Lyell Announces Two Oral Presentations from the Phase 1/2 Clinical Trial of Ronde-Cel for the Treatment of Aggressive Large B-Cell Lymphoma at the 67th ASH Annual Meeting and Exposition

November 3, 2025

SOUTH SAN FRANCISCO, Calif., Nov. 03, 2025 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a late-stage clinical company advancing a pipeline of next-generation CAR T-cell therapies for patients with cancer, today announced that two abstracts highlighting new clinical and translational data from the Phase 1/2 clinical trial of rondecabtagene autoleucel (ronde-cel, also known as LYL314) for the treatment of aggressive large B-cell lymphoma (LBCL) will be presented at the 67th American Society of Hematology (ASH) Annual Meeting and Exposition. Ronde-cel is a next-generation dual-targeting CD19/CD20 CAR T-cell product candidate, currently in pivotal development for the treatment of LBCL, that is designed to increase complete response rates and prolong the duration of response as compared to approved CD19-targeted CAR T-cell therapies. The FDA has granted ronde-cel Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations for the treatment of relapsed and/or refractory diffuse LBCL in the third- or later-line setting.

“We are looking forward to presenting new clinical and translational data from the ongoing Phase 1/2 trial of ronde-cel that support the potential of targeting both CD19 and CD20 to deliver differentiated benefit for patients with aggressive large B-cell lymphoma,” said David Shook, MD, Lyell’s Chief Medical Officer. “Lyell continues to enroll patients in the PiNACLE single-arm registration trial for patients with LBCL in the third- or later-line setting and is initiating a randomized controlled trial of ronde-cel versus investigator’s choice of an approved CD19 CAR T-cell therapy in the second-line setting.”

Details of the presentations are below:

Rondecabtagene Autoleucel, an Autologous, Dual-Targeting CD19/CD20 CAR T-Cell Candidate Manufactured from CD62L+ Enriched T Cells, Achieves Durable Responses in Patients with Large B-Cell Lymphoma

The presentation will highlight new clinical data from the ongoing Phase 1/2 trial of ronde-cel in patients with LBCL. As of the abstract’s June 27, 2025 data cut-off date, high-risk patients with LBCL treated with ronde-cel achieved high overall response rates and complete response rates with an encouraging safety profile. New safety and efficacy data from patients receiving treatment in both the second-line and the third- or later-line settings will be presented.

- Session Name: 628. Aggressive Lymphomas: Cellular Therapies: Novel Cellular Therapeutic Strategies for Aggressive Lymphomas
- Session Date and Time: 12/7/2025, 4:30 PM - 6:00 PM
- Presentation Time: 4:45 PM – 5:00 PM
- Location: OCCC - Tangerine Ballroom F3-4
- Publication Number: 668

CD62L Enrichment Achieves Robust Expansion and Memory Phenotype Post-Infusion in Patients with LBCL Treated with Rondecabtagene Autoleucel, an Autologous, Dual-Targeting CD19/CD20 CAR T-Cell Candidate

Ronde-cel is manufactured with a process that enriches for CD62L-positive cells to generate more naïve and central memory CAR T cells with enhanced stemlike features and antitumor activity. This presentation will review translational data from the ongoing Phase 1/2 clinical trial in patients receiving treatment in the second or third- or later-line settings, highlighting that CD62L-positive cell enrichment achieves greater memory phenotype expression and in vivo cell expansion compared to published data from U.S. Food and Drug Administration-approved CAR T-cell therapies for LBCL.

- Session Name: 702. CAR-T Cell Therapies: Basic and Translational: Product biology and single-cell states shaping CAR-T cell outcomes
- Session Date and Time: 12/7/2025, 9:30 AM - 11:00 AM

- Presentation Time: 10:00 AM – 10:15 AM
- Location: OCCC - Sunburst Room (W340)
- Publication Number: 501

About Lyell

Lyell is a late-stage clinical company advancing a pipeline of next-generation CAR T-cell therapies for patients with hematologic malignancies or 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 high rates of long-lasting clinical responses, including the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment. The Lyell LyFE Manufacturing Center™ has commercial launch capability and can manufacture more than 1,200 CAR T-cell doses at full capacity. 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 expectations around presenting new clinical and translational data at the ASH meeting; the anticipated benefits of RMAT and Fast Track designations for ronde-cel; Lyell's expectations around the progress of the ongoing PiNACLE trial for patients with aggressive LBCL receiving treatment in the third- or later-line setting; Lyell's expectations around the initiation of a randomized controlled trial of ronde-cel versus investigator's choice of an approved CD19 CAR T-cell therapy for patients with aggressive LBCL receiving treatment in the second-line setting; the sufficiency of the capacity of LyFE to manufacture drug supply for Lyell's ongoing and planned pivotal trials and through potential commercial launch; the potential clinical benefits and therapeutic potential of ronde-cel; 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: Lyell's limited experience as a company in initiating and conducting clinical trials, and lack of experience in completing 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; Lyell's ability to submit planned INDs or initiate or progress clinical trials on the anticipated timelines, if at all; RMAT and Fast Track designations may not actually lead to faster development, regulatory review or approval process, and do not assure ultimate FDA approval; 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; the complexity of manufacturing cellular therapies and Lyell's ability to manufacture and supply its product candidates for its clinical trials; 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; the effects of macroeconomic conditions, including the effects of disruption between the U.S. and its trading partners due to tariffs or other policies, and any geopolitical instability; potential changes to U.S. drug pricing, including the potential for "most-favored nations" pricing limitations; other risks, including general economic conditions and regulatory developments, not within our control; and other risks, including those described under the heading "Risk Factors" in Lyell's Annual Report on Form 10-K for the fiscal year ended December 31, 2024, filed with the Securities and Exchange Commission on March 11, 2025 and in Lyell's Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, previously filed with the Securities and Exchange Commission on August 12, 2025. 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