Lyell Immunopharma Reports Business Highlights and Financial Results for the First Quarter 2025

May 13, 2025

- Presenting new clinical data from Phase 1/2 multi-center clinical trial of LYL314, a next-generation dual-targeting CD19/CD20 CAR T-cell product candidate for the treatment of relapsed and/or refractory large B-cell lymphoma at the 18th International Conference on Malignant Lymphoma.
- Received Regenerative Medicine Advanced Therapy (RMAT) designation from the United States Food and Drug Administration (FDA) for LYL314 for the treatment of relapsed and/or refractory diffuse large B-cell lymphoma in the third- or later-line setting.
- LYL314 clinical supply now manufactured at Lyell's LyFE Manufacturing Center™, following successful technology transfer and clearance by the FDA of an Investigational New Drug Amendment.
- Remain on track to initiate a pivotal trial of LYL314 in the third- or later-line setting in mid-2025 and expect to initiate a pivotal trial in the second-line setting by early 2026.
- Cash, cash equivalents and marketable securities of $330.1 million as of March 31, 2025 support advancing pipeline into 2027 through multiple clinical milestones.

SOUTH SAN FRANCISCO, Calif., May 13, 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 reported financial results and business highlights for the first quarter ended March 31, 2025. Lyell's lead clinical program, LYL314 (formerly known as IMPT-314), is an autologous CD19/CD20 dual-targeting CAR T-cell product candidate under evaluation in a Phase 1/2 trial enrolling patients with relapsed and/or refractory large B-cell lymphoma (LBCL). LYL314 was recently granted RMAT designation by the United States FDA in recognition of its potential to address significant unmet needs in patients with aggressive LBCL in the third- or later-line setting.

"We are pleased with the progress we are making with our LYL314 clinical development strategy and look forward to presenting new clinical data from patients with aggressive large B-cell lymphoma who have not previously received CAR T-cell therapy at the International Conference on Malignant Lymphoma in Lugano, Switzerland in June," said Lynn Seely, M.D., President and CEO of Lyell. "Based on promising clinical data, Lyell remains on track to initiate two pivotal programs for LYL314: one for patients in the third- or later-line setting by mid-2025 and a second for patients in the second-line setting by early 2026. In addition, our LyFE Manufacturing Center in Bothell, Washington is now manufacturing the LYL314 clinical supply following completion of a successful technology transfer and FDA clearance of an IND amendment."

First Quarter Updates and Recent Business Highlights

Lyell is advancing a pipeline of next-generation CAR T-cell product candidates. Its lead program, LYL314, is in Phase 1/2 clinical development for relapsed and/or refractory LBCL and its preclinical programs target solid tumor indications. Lyell's programs target cancers with large unmet need with substantial patient populations.

LYL314: A next-generation dual-targeting CD19/CD20 CAR T-cell product candidate designed to increase complete response rates and prolong the duration of response as compared to the approved CD19-targeted CAR T-cell therapies for the treatment of LBCL

LYL314 is an autologous CAR T-cell product candidate with a true 'OR' logic gate to target B cells that express either CD19 or CD20 with full potency and that 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. LYL314 is currently being evaluated in a multi-center, open-label trial that is enrolling patients in the third- or later-line and second-line settings who have not previously received CAR T-cell therapy. The trial is designed to evaluate the tolerability and clinical benefit of LYL314 in patients with relapsed and/or refractory LBCL and determine a recommended Phase 2 dose. The FDA has granted LYL314 RMAT and Fast Track designations for the treatment of relapsed and/or refractory diffuse LBCL in the third- or later-line setting. RMAT provides all the benefits of the Fast Track and Breakthrough Therapy designation programs and enables increased frequency of

communications with the FDA on the development of LYL314.

- New clinical data from the Phase 1/2 multi-center clinical trial of LYL314 in patients with relapsed and/or refractory LBCL will be presented at the 18th International Conference on Malignant Lymphoma in June, including more mature data from patients treated in the third- or later-line setting and initial data from patients treated in the second-line setting. The data will be highlighted in an oral presentation titled “LYL314, a CD19/CD20 CAR T-cell candidate enriched for CD62L+ stem-like cells, achieves high rates of durable complete responses in R/R large B-cell lymphoma” to be presented on June 18th at 5:40 pm CEST.
- Initial clinical data in 23 patients treated with LYL314 from the ongoing Phase 1/2 clinical trial were presented at the American Society for Hematology 2024 Annual Meeting on December 9, 2024. The efficacy evaluable population consisted of 17 patients with relapsed and/or refractory LBCL in the third- or later-line setting who had not previously received a CAR T-cell therapy prior to LYL314 administration. The overall response rate was 94% (16/17) of patients, and 71% (12/17) of patients achieved a complete response by three months. The median follow up was 6.3 months (range 1.2 – 12.5 months) and 71% of patients experienced a response at last follow-up. In the safety evaluable population of 23 patients, no event of Grade 3 or greater cytokine release syndrome was reported. Grade 3 immune effector cell-associated neurotoxicity syndrome (ICANS) was reported in 13% (3/23) of patients with a median time to ICANS resolution of 5 days, and rapid improvement to Grade 2 or lower with standard therapy.
- LYL314 clinical supply is now manufactured at the LyFE Manufacturing Center in Bothell, Washington following successful technology transfer and clearance by the FDA of an IND amendment. LyFE is a state-of-the-art cell therapy manufacturing facility with the capacity to provide drug supply for Lyell’s ongoing and planned pivotal trials and through potential commercial launch, with a capacity over 1,000 CAR T-cell therapy doses per year.
- A pivotal trial in the third- or later-line setting is expected to be initiated in mid-2025 in patients with relapsed and/or refractory LBCL who have not previously received CAR T-cell therapy.
- More mature data from the ongoing Phase 1/2 trial in the second-line setting are expected to be presented in late-2025.
- A pivotal trial in the second-line setting is expected to be initiated by early 2026 in patients with relapsed and/or refractory LBCL who have not previously received CAR T-cell therapy.

Preclinical Pipeline, Technologies and Manufacturing Protocols

Lyell is advancing next-generation fully-armed CAR T-cell product candidates, each including multiple technologies, designed to overcome T-cell exhaustion and lack of durable stemness, as well as immune suppression within the hostile tumor microenvironment.

- The first IND for a fully-armed CAR T-cell product candidate with an undisclosed target for solid tumors is expected in 2026.
- An abstract titled “Engineered T Cells Combining Stackable Reprogramming Technologies Enable Durable Anti-tumor Activity in Xenograft Solid Tumors” has been accepted for an oral presentation at the 28th Annual Meeting of the American Society of Gene & Cell Therapy (ASGCT), on May 16, 2025, in New Orleans, LA. The presentation will highlight preclinical data demonstrating that engineered T cells enhanced with c-Jun overexpression, a chimeric co-stimulatory receptor and localized cytokine signaling technologies exhibit potent tumor cell killing in vitro, T-cell viability in vitro and in vivo without cytokine support and effective durable antitumor activity in preclinical solid tumor models.
- An abstract titled “Optimizing Stim-R™, a synthetic stimulatory agent, for feeder-free tumor-infiltrating lymphocyte manufacturing” was presented at the American Association for Cancer Research Annual Meeting 2025. The presented work demonstrated that Stim-R, Lyell’s customizable synthetic T-cell activation reagent designed to emulate natural antigen presentation, has the potential to overcome scalability limitations in tumor-infiltrating lymphocyte manufacturing processes by providing a synthetic replacement for feeder cells.

First Quarter 2025 Financial Results

Lyell reported a net loss of $52.2 million for the first quarter ended March 31, 2025, compared to a net loss of $60.7 million for the same period in 2024. The $8.5 million decrease in net loss was primarily driven by $13.0 million in impairment expenses recognized in the prior year period that did not occur in 2025, partially offset by lower interest income of $3.0 million primarily driven by lower interest rates in 2025, coupled with lower cash equivalent and marketable securities balances. Non-GAAP net loss, which excludes stock-based compensation, non-cash expenses related to the change in the estimated fair value of success payment liabilities and certain non-cash investment gains and charges, increased to $46.3 million for the first quarter ended March 31, 2025, compared to $37.5 million for the same period in 2024 due primarily to increased personnel costs and lower interest income in 2025.

GAAP and Non-GAAP Operating Expenses

- Research and development (R&D) expenses were $43.4 million for the first quarter ended March 31, 2025, compared to $43.2 million for the same period in 2024. The increase in first quarter 2025 R&D expenses of $0.3 million was primarily

due to a $3.1 million increase in personnel expenses, due primarily to severance expenses resulting from Lyell's 2025 workforce reduction related to the closure of the West Hills manufacturing facility acquired as part of Lyell's acquisition of ImmPACT in 2024, partially offset by reductions in collaboration agreement and leasehold improvement depreciation costs. Non-GAAP R&D expenses, which exclude non-cash stock-based compensation and non-cash expenses related to the change in the estimated fair value of success payment liabilities for the first quarter ended March 31, 2025 were $41.1 million compared to $38.9 million for the same period in 2024.

- General and administrative (G&A) expenses were $14.0 million for the first quarter ended March 31, 2025, respectively, compared to $13.5 million for the same period in 2024. The increase in first quarter 2025 G&A expenses of $0.6 million was primarily driven by an increase of $2.4 million in personnel-related expenses due to higher headcount associated with Lyell's acquisition of ImmPACT and severance expenses related to the West Hills facility closure, partially offset by $1.7 million in decreased stock-based compensation expense due to a decrease in the value of awards granted. Non-GAAP G&A expenses, which exclude non-cash stock-based compensation, for the first quarter ended March 31, 2025 were $10.4 million, compared to $8.1 million for the same period in 2024. The $2.3 million increase in first quarter 2025 non-GAAP G&A expenses was primarily driven by increased headcount and severance expenses.

A discussion of non-GAAP financial measures, including reconciliations of the most comparable GAAP measures to non-GAAP financial measures, is presented below under "Non-GAAP Financial Measures."

Cash, cash equivalents and marketable securities

Cash, cash equivalents and marketable securities as of March 31, 2025 were $330.1 million compared to $383.5 million as of December 31, 2024. Lyell believes that its cash, cash equivalents and marketable securities balances will be sufficient to meet working capital and capital expenditure needs into 2027.

About Lyell Immunopharma, Inc.

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, including the ability to resist exhaustion, maintain qualities of durable stemness and function in the hostile tumor microenvironment. 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 plans to present new LYL314 clinical data from the ongoing Phase 1/2 trial of LYL314; the anticipated benefits of RMAT designation for LYL314; the sufficiency of the capacity of LyFE to manufacture drug supply for Lyell's ongoing and planned pivotal trials and through potential commercial launch; Lyell's initiation of pivotal trials in 2025 and 2026 for LYL314; expectations around enrollment and the timing of additional clinical data from Lyell's Phase 1/2 trials for LYL314; timing of Lyell's submission of a new IND in 2026 for a CAR T-cell product candidate with an undisclosed target for solid tumors; 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 and meet working capital and capital expenditure needs into 2027; 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 complexity of manufacturing cellular therapies, which subjects us to a multitude of manufacturing risks, any of which could substantially increase our costs, delay our programs or limit supply of our product candidates; RMAT designation may not actually lead to faster development, regulatory review or approval process, and does not assure ultimate FDA approval; the effects of macroeconomic conditions, including the effects of disruption between the U.S. and its trading partners due to tariffs or other policies, 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; 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, 2024, filed with the Securities and Exchange Commission (SEC) on March 11, 2025, and Lyell's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, being filed with the SEC today. 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 Immunopharma, Inc.

Unaudited Selected Consolidated Financial Data

(in thousands)

Statement of Operations Data:

	Three Months Ended March 31,	
	2025	**2024**
Revenue	$ 7	$ 3
Operating expenses:		
Research and development[(1)]	43,447	43,174
General and administrative	14,046	13,494
Other operating income, net	(119)	(1,090)
Total operating expenses	57,374	55,578
Loss from operations	(57,367)	(55,575)
Interest income, net	3,862	6,819
Other income, net[(1)]	1,310	1,090
Impairment of other investments	—	(13,001)
Total other income (loss), net	5,172	(5,092)
Net loss	$ (52,195)	$ (60,667)

(1) As of October 1, 2024, the Company's success payment liability was recognized at fair value as Stanford had provided the requisite service obligation to earn the potential success payment consideration. The change in the estimated fair value of Stanford success payment liabilities in the first quarter of 2025 was recognized within other income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities in the first quarter of 2024 was recognized within research and development expenses in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Fred Hutch success payment liabilities was recognized within other income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Balance Sheet Data:

	As of March 31, 2025	As of December 31, 2024
Cash, cash equivalents and marketable securities	$ 330,126	$ 383,541
Property and equipment, net	$ 44,195	$ 48,200
Total assets	$ 429,798	$ 490,859
Total stockholders' equity	$ 336,521	$ 382,824

Non-GAAP Financial Measures

To supplement our financial results and guidance presented in accordance with U.S. generally accepted accounting principles (GAAP), we present non-GAAP net loss, non-GAAP R&D expenses and non-GAAP G&A expenses. Non-GAAP net loss and non-GAAP R&D expenses exclude non-cash stock-based compensation expense and non-cash expenses related to the change in the estimated fair value of success payment liabilities from GAAP net loss and GAAP R&D expenses. Non-GAAP net loss further adjusts non-cash investment gains and charges, as applicable. Non-GAAP G&A expenses exclude non-cash stock-based compensation expense from GAAP G&A expenses. We believe that these non-GAAP financial measures, when considered together with our financial information prepared in accordance with GAAP, can enhance investors' and analysts' ability to meaningfully compare our results from period to period, and to identify operating trends in our business. We have excluded stock-based compensation expense, changes in the estimated fair value of success payment liabilities, and non-cash investment gains and charges from our non-GAAP financial measures because they are non-cash gains and charges that may vary significantly from period to period as a result of changes not directly or immediately related to the operational performance for the periods presented. We also regularly use these non-GAAP financial measures internally to understand, manage and evaluate our business and to make operating decisions. These non-GAAP financial measures are in addition to, and not a substitute for or superior to, measures of financial performance prepared in accordance with GAAP. In addition, these non-GAAP financial measures have no standardized meaning prescribed by GAAP and are not prepared under any comprehensive set of accounting rules or principles and, therefore, have limits in their usefulness to investors. We encourage investors to carefully consider our results under GAAP, as well as our supplemental non-GAAP financial information, to more fully understand our business.

Lyell Immunopharma, Inc.

Unaudited Reconciliation of GAAP to Non-GAAP Net Loss

(in thousands)

	Three Months Ended March 31,	
	2025	**2024**
Net loss - GAAP	$ (52,195)	$ (60,667)
Adjustments:		
Stock-based compensation expense	6,024	9,155
Change in the estimated fair value of success payment liabilities	(125)	968
Impairment of other investments	—	13,001
Net loss - Non-GAAP[(1)]	$ (46,296)	$ (37,543)

(1) There was no income tax effect related to the adjustments made to calculate non-GAAP net loss because of the full valuation allowance on our net deferred tax assets for all periods presented.

Lyell Immunopharma, Inc.

Unaudited Reconciliation of GAAP to Non-GAAP Research and Development Expenses

(in thousands)

	Three Months Ended March 31,	
	2025	**2024**
Research and development - GAAP	$ 43,447	$ 43,174
Adjustments:		
Stock-based compensation expense	(2,388)	(3,792)
Change in the estimated fair value of success payment liabilities[(1)]	—	(525)
Research and development - Non-GAAP	$ 41,059	$ 38,857

(1) As of October 1, 2024, the Company's success payment liability was recognized at fair value as Stanford had provided the requisite service obligation to earn the potential success payment consideration. The change in the estimated fair value of Stanford success payment liabilities in the first quarter of 2025 was recognized within other income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Stanford success payment liabilities in the first quarter of 2024 was recognized within research and development expenses in the Condensed Consolidated Statements of Operations and Comprehensive Loss. The change in the estimated fair value of Fred Hutch success payment liabilities was recognized within other income, net in the Condensed Consolidated Statements of Operations and Comprehensive Loss.

Lyell Immunopharma, Inc.

Unaudited Reconciliation of GAAP to Non-GAAP General and Administrative Expenses

(in thousands)

	Three Months Ended March 31,	
	2025	**2024**
General and administrative - GAAP	$ 14,046	$ 13,494
Adjustments:		
Stock-based compensation expense	(3,636)	(5,363)
General and administrative - Non-GAAP	$ 10,410	$ 8,131

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