Lyell to Highlight Vision for its Next-Generation CAR T-Cell Therapy Pipeline at 43rd Annual JP Morgan Healthcare Conference

January 9, 2025 at 9:00 AM EST

- Accelerating IMPT-314 in large B-cell lymphoma; remain on track to initiate pivotal trial in the 3rd line+ setting in 2025 and expect to initiate a pivotal trial in the 2nd line by early 2026
- Presenting additional data from the ongoing Phase 1-2 trial in 3rd line+ setting and initial clinical data in 2nd line setting in mid-2025
- Discontinuing development of LYL119, a ROR1-targeting CAR T-cell product candidate for solid tumors, to focus resources on acceleration of pivotal trials of IMPT-314 and next-generation solid tumor CAR T cell programs in preclinical development
- Expected net cash use of $175 million - $185 million for 2025 extends cash runway further into 2027 through multiple value-creating clinical catalysts, including new pivotal programs
- Lynn Seely, MD, President and Chief Executive Officer, to present at J.P. Morgan conference on January 15th at 9:00 a.m. PT

SOUTH SAN FRANCISCO, Calif., Jan. 09, 2025 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a clinical-stage company advancing a pipeline of next-generation CAR T-cell therapies for patients with cancer, today announced pipeline updates, including its plans to advance IMPT-314, a potentially best-in-class therapy for aggressive large B-cell lymphoma, into pivotal trials. IMPT-314 is an autologous dual-targeting CD19/CD20 chimeric antigen receptor (CAR) T-cell product candidate designed to increase complete response rates and prolong the duration of the responses as compared to the approved CD19-targeted CAR therapies for the treatment of large B-cell lymphoma.

“Based on the positive initial clinical data reported at ASH and the promising emerging clinical profile, we are accelerating the development of IMPT-314 as a potentially transformative product with differentiated benefit in overall and complete response rates as well as duration of response over first-generation CD19 CAR therapies in patients with aggressive large B-cell lymphoma,” said Lynn Seely, M.D., Lyell’s President and Chief Executive Officer. “Having presented an initial dataset that demonstrated an overall response rate of 94% and a complete response rate of 71% in patients treated in the 3rd-line+ setting, we are focusing our resources on advancing IMPT-314 for patients with large B-cell lymphoma in both the 2nd and 3rd line+ settings. To ensure a sustainable cost structure that delivers multiple clinical readouts with our current balance sheet, we have streamlined and focused our pipeline and organization to prioritize investment in IMPT-314 and early-stage research programs for solid tumors.”

Pipeline Focus

Lyell is focused on advancing next-generation CAR T cell therapies with the potential to deliver higher response rates and longer duration of responses for patients with hematologic malignancies and solid tumors. Lyell is developing products enhanced with its novel technologies and manufacturing protocols.

In hematologic malignancies, Lyell is focused on advancing products designed to deliver improved outcomes over first-generation CD19 CAR T cell therapies. Lyell’s lead program, IMPT-314, is a dual-targeting CD19/CD20 CAR T-cell product candidate designed to increase complete response rates and prolong the duration of the responses as compared to the currently approved CD19-targeted CAR therapies for the treatment of large B-cell lymphoma. IMPT-314 is designed with a true ‘OR’ logic gate to target B-cells that express either CD19, CD20 or both and is manufactured through a process that enriches for CD62L-expressing cells to generate more naïve central memory CAR T cells with enhanced stemlike features and antitumor activity.

To realize the potential of cell therapy for solid tumors, Lyell is also developing next-generation CAR T-cell product candidates enhanced with anti-exhaustion and additional arming technologies, and manufactured with proprietary protocols. These approaches are designed to endow CAR T cells with attributes needed to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical responses – the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment.

Upcoming Milestones and Financial Outlook

For IMPT-314, a next-generation dual-targeting CD19/CD20 CAR T-cell product candidate for the treatment of large B-cell lymphoma:

- Present data from the ongoing Phase 1-2 trial in mid-2025, including more mature data from the 3rd line+ cohort and initial data from the 2nd line cohort
- Present more mature clinical data from the 2nd line cohort in late 2025
- Initiate a pivotal trial in the 3rd line+ setting in mid-2025
- Initiate a pivotal trial in the 2nd line setting by early 2026

For early-stage solid tumor programs:

- Submit first IND application for a new solid tumor CAR T-cell product candidate in 2026

To accelerate the pivotal trials of IMPT-314 and focus resources on next-generation solid tumor CAR T-cell programs in preclinical development, Lyell has streamlined its operations and is discontinuing development of LYL119, its ROR1-targeting CAR T cell product candidate, and IMPT-514, an autoimmune disease program previously initiated by ImmPACT Bio that was acquired by Lyell in connection with its acquisition of ImmPACT Bio.

Lyell expects net cash use in 2025 to be $175 million - $185 million, which extends its cash runway further into 2027 through multiple clinical milestones.

J.P. Morgan Healthcare Conference

Members of Lyell's senior management team will present and participate in the 43 rd Annual J.P. Morgan Healthcare Conference on Wednesday, January 15th at 9:00 am PT.

A live webcast of the presentation can be accessed through the Investors section of the Company's website at www.lyell.com. Following the live presentation, a replay of the webcast will be available on the Company's website.

About IMPT-314

IMPT-314 is a next-generation dual-targeting CD19/CD20 CAR T-cell product candidate designed to increase complete response rates and prolong the duration of the responses as compared to the approved CD19-targeted CAR therapies for the treatment of large B-cell lymphoma.

IMPT-314 is designed with a true 'OR' logic gate to target, with high potency, B cells that express either CD19, CD20 or both. IMPT-314 is manufactured to produce a CAR T-cell product with higher proportions of naïve and central memory T cells through a process that enriches for CD62L-expressing cells. This manufacturing process is designed to generate more naïve central memory CAR T cells with enhanced stemlike features and antitumor activity.

IMPT-314 has received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of relapsed/refractory aggressive B-cell lymphoma.

Initial data from 23 patients with relapsed or refractory, CAR T-naive large B-cell lymphoma who received IMPT-314 were reported at the 2024 American Society of Hematology Annual Meeting. The efficacy evaluable population consisted of 17 patients. The overall response rate was 94% (16/17 patients), with 71% (12/17 patients) achieving a complete response by three months. The median follow up was 6.3 months (range 1.2 – 12.5 months) and 71% of patients were in response at last follow-up. In the safety evaluable population of 23 patients, no Grade 3+ CRS was reported. Grade 3 ICANS was reported in 13% (3/23) of patients with a median time to complete ICANS resolution of 5 days, and rapid improvement to Grade 2 or lower with standard therapy.

About Lyell

Lyell is a clinical-stage company advancing a pipeline of next-generation CAR T-cell therapies for patients with hematologic malignancies and solid tumors. To realize the potential of cell therapy for cancer, Lyell utilizes a suite of technologies to endow CAR T cells with attributes needed to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical responses – the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment. Lyell is based in South San Francisco, California with facilities in West Hills, California and 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 anticipated benefits IMPT-314, including its potential to increase complete response rates and prolong duration of the responses as compared to approved CD19-targeted CAR therapies for the treatment of B-cell lymphoma; the continued clinical progress of the IMPT-314 trials and expectations around the timing of updated clinical data and the timing and design of pivotal trials of IMPT-314; the timing of the submission of an IND application for a solid tumor CAR T-cell product; Lyell's expectation regarding its net cash use and cost structure and that its financial position and cash runway will support advancement of its pipeline through multiple clinical milestones into 2027; the ability of Lyell's technology to generate CAR T cells with attributes needed to drive durable tumor cytotoxicity in the setting of a hostile solid tumor microenvironment, resist exhaustion and maintain qualities of durable stemness to achieve consistent and long-lasting clinical responses; Lyell's anticipated progress, business plans, business strategy and clinical trials; 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 inability to recognize the anticipated benefits of Lyell's recent acquisition of ImmPACT Bio and successful integration of ImmPACT Bio's business with Lyell's; the effects of macroeconomic conditions, including any geopolitical instability and actual or perceived changes in interest rates and economic inflation; 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 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 September 30, 2024, filed with the SEC on November 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.

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