biotechnology company focused on further improving, applying and deploying its proprietary C1-cell protein production platform to accelerate development, lower production costs and improve the performance of biologic vaccines and drugs at flexible commercial scales, today announced that the Company’s initial C1 produced SARS-CoV-2-S-RBD vaccine candidate, DYAI-100, is moving towards an anticipated safety and preliminary efficacy first in human Phase 1 clinical trial. Dyadic has entered into a master services agreement with CR2O, a full-service global contract research organization specializing in vaccinology, to manage preclinical and clinical development of DYAI-100.

CR2O’s Chief Scientific Officer, Prof. Dr. Albert Osterhaus commented, “In response to the COVID-19 pandemic, pharmaceutical companies have developed vaccines within the unprecedented period of less than one year. To this end, and in close collaboration with strategic partners, they have implemented state-of-the-art technologies including the use of mRNA, viral vectors, and novel adjuvants. To effectively combat the COVID-19 pandemic worldwide, second generation variants of concern vaccines, produced at low cost and in large scale, are now urgently needed. The collaboration with Dyadic to use their highly-productive fungal C1-cell protein manufacturing system for this purpose appears to be a logical and

promising way forward."

"The ongoing devastating COVID-19 pandemic requires new variant of concern vaccine approaches that are not only safe, effective and protective but can also be scaled up to meet the global need for billions of doses of vaccines at an affordable price. We are honored to partner with Dyadic and its strategic partners in developing an affordable, scalable, protective and safe vaccine to combat this disease that continues to impact our everyday life," added Hadil Es-Sbai, CR2O's Chief Executive Officer.

Dyadic's Chief Scientific Officer, Ronen Tchelet PhD added, "Moving DYAI-100 into a first in human Phase 1 clinical trial is a major milestone for Dyadic International. We believe that demonstrating the safety and preliminary efficacy of DYAI-100 and potential variants of concern vaccine candidates in humans will open the door for a significant number of opportunities for Dyadic and our collaborators to manufacture, partner and commercialize vaccines for human and animal protection. With CR2O, we continue to build momentum in our efforts to develop safe, effective, and protective vaccine candidates that can be rapidly and efficiently manufactured which are well suited for global commercialization of variants of concern multivalent vaccines. Preclinical results for the SARS-CoV-2-S-RBD produced from C1-cells indicate safety, efficacy and protection in animal studies conducted by the IIBR, including the recently reported successful challenge studies using human ACE2 transgenic mice vaccinated with their SARS-CoV-2-S-RBD vaccine candidate produced from C1-cells. Further, as the SARS-CoV-2 virus continues to mutate into different variants of concern, we are developing vaccine candidates with the potential to confer broader efficacy against SARS-CoV-2 variants of concern."

Mark Emalfarb, Dyadic's Founder and Chief Executive Officer said, "We have demonstrated the potential to efficiently manufacture large quantities of affordable recombinant protein antigens produced from C1-cells. This clinical program will enable two key strategic advancements for Dyadic, demonstrating that recombinant vaccine antigens produced from C1-cells are safe and immunogenic in human subjects. Dyadic's strategy is to manufacture, partner and commercialize safe, effective, and protective human and animal vaccines including variants of concern for SARS-CoV-2. In parallel with advancing DYAI-100, Dyadic is engineering additional C1-cell lines to manufacture SARS-CoV-2 variant antigens for monovalent and/or multivalent vaccine candidates."

About CR2O

CR2O is a full service CRO, specialized in managing and operating clinical development activities towards infectious disease interventions. In the past decade, CR2O clinical experts contributed to >100 clinical trials in over 30 countries. Headquartered near Utrecht, The Netherlands, CR2O will continue to combine its scientific expertise and operational excellence to meet unmet medical needs in the virology field. More information can be found at

www.cr2o.nl

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 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 C1 technology 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 http://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 http://www.dyadic.com.

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