

February 13, 2024



## **Dyadic and Cygnus Technologies Announce Partnership To Provide C1 HCP ELISA Assay to Enhance Quality Assurance in Biomanufacturing**

JUPITER, Fla. and LELAND, N.C., Feb. 13, 2024 (GLOBE NEWSWIRE) -- Dyadic International Inc. ("Dyadic", or the "Company") (Nasdaq: DYAI) and Cygnus Technologies®, part of Maravai LifeSciences® (Nasdaq: MRVI), announced today a strategic partnership for the quantification of Host Cell Proteins ("HCP") from the proprietary and patented C1-cells filamentous fungus *Thermothelomyces heterothallica*, (formerly *Myceliophthora thermophila*). Under the terms of the partnership agreement, Cygnus has developed the C1 HCP ELISA Kit, which will be made available to Dyadic and Cygnus customers.

HCP measurements are critical quality-control steps in biopharmaceutical development because the presence of these impurities in the final product can potentially interfere with drug efficacy, induce an undesired immune response, or impact drug stability. Biopharmaceutical manufacturers monitor HCPs to demonstrate reproducibility of their purification process, ensure HCP clearance and perform product lot release testing. The development of the C1 HCP ELISA Kit further demonstrates that Dyadic's C1 protein expression platform is keeping pace with industry standards for HCP analysis in biopharmaceutical manufacturing.

Cygnus Technologies is an industry pioneer responsible for developing and commercializing the first generic assay kits for HCP detection. Cygnus Technologies' HCP ELISA Kits have long been considered the gold standard in HCP impurity quantification, and its reputation for quality is recognized by industry and global regulatory agencies. The antibody used in the kit has been evaluated for reactivity to more than 1,000 individual HCPs present in C1 strains by state-of-the-art antibody affinity extraction and mass spectrometry methods. The kit has been qualified with many drug substances and in-process samples, providing the specificity and sensitivity to detect C1-HCP impurities with reproducibility that supports downstream purification monitoring, product lot release and regulatory compliance.

Mark Emalfarb, CEO of Dyadic, commented, "I can't stress enough the significance of our partnership with Cygnus, the C1 HCP assay provides adopters of our C1 microbial production platform a solution for testing C1 HCP impurity during product lot release testing, thereby enhancing the quality assurance process in biomanufacturing. The biopharmaceutical industry demands a fast, efficient, and reliable method for monitoring HCPs during manufacturing to ensure the delivery of safe and efficacious products in a cost-effective manner. Our collaboration with Cygnus resulted in the development of a first-in-

class C1 HCP ELISA assay, making a significant step toward greater adoption of the C1 technology globally.”

Christine Dolan, Cygnus Technologies Chief Operating Officer, stated, “We are very excited about the launch of the highly anticipated C1 HCP ELISA Assay. The assay is expected to play an important role in facilitating the broad adoption of Dyadic's C1 protein production platform which enables rapid and efficient low-cost production of antigens, monoclonal antibodies, and other therapeutic proteins. We are proud to partner with Dyadic to help accelerate the adoption of their C1 platform, ultimately aiming to enhance access and affordability of healthcare for patients in developed and developing countries.”

### **About Cygnus Technologies, LLC**

Cygnus Technologies, part of Maravai LifeSciences, is the biopharmaceutical industry's partner in host cell protein (HCP) and other process-related impurity detection and analytics as well as in innovative viral clearance solutions. Cygnus helps companies developing therapeutic proteins, vaccines, antibodies, plasma derivatives and gene therapies to ensure the safety of biotherapeutics prior to human trials, regulatory approval and commercial release. For more information on Cygnus Technologies, please visit [www.cygnustechnologies.com](http://www.cygnustechnologies.com).

### **About Maravai**

Maravai is a leading life sciences company providing critical products to enable the development of drug therapies, diagnostics and novel vaccines. Maravai's companies are leaders in providing products and services in the fields of nucleic acid synthesis and biologics safety testing to many of the world's leading biopharmaceutical, vaccine, diagnostics, and cell and gene therapy companies. For more information about Maravai LifeSciences, visit [www.maravai.com](http://www.maravai.com).

Media Contact:  
Deb Hart  
Maravai LifeSciences  
+ 1 858-988-5917  
[ir@maravai.com](mailto:ir@maravai.com)

### **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 and alternative proteins 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).

### **Contact:**

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



Source: Dyadic International, Inc.

