Cellares and Lyell to Evaluate Automated Manufacturing of Lyell's CAR T-Cell Therapy on Cellares' Cell Shuttle Platform

September 11, 2023 at 8:00 AM EDT

- *Proof-of-concept manufacturing to be provided by Cellares for a key Lyell CAR T-cell therapy using Cellares' exclusive Cell Shuttle*
- *Collaboration to evaluate potential utilization of the Cell Shuttle for future Lyell CAR T-cell clinical trials and commercialization*

SOUTH SAN FRANCISCO. Calif., Sept. 11, 2023 (GLOBE NEWSWIRE) -- Cellares, the first Integrated Development and Manufacturing Organization (IDMO) dedicated to clinical and industrial-scale cell therapy manufacturing, and Lyell Immunopharma (NASDAQ: LYEL), a clinical-stage T-cell reprogramming company advancing a diverse pipeline of cell therapies for patients with solid tumors, today announced Lyell will evaluate Cellares' automated manufacturing platform, the Cell Shuttle™, through Cellares' Technology Adoption Partnership (TAP) program. As part of the collaboration, the companies have agreed on a proof-of-concept technology transfer process for the manufacture of Lyell's LYL797 CAR T-cell therapy, using the Cell Shuttle.

CAR T-cell therapy is a personalized immunotherapy that takes a patient's own T cells and modifies them to recognize and kill cancer cells that have a specific biomarker. LYL797 is an investigational CAR T-cell therapy in development for the treatment of solid tumors that express ROR1, a protein present on the surface of various solid tumors. LYL797 is enhanced with Lyell's novel genetic and epigenetic reprogramming technologies designed to generate highly tumor-reactive, longer-lasting functional T cells. Lyell is enrolling patients with triple-negative breast cancer and non-small cell lung cancer in a Phase 1 clinical trial evaluating LYL797.

"We are excited to work with Cellares to evaluate their innovative automated manufacturing processes as part of our overall manufacturing strategy to efficiently, rapidly, and cost-effectively scale manufacturing capacity for our CAR T-cell product candidates for future clinical trials and potential commercialization," said Stephen Hill, Chief Operating Officer of Lyell. "We are impressed with the progress Cellares has made with their manufacturing capabilities, and the commitment and vision of the Cellares team to apply these technologies to help deliver new and potentially transformative therapies to patients."

Cellares' TAP program offers cell therapy developers a swift and low-risk pathway to embrace the company's automated manufacturing technology for their pipeline products. Lyell is utilizing this program to assess the automated manufacturing process and generate data that validates the Cell Shuttle's viability as a manufacturing option for CAR T-cell therapies. Cellares partners with prominent cell therapy developers through its TAP program to integrate the Cell Shuttle as a GMP manufacturing solution in both clinical and commercial stages at their IDMO Smart Factories.

"By integrating LYL797 into our TAP program, we seek to demonstrate the ability to seamlessly adapt Lyell's CAR T-cell manufacturing process to our Cell Shuttle platform," said Fabian Gerlinghaus, CEO of Cellares. "This collaboration represents a significant step towards fulfilling our vision of accelerating access to life-saving cell therapies, reducing process failure rates, and meeting total patient demand through the efficient utilization of the Cell Shuttle platform at global scale."

Cellares' innovative manufacturing technology transforms autologous and allogeneic cell therapy processes, covering nearly 90% of cell therapy modalities. Through their TAP program, Cellares can facilitate the automation and tech transfer of manual processes onto the Cell Shuttle manufacturing platform in just six months. This program allows cell therapy developers to seamlessly integrate their processes onto a Cell Shuttle at any stage of development - from pre-clinical to post-regulatory approval. With automation, standardization, and software-defined manufacturing (SDM), subsequent tech transfers become instant to any other Cell Shuttle into any IDMO Smart Factory worldwide.

Please visit cellares.com/partnering/ to learn more about the TAP program and request a meeting with a business development representative.

About Cellares
Cellares is the first Integrated Development and Manufacturing Organization (IDMO) and takes an Industry 4.0 approach to mass manufacturing the living drugs of the 21st century. The company is both developing and operating integrated technologies for cell therapy manufacturing to accelerate access to life-saving cell therapies. The company's Cell Shuttle integrates all the technologies required for the entire manufacturing process in a flexible and high-throughput platform that delivers true walk-away, end-to-end automation. Cell Shuttles will be deployed in Cellares' Smart Factories worldwide to meet total patient demand for cell therapies at global scale. Partnering with Cellares enables academics, biotechs, and pharma companies to accelerate drug development and scale out manufacturing, lower process failure rates, lower manufacturing costs, and meet global patient demand.

The company is headquartered in South San Francisco, California with its commercial-scale IDMO Smart Factory in Bridgewater, New Jersey. The company is backed by world-class investors and has raised over $355 million in financing.

For more information about Cellares, please visit cellares.com.

About Lyell Immunopharma, Inc.
Lyell is a clinical-stage T-cell reprogramming company advancing a diverse pipeline of cell therapies for patients with solid tumors. Lyell is currently enrolling a Phase 1 clinical trial evaluating a ROR1-targeted CAR T-cell therapy in patients with relapsed refractory triple-negative breast cancer and

non-small cell lung cancer (NSCLC) and a second Phase 1 clinical trial evaluating reprogrammed tumor infiltrating lymphocytes (TIL) in patients with advanced melanoma, NSCLC and colorectal cancer. The technologies powering its product candidates are designed to address barriers that limit consistent and long-lasting responses to cell therapy for solid tumors: T-cell exhaustion and lack of durable stemness, which includes the ability to persist and self-renew to drive durable tumor cytotoxicity. Lyell is applying its proprietary ex vivo genetic and epigenetic reprogramming technologies to address these barriers in order to develop new medicines with improved durable clinical outcomes. Lyell is based in South San Francisco, California with facilities in Seattle and Bothell, Washington. To learn more, please visit www.lyell.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements expressed or implied in this press release include, but are not limited to, statements regarding: Lyell's advancement of its pipeline of cell therapies; the planned collaboration between Cellares and Lyell and technology transfer process for the manufacture of Lyell's LYL797 CART-cell therapy; the potential clinical benefits and therapeutic potential of Lyell's product candidates; expectations around patient profiles and enrollment from Lyell's Phase 1 trials for LYL797; Lyell's anticipated progress, manufacturing strategy, clinical trials and potential commercialization; the anticipated benefits and timing of Cellares' automated manufacturing platform; and other statements that are not historical fact. These statements are based on Lyell's current plans, objectives, estimates, expectations and intentions, are not guarantees of future performance and inherently involve significant risks and uncertainties. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, but are not limited to, risks and uncertainties related to: the effects of geopolitical instability; macroeconomic conditions and the lingering effects of the COVID-19 pandemic; Lyell's ability to submit planned INDs or initiate or progress clinical trials on the anticipated timelines, if at all; Lyell's limited experience as a company in enrolling and conducting clinical trials, and lack of experience in completing clinical trials; Lyell's ability to manufacture and supply its product candidates for its clinical trials; the nonclinical profiles of Lyell's product candidates not translating in clinical trials; the potential for results from clinical trials to differ from nonclinical, early clinical, preliminary or expected results; significant adverse events, toxicities or other undesirable side effects associated with Lyell's product candidates; the significant uncertainty associated with Lyell's product candidates ever receiving any regulatory approvals; Lyell's ability to obtain, maintain or protect intellectual property rights related to its product candidates; implementation of Lyell's strategic plans for its business and product candidates; the sufficiency of Lyell's capital resources and need for additional capital to achieve its goals; and other risks, including those described under the heading "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2022, filed with the Securities and Exchange Commission (SEC) on February 28, 2023, and the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, filed with the SEC on August 8, 2023. Forward-looking statements contained in this press release are made as of this date, and Lyell undertakes no duty to update such information except as required under applicable law.

Media Contact:
Consort Partners for Cellares
cellares@consortpartners.com

Media Contact, Lyell Immunopharma
Ellen Rose
Senior Vice President, Communications and Investor Relations
erose@lyell.com