Lyell Immunopharma Presents Updated Safety Data and Translational Insights for Rondecabtagene Autoleucel (Ronde-Cel) in Patients with Large B-Cell Lymphoma at European Hematology Association 2026 Congress

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- More than 100 patients treated with ronde-cel in 2L and 3L+ LBCL, with a manufacturing success rate of 97%
- No Grade ≥ 3 CRS and low rates of Grade ≥ 3 ICANS, supporting outpatient administration
- Translational data support biological basis for durable responses, including enhanced memory potential of cytotoxic effector cells from CD62L+ enrichment, and CD19/CD20 dual-targeting to overcome low antigen expression
- PiNACLE pivotal clinical trial in 3L+ setting data update expected in second half of 2026; pivotal data readout expected in mid-2027, with BLA submission to follow in the second half of 2027

SOUTH SAN FRANCISCO, Calif., June 12, 2026 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a late-stage clinical company advancing a pipeline of next-generation chimeric antigen receptor (CAR) T-cell therapies for patients with cancer, is announcing today new safety data from the ongoing Phase 1/2 clinical trial of rondecabtagene autoleucel (ronde-cel) in patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) in the second-line (2L) and third- and later-line (3L+) settings and new translational data for ronde-cel. The new data will be presented today in two poster presentations at the European Hematology Association (EHA) 2026 Congress in Stockholm, Sweden.

“The clinical data presented today reinforce the differentiated profile of ronde-cel in more than 100 patients with relapsed or refractory large B-cell lymphoma,” said Lynn Seely, M.D., President and Chief Executive Officer of Lyell. “The updated safety profile, with no Grade 3 or higher CRS and low rates of Grade 3 or higher ICANS, supports outpatient administration. The translational data extend our understanding of ronde-cel’s durable clinical responses. Our data indicate they are achieved through next-generation dual-antigen targeting and production of CD62L-enriched CAR T-cells with enhanced memory phenotype.”

Low-Grade CRS and ICANS with Rondecabtagene Autoleucel, a Dual-Targeting CD19/CD20 CAR T-Cell Product Candidate, in Patients with Large B-Cell Lymphoma: Updated Safety Analysis (Poster: PF962)

A total of 108 patients with R/R LBCL (43 2L and 65 3L+) were treated with ronde-cel in the ongoing Phase 1/2 trial as of the data cutoff date of May 5, 2026. The population reflected high-risk disease: median age 64 years (range, 20 to 87), 67% (72/108) with primary refractory disease, and 28% (30/108) had an International Prognostic Index score of 3 or 4. Of the patients treated, 59% (64/108) received dexamethasone prophylaxis, 10 mg daily for three days at the time of CAR T-cell administration.

Key Safety Findings:

- Cytokine Release Syndrome (CRS): There were no reports of Grade ≥ 3 events in patients treated with or without dexamethasone prophylaxis. Grade 1 CRS events were reported in 56% (36/64) and Grade 2 in 13% (8/64) of patients receiving prophylaxis, compared with cases of Grade 1 CRS reported in 30% (13/44) or Grade 2 in 39% (17/44) of patients who did not receive prophylaxis.
- Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS): Grade ≥ 3 events of ICANS occurred in 8% (5/64) of patients receiving prophylaxis vs. 16% (7/44) of patients who did not receive prophylaxis. Grade 1 events were reported in 6% (4/64) and Grade 2 in 2% (1/64) of patients receiving prophylaxis vs. 11% (5/44) or 5% (2/44) who did not receive prophylaxis.

With over 100 patients treated, ronde-cel continues to show a consistent and manageable safety profile, supporting the potential for outpatient administration. Notably, dexamethasone prophylaxis did not change ronde-cel cell expansion and pharmacokinetics. Manufacturing has also proven reliable to date, with a 97% success rate across these patients.

Durable Responses with Rondecabtagene Autoleucel (Dual-Targeting CD19/CD20 CAR T-Cells) Are Associated with Higher Proportion of Cytotoxic T Cells with Memory Potential in Infusion Products (Poster: PF1097)

The purpose of this study was to explore the roles of CD62L+ enrichment and CD19/CD20 dual-targeting in ronde-cel infusion products on clinical response observed in patients with R/R LBCL.

Single-cell RNA sequencing was conducted on ronde-cel infusion products to assess memory potential of cytotoxic effector cells compared to FDA-approved CD19 CAR T-cell therapies. Cluster analysis identified a population of cytotoxic effector cells (defined by high GZMB, IFNG, CCL4, CCL5, KLRD1 gene expression) that had higher expression of memory-associated genes (CD62L, IL7R, LEF1) compared to an analogous cytotoxic cluster from FDA-approved CD19 CAR T-cell therapies. These cells co-expressing cytotoxic genes and memory-associated genes are referred to as Cytotoxic T cells with Memory Potential (T_{cmp}) in this study.

Key Translational Findings:

- T_{cmp} cells were more abundant in the ronde-cel products of patients with durable responses (>12 months) than in patients with progressive disease
- Ronde-cel drug product T_{cmp} cells have a stronger memory potential compared to axicabtagene ciloleucel's cytotoxic effector cells
- Ronde-cel T_{cmp} cells following CD62L enrichment also had higher survival and expansion in vitro compared to cytotoxic effector cells with CD4/CD8 enrichment.
- Ronde-cel CAR+ T cells collected from patients two months after infusion sustained the capacity to proliferate, kill tumor cells, and secrete cytokines
- Durable complete responses > 12 months observed in patients with LBCL with low CD19 or CD20 antigen expression on tumor biopsies at baseline

Collectively, these data offer a potential biological rationale for the benefits of CD62L+ enrichment during manufacturing and CD19/CD20 dual-targeting, which are thought to underpin the high rates of durable complete responses previously reported with ronde-cel.

Ronde-cel is currently being evaluated for the treatment of R/R LBCL across two pivotal clinical trials. In the 3L+ setting, the ongoing single-arm PiNACLE trial is expected to report updated data in the second half of 2026 and pivotal data by mid-2027, setting up a subsequent Biologics License Application (BLA) submission in the second half of 2027. In the 2L setting, the Phase 3 randomized PiNACLE-H2H trial is evaluating ronde-cel against investigator's choice of axicabtagene ciloleucel or lisocabtagene maraleucel.

About Lyell Immunopharma, Inc.

Lyell is a late-stage clinical 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 arm CAR T cells with enhancements needed to drive durable tumor cytotoxicity and achieve consistent and long-lasting clinical responses, including the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment. LyFE has commercial launch capability and is expected to have the capacity to manufacture more than 1,200 CAR T-cell doses per year. 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 planned presentations at a medical congress; the potential clinical benefits and therapeutic potential of ronde-cel; Lyell's expected timing for the reporting of PiNACLE clinical data and the submission of a BLA; and the sufficiency of the capacity of LyFE to manufacture drug supply through potential commercial launch. 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: our operating in a rapidly evolving industry and having a limited operating history; Lyell's ability to successfully develop, manufacture and commercialize product candidates or its experiencing significant delays in doing so; Lyell's dependence on the enrollment and retention of patients in its current and planned clinical trials for its product candidates; the potential for results of Lyell's research, nonclinical studies or earlier clinical trials to not be predictive of future results; clinical development involving a lengthy and expensive process with uncertain outcomes; Lyell's product candidates and technologies being based on novel technologies that are unproven and may not result in approvable or marketable products; significant adverse events, toxicities or other undesirable side effects associated with Lyell's product candidates; Lyell facing substantial competition in a rapidly changing industry, which may result in others discovering, developing or commercializing products before or more successfully than it does; the complexity of manufacturing cellular therapies; Lyell's ability to manufacture drug products for its clinical trials itself and any potential delays in further qualifying or in receiving regulatory approvals for any manufacturing facility or product candidates or in expanding its manufacturing capacity; Lyell's reliance on third parties; implementation of Lyell's strategic plans for its business and product candidates and Lyell's realization of the expected benefits of such plans; 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 Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, filed with the Securities and Exchange Commission on May 6, 2026. 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.

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