



Lyell Immunopharma to Acquire ImmPACT Bio and Prioritizes its Pipeline to Focus on Next-Generation CAR T-cell Therapies

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- Strengthens Lyell's clinical pipeline with the addition of IMPT-314, a dual-targeting CD19/CD20 CAR T-cell product candidate
- Data from ImmPACT's multi-center Phase 1-2 clinical trial of IMPT-314 in patients with large B-cell lymphoma treated in the 3rd line CAR-naïve setting to be presented at a major medical conference later this year; initiation of a pivotal trial for IMPT-314 expected in 2025
- Lyell has prioritized its pipeline to focus on next-generation CAR T-cell therapies, including IMPT-314 and LYL119, and is discontinuing development of LYL797, LYL845 and earlier-stage TIL programs
- Cash runway following the close of the transaction is expected to fund operations into 2027, through important clinical milestones for each pipeline program
- Lyell will host an investor webcast at 4:30 PM ET today

SOUTH SAN FRANCISCO, Calif., Oct. 24, 2024 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Nasdaq: LYEL) announced today that it has entered into a definitive agreement to acquire ImmPACT Bio USA Inc. ("ImmPACT"), a privately-owned clinical-stage biotechnology company. ImmPACT's lead program, IMPT-314, is a CD19/20-targeting chimeric antigen receptor (CAR) T-cell product candidate that Lyell will continue to develop for hematologic malignancies, including large B-cell lymphoma. IMPT-314 was designed to outperform the efficacy of approved CD19 CAR T-cell therapies via a dual-targeting CAR T-cell design and to improve CAR T-cell persistence by enriching for naïve and central memory T cells during manufacturing. The acquisition of ImmPACT is expected to significantly strengthen Lyell's clinical-stage pipeline of next-generation CAR T-cell therapies and complement its suite of proprietary technologies designed to generate longer-lasting, functional T cells to achieve more durable outcomes for patients with solid tumors and hematologic malignancies.

"Lyell's vision is to bring meaningful and durable clinical benefit to patients suffering from cancer with our next-generation cell therapies," stated Lynn Seely, M.D., Lyell's President and Chief Executive Officer. "The emerging data from ImmPACT's ongoing Phase 1-2 trial and the Phase 1 clinical data from a published UCLA-sponsored trial suggest the potential of IMPT-314 to have improved complete response rates and duration of response compared to the approved CD19 CAR T-cell therapies in CAR-naïve patients with aggressive B-cell lymphoma. Since licensing this product candidate from UCLA, the team at ImmPACT has made impressive progress in the multi-center IMPT-314 Phase 1-2 clinical program. We look forward to presenting initial data from this program at a major medical conference later this year and initiating a pivotal trial for IMPT-314 in 2025."

"I am incredibly proud of the ImmPACT team and all of their accomplishments in developing next-generation CAR T-cell therapies," stated Sumant Ramachandra, M.D., Ph.D., Chief Executive Officer of ImmPACT. "This transaction validates our novel science and enhances the potential for this therapy to make a meaningful impact on patients' lives. I am confident that in Lyell, we have found a team that shares our passion for advancing novel science to benefit patients."

Strengthening the Pipeline with IMPT-314

ImmPACT licensed its dual-targeting CD19/CD20 CAR T-cell product candidate from the University of California, Los Angeles (UCLA). Phase 1 data in 13 patients with relapsed/refractory (R/R) aggressive non-Hodgkin lymphoma treated in a UCLA-sponsored clinical trial were presented at the 2024 AACR Special Conference in Cancer Research: Tumor Immunology and Immunotherapy. CAR T-cell naïve patients with R/R diffuse large B-cell lymphoma or primary mediastinal B-cell lymphoma after at least two lines of therapy or mantle cell lymphoma, follicular lymphoma or chronic lymphocytic leukemia/small lymphocytic lymphoma after at least three lines of therapy were evaluated. Autologous T cells were obtained and enriched for CD14-/CD25-/CD62L+ naïve or memory T cells. Twelve out of 13 patients achieved a complete or partial response (92% objective response rate), with ten achieving a confirmed complete response (CR) (77% CR rate). The median progression-free survival was 50.1 months, and median overall survival was not reached with a median follow up of 32 months (range: 5.7 – not estimable). A favorable safety profile was observed.

The ongoing Phase 1-2 clinical trial initiated by ImmPACT is a multi-center, open-label clinical trial designed to evaluate the tolerability and clinical benefit of IMPT-314 in patients with R/R aggressive B-cell lymphoma and determine a recommended Phase 2 dose. Initial Phase 1-2 clinical data evaluating IMPT-314 primarily in patients who have received at least two prior lines of therapy for large B-cell lymphoma will be presented at a major medical conference this year. IMPT-314 has received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of R/R aggressive B-cell lymphoma.

Lyell expects to initiate a pivotal trial in 2025 for IMPT-314 in patients in the 3rd line setting who have not yet been exposed to CAR T-cell therapy.

Lyell Pipeline Prioritization

In connection with the acquisition, Lyell has prioritized its pipeline to focus resources on its most differentiated CAR T-cell clinical programs, including IMPT-314 following the close of the acquisition and LYL119. The enhanced anti-exhaustion technology incorporated into LYL119, including c-Jun overexpression, NR4A3 knockout, Epi-R and Stim R, has the potential to achieve improved efficacy at lower cell doses with an acceptable safety profile. In a validated in vivo preclinical model of non-small cell lung cancer, LYL119 achieved tumor control at a 10-fold lower cell dose than LYL797 with more gradual cell expansion to peak, and a substantial increase in the duration of cell killing demonstrated by a repetitive tumor cell killing assay

in vitro.

Lyell is discontinuing development of LYL797, its ROR1-targeted CAR T-cell product candidate to focus on the Phase 1 clinical trial of its next-generation ROR1-targeted CAR T-cell product candidate LYL119, which is expected to initiate enrollment of patients with platinum-resistant ovarian cancer or relapsed/refractory endometrial cancer this year or early next year.

The LYL845 tumor-infiltrating lymphocyte (TIL) program is also being discontinued as the clinical data in patients with advanced melanoma did not meet our rigorous pre-determined criteria for continued development. Its next-generation TIL and rejuvenation programs that are in preclinical development will also be discontinued.

Following the close of the transaction, Lyell expects its cash balance will fund operations into 2027, through important clinical milestones for each pipeline program, including initiation of a pivotal trial for IMPT-314, which is expected to start in 2025.

Details of the Transaction

Upon closing, Lyell will acquire worldwide rights to ImmPACT's pipeline, including the next-generation bispecific CD19/CD20 autologous CAR T-cell therapy, currently in clinical development for B-cell lymphoma and autoimmune diseases, and an activating TGF-beta Claudin 18.2 CAR T-cell candidate, which is in preclinical development. Lyell will prioritize the development of IMPT-314 for patients with B-cell lymphoma.

Deal terms include upfront consideration payable upon closing the potential transaction of \$30 million in cash, subject to certain adjustments, and 37.5 million shares of Lyell common stock. ImmPACT shareholders will also be eligible to receive contingent consideration consisting of 12.5 million shares of Lyell common stock that may be earned upon the achievement of a value-enhancing clinical milestone and a low single-digit royalty on future net sales of the dual-targeting CD19/20 CAR T-cell product in the United States.

The proposed transaction, which has been unanimously approved by the Boards of Directors of both companies, is expected to close in the fourth quarter of 2024. The closing of the proposed transaction is subject to expiration of the Hart-Scott-Rodino antitrust waiting period and the satisfaction of other customary closing conditions. Goldman Sachs & Co LLC is acting as sole financial advisor to Lyell in this transaction and Skadden, Arps, Slate, Meagher & Flom LLP is acting as its legal advisor. Cooley LLP is acting as ImmPACT's legal advisor.

Conference Call Details

Lyell's management will host an investor conference call and Webcast beginning at 4:30 pm ET today. The Webcast can be accessed [here](#).

A replay of the event and presentation materials will be archived on the Investor page of the Lyell Website following the end of the event.

About Lyell

Lyell is a clinical-stage company advancing a pipeline of next-generation CAR T-cell therapies for patients with solid tumors or hematologic malignancies. Lyell's product candidates are enhanced with novel technology designed to generate T cells that resist exhaustion and have qualities of durable stemness in order to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical response. 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: the timing of the consummation of the proposed transaction; the anticipated benefits of the proposed transaction; the continued clinical progress of the LYL119 and IMPT-314 trials; Lyell's development plans for LYL119 and the effectiveness of any technologies incorporated into LYL119; the ability of Lyell's anti-exhaustion technology to address barriers that limit consistent and long-lasting responses to cell therapy for solid tumors: T-cell exhaustion and lack of durable stemness, and for its reprogramming technology to address these barriers to develop new medicines with improved durable clinical outcomes; Lyell's anticipated progress, business plans, business strategy and clinical trials; Lyell's advancement of its pipeline and its research, development and clinical capabilities; the potential clinical benefits and therapeutic potential of Lyell's product candidates; the advancement of Lyell's technology platform; Lyell's expectation that its financial position and cash runway will support advancement of its pipeline through multiple clinical milestones into 2027; expectations around enrollment and the timing of initial and updated clinical and translational data from Lyell's Phase 1 trials for LYL119; 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: delays in or the inability to satisfy the conditions to complete the potential transaction; the inability to recognize the anticipated benefits of the potential transaction; business disruption during the pendency of or following the potential transaction; the effects of macroeconomic conditions, including any geopolitical instability and actual or perceived changes in interest rates and economic inflation; Lyell or ImmPACT'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 or technology 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 Lyell's Annual Report on Form 10-K for the year ended December 31, 2023, filed with the Securities and Exchange Commission (SEC) on February 28, 2024, and the Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, filed with the SEC on August 7, 2024. 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.

This press release is not an offer to sell any securities of Lyell and is not a solicitation of an offer to buy any securities of Lyell.

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