



Legend Biotech Announces Exclusive, Global License Agreement for Certain CAR-T Therapies Targeting DLL3

November 13, 2023

- *The deal with Novartis seeks to advance Legend Biotech's autologous CAR-T cell therapy candidate, LB2102, and other potential CAR-T cell therapies targeting Delta-like ligand protein 3 (DLL3), using the Novartis next-generation T-Charge™ CAR-T cell therapy platform*
- *Legend Biotech will receive a \$100M upfront payment and will be eligible to receive potential milestone payments plus tiered royalties on net sales*

SOMERSET, N.J.--(BUSINESS WIRE)--Nov. 13, 2023-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global biotechnology company developing, manufacturing and commercializing novel therapies to treat life-threatening diseases, announced today that Legend Biotech Ireland Limited, a wholly owned subsidiary of Legend Biotech, has entered into an exclusive, global license agreement (License Agreement) with Novartis Pharma AG for certain Legend Biotech chimeric antigen receptor T-cell (CAR-T) cell therapies targeting DLL3, including its autologous CAR-T cell therapy candidate, LB2102 ([NCT05680922](#)).¹ The License Agreement grants Novartis the exclusive worldwide rights to develop, manufacture and commercialize these cell therapies, and Novartis may apply its T-Charge™ platform to their manufacture.

Legend Biotech is initiating clinical development of LB2102 for the treatment of extensive stage small cell lung cancer and large cell neuroendocrine carcinoma after the U.S. Food and Drug Administration (FDA) cleared its investigational new drug application in 2022. In 2023, the FDA granted the product candidate Orphan Drug Designation, a status conferred to drugs or biologics that are intended to treat, diagnose or prevent rare diseases and conditions.^{2,3}

The Novartis T-Charge platform is a next-generation CAR-T cell therapy manufacturing platform designed to preserve T cell stemness and facilitate CAR-T cell expansion primarily *in vivo*. The T-Charge platform is designed to reduce the need for extensive culture time outside the body and results in T cells with greater proliferative potential, as well as fewer exhausted T cells.⁴ LB2102 would be the first application of T-Charge by Novartis to a cell therapy candidate targeting solid tumors.

"We believe LB2102 has an innovative CAR design and armor mechanism that increases its anti-tumor activity. The preclinical evidence shows that an autologous CAR-T could be a differentiated treatment option for patients with small cell lung cancer," said Guowei Fang, Chief Scientific Officer and Head of Business Development of Legend Biotech. "We are excited that a major pharmaceutical company with deep roots in oncology and cell therapy has chosen to further this product candidate in the clinic. We are delighted that a combination of our unique candidate design in LB2102 with the T-Charge platform may potentially offer transformative benefits to small cell lung cancer patients."

Under the License Agreement, Legend Biotech will conduct a Phase 1 clinical trial for LB2102 in the U.S. Novartis will conduct all other development for the licensed products.

Under the terms of the License Agreement, Legend Biotech will receive a \$100 million upfront payment and will be eligible to receive up to \$1.01 billion in clinical, regulatory and commercial milestone payments and tiered royalties. Closing of the transaction is subject to the parties' receipt of any necessary consents or approvals, including the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976.

About Legend Biotech

Legend Biotech is a global biotechnology company dedicated to treating, and one day curing, life-threatening diseases. Headquartered in Somerset, New Jersey, we are developing advanced cell therapies across a diverse array of technology platforms, including autologous and allogeneic chimeric antigen receptor T-cell, gamma-delta T cell and natural killer (NK) cell-based immunotherapy. From our three R&D sites around the world, we apply these innovative technologies to pursue the discovery of cutting-edge therapeutics for patients worldwide.

Learn more at <https://legendbiotech.com/> and follow us on [Twitter](#) and [LinkedIn](#).

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the anticipated completion of the proposed transaction with Novartis, potential payments that may be received by Legend Biotech under the License Agreement, including for potential milestones and royalties, the ability of Legend Biotech and Novartis to develop licensed product from clinic to market, the potential benefits of licensed product, the potential benefits from synergies of licensed product with the T-Charge™ platform, and Legend Biotech's and Novartis' rights and obligations under the License Agreement. The forward-looking statements contained herein are based upon Legend Biotech's current expectations and involve assumptions that may never materialize or may prove to be incorrect. These forward-looking statements are neither promises nor guarantees and are subject to a variety of risks and uncertainties, including that the proposed transaction will be completed in a timely manner or at all, the possibility that certain closing conditions to the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits and opportunities of the proposed transaction may not be realized or make take longer to realize or may cost more than expected; risks of unexpected hurdles, costs or delays; challenges in technology transfer and cell therapy

manufacturing, particularly scaling up to commercial supply volumes, can limit the benefits of the transaction; challenges inherent in new product candidate development, including the uncertainty of clinical success or receipt of unexpected clinical data; unexpected regulatory actions or delays; challenges associated with collaborating with third parties, including intellectual property, operational, financial and other risks; uncertainty of commercial success for new products; the ability of Legend Biotech and/or Novartis to successfully execute their strategic plans; government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by third parties; uncertainties arising from challenges to the Legend Biotech's patent or other proprietary intellectual property protection, including the uncertainties involved in the U.S. litigation process; competition in general; government, industry, and general public pricing and other political pressures; the duration and severity of the COVID-19 pandemic and governmental and regulatory measures implemented in response to the evolving situation; as well as the other factors discussed in the "Risk Factors" section of Legend Biotech's Annual Report on Form 20-F filed with the Securities and Exchange Commission on March 30, 2023. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described in this press release as anticipated, believed, estimated or expected. Any forward-looking statements contained in this press release speak only as of the date of this press release. Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

¹ [ClinicalTrials.gov](https://clinicaltrials.gov). DLL3-Directed Chimeric Antigen Receptor T-cells in Subjects With Extensive Stage Small Cell Lung Cancer. Available at: <https://classic.clinicaltrials.gov/ct2/show/NCT05680922>. Last accessed Nov 2023.

² Legend Biotech Announces FDA Clearance of IND Application for LB2102 in Extensive Stage Small Cell Lung Cancer. Available at: [Legend Biotech Announces FDA Clearance of IND Application for LB2102 in Extensive Stage Small Cell Lung Cancer – Legend Biotech](#). Accessed Nov 2023.

³ [FDA.gov](#). Designating an Orphan Product: Drugs and Biological Products. Available at: [Designating an Orphan Product: Drugs and Biological Products | FDA](#). Last accessed Nov 2023.

⁴ Cancer Discov. 2023 Sep 6;13(9):1982-1997. doi: 10.1158/2159-8290.CD-22-1276. A Novel Autologous CAR-T Therapy, YTB323, with Preserved T-cell Stemness Shows Enhanced CAR T-cell Efficacy in Preclinical and Early Clinical Development

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