Lyell Immunopharma to Present Positive Updated Ronde-Cel Data in More than 80 Patients at ASH 2026 from PiNACLE Pivotal Trial in 3L+ and from Phase 1/2 2L Cohort in Patients with Relapsed/Refractory Large B-Cell Lymphoma

November 4, 2026

- *Ronde-cel achieved a 91% overall response rate and 77% complete response rate; median progression-free survival not reached and estimated 6-month duration of complete response of 92% in 44 patients with 3L+ R/R LBCL in the PiNACLE pivotal trial*
- *Ronde-cel achieved a 95% overall response rate and 76% complete response rate; median progression-free survival not reached and estimated 6-month duration of complete response of 92% in 37 patients with 2L R/R LBCL in the Phase 1/2 trial*
- *No Grade ≥ 3 cytokine release syndrome was observed in either cohort and Grade ≥ 3 neurotoxicity was reported in < 10% of patients supporting outpatient administration*

SOUTH SAN FRANCISCO, Calif., Nov. 04, 2026 (GLOBE NEWSWIRE) -- Lyell Immunopharma, Inc. (Nasdaq: LYEL), a late-stage clinical company advancing next-generation chimeric antigen receptor (CAR) T-cell therapies for patients with cancer, today announced that two abstracts featuring positive updated clinical data for rondecabtagene autoleucel (ronde-cel) have been accepted for presentation at the 68th American Society of Hematology (ASH) Annual Meeting and Exposition, taking place December 12–15, 2026, in New Orleans (ASH 2026).

The abstracts highlight results in patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) in the third- or later-line (3L+) setting in an oral presentation, and in the second-line (2L) setting in a poster presentation. Ronde-cel is a dual-targeting CD19/CD20 autologous CAR T-cell product candidate currently being evaluated in two pivotal trials: PiNACLE, a single-arm trial in the 3L+ LBCL setting intended to support an initial BLA submission for regular marketing approval, and PiNACLE-H2H, a Phase 3 randomized controlled trial comparing ronde-cel to investigator's choice of an approved CD19-directed CAR T-cell therapy in the 2L setting. Ronde-cel has received Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations from the U.S. Food and Drug Administration (FDA) for R/R diffuse LBCL in the 3L+ setting, as well as RMAT designation for LBCL in the 2L setting.

"We believe the high complete response rates and durability of remissions observed with ronde-cel in both the second-line and third- or later-line settings, including in patients with high-risk disease, are impressive," said Jarrad Aguirre, M.D., Chief Medical Officer of Lyell. "The potential to deliver deep, lasting remissions for patients with large B-cell lymphoma is particularly compelling and reinforces our confidence in ronde-cel's ability to meaningfully improve patient outcomes. We look forward to presenting updated results at ASH, including additional patients and longer follow-up, as we advance ronde-cel toward potential registration."

Third- or Later-Line (3L+) LBCL Oral Abstract and Clinical Highlights

Overall, 58 patients received ronde-cel as of the June 18, 2026 data cutoff date. The median age was 64 years, approximately 50% of treated patients had primary refractory disease, and 64% were refractory to their last therapy. Of 44 patients response-evaluable at Day 84, the overall response rate was 91% (40/44) and the complete response rate was 77% (34/44). Median duration of complete response was not reached. Among patients with a complete response, 92% remained in complete response at six months and 75% at 12 months. The median progression-free survival (PFS) was not reached, with estimated PFS rates of 76%, 63% and 54% at six, 12 and 24 months, respectively; median PFS follow-up was 12 months.

No Grade ≥ 3 cytokine release syndrome (CRS) was observed among all treated patients (N = 58). Grade 1 CRS occurred in 48% of patients and Grade 2 in 22% of patients. Grade ≥ 3 immune effector cell-associated neurotoxicity syndrome (ICANS) occurred in 9% of patients.

Updated results, including additional patients and longer follow-up, are expected to be presented at ASH 2026.

Second-Line (2L) LBCL Poster Abstract and Clinical Highlights

In the fully enrolled Phase 1/2 second-line cohort, 43 patients received ronde-cel, including 86% (37/43) with primary refractory disease. Among 37 patients response-evaluable at Day 84, the overall response rate was 95% (35/37) and complete response rate was 76% (28/37). Median duration of complete response was not reached. Among patients with a complete response, 92% remained in complete response at six months and 67% at 12 months. Median PFS was not reached, with estimated PFS rates of 75% at six months and 55% at 12 months; median PFS follow-up was nine months.

No Grade ≥ 3 CRS was observed among all treated patients (N = 43). Grade 1 CRS occurred in 49% of patients and Grade 2 in 19% of patients. Grade ≥ 3 ICANS occurred in 9% of patients.

Updated results, including longer follow-up, are expected to be presented at ASH 2026. Ronde-cel is also being evaluated in PiNACLE-H2H, an ongoing randomized Phase 3 trial in the 2L setting.

Abstract Details:

Oral Abstract 1028: **Durable progression-free survival and high complete response rates with rondecabtagene autoleucel, a CD19/CD20 CAR T-cell candidate, in patients with 3L+ relapsed/refractory large B-cell lymphoma: results from the ongoing pivotal PiNACLE trial**

Presenting author: Sarah M. Larson, M.D., Associate Professor in the Division of Hematology-Oncology, David Geffen School of Medicine, UCLA

Session: Monday, December 14, 2026, 4:45 CST

Poster Abstract 2402: Durable progression-free survival and high complete response rates with rondecabtagene autoleucel, a CD19/CD20 CAR T-cell candidate, in patients with predominantly primary refractory, second-line relapsed/refractory large B-cell lymphoma

Presenting author: Akil Merchant, M.D., Associate Professor and Co-Director of the Lymphoma Program, Samuel Oschin Cancer Center, Cedars-Sinai Medical Center

Session: Saturday, December 12, 2026, 5:30 CST

About Ronde-Cel

Rondecabtagene autoleucel (ronde-cel) is a next-generation, dual-targeting CD19/CD20 autologous CAR T-cell product candidate designed to increase complete response rates and prolong the duration of response compared to approved CD19-targeted CAR T-cell therapies for R/R LBCL. Ronde-cel targets B cells expressing either CD19 or CD20 and is manufactured using a process that enriches for CD62L-positive cells designed to generate more naïve and central memory CAR T cells to improve the durability of responses by promoting in vivo persistence and the antitumor activity of CAR T cells.

Ronde-cel is being evaluated in two pivotal trials in R/R LBCL: PiNACLE is a multi-center single-arm pivotal trial in the 3L+ setting. Full pivotal data from this trial are expected in mid-2027 with BLA submission expected to follow in the second half of 2027. PiNACLE-H2H is a Phase 3 randomized controlled head-to-head CAR T-cell trial in the 2L setting. Patients with R/R LBCL following one prior line of therapy are randomized to receive ronde-cel or investigator's choice of one of two approved CD19 CAR T-cell therapies. The FDA has granted ronde-cel Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations in the 3L+ setting and RMAT designation in the 2L setting.

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 3,000 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: the potential clinical benefits and therapeutic potential of ronde-cel; Lyell's expectations around the progress of the PiNACLE and PiNACLE-H2H trials, including the expected timing for release of additional data at ASH 2026, regulatory actions and the anticipated benefits of regulatory designations; the capability of LyFE to manufacture ronde-cel through potential commercial launch and its expected manufacturing capacity; 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 operates in a rapidly evolving industry and has 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; 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; Lyell's ability to obtain and maintain sufficient intellectual property protection for its product candidates; 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 potential reduction of Lyell's cash resources and fluctuations in Lyell's operating results and financial condition as a result of Lyell's milestone, royalty and success payment obligations; 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 June 30, 2026, filed with the U.S. Securities and Exchange Commission on August 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.

Lyell Investor Relations

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