



## Legend Biotech Announces FDA Clinical Hold of its Phase 1 Clinical Trial for LB1901

February 15, 2022

SOMERSET, N.J.--(BUSINESS WIRE)--Feb. 15, 2022-- Legend Biotech Corporation (NASDAQ: LEGN) (Legend Biotech), a global, clinical-stage biotechnology company developing and manufacturing novel therapies, today announced that on Friday, February 11, 2022, the company was informed by the U.S Food and Drug Administration (FDA) via e-mail communication that its Phase 1 clinical trial for LB1901 has been placed on clinical hold. LB1901 is the company's investigational autologous chimeric antigen receptor T-cell (CAR-T) therapy targeting malignant CD4+ T-cells for the treatment of adults with relapsed or refractory T-cell lymphoma (TCL). The FDA indicated they will provide an official clinical hold letter to Legend Biotech by March 11, 2022.

To date, one patient has been dosed in the clinical trial. Before receiving the FDA's clinical hold communication, Legend Biotech had, in accordance with the protocol, paused the clinical trial due to low CD4+ T-cell counts in the patient's peripheral blood and notified the FDA. The patient has not experienced drug-related serious adverse events (SAEs) and is being monitored in accordance with the protocol.

### About Legend Biotech

Legend Biotech is a global, clinical-stage 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 allogenic chimeric antigen receptor T-cell, T-cell receptor (TCR-T), 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 safe, efficacious and cutting-edge therapeutics for patients worldwide.

Learn more at [www.legendbiotech.com](http://www.legendbiotech.com) and follow us on [Twitter](#) and [LinkedIn](#).

### Cautionary Statement:

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. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors. Legend Biotech's expectations could be affected by, among other things, uncertainties involved in the development of new pharmaceutical products; unexpected clinical trial or preclinical study results, including as a result of additional analysis of existing data or unexpected new data; unexpected regulatory actions or delays, including requests for additional safety and/or efficacy data or analysis of data, or government regulation generally; unexpected delays as a result of actions undertaken, or failures to act, by our third party partners; uncertainties arising from challenges to Legend Biotech's patent or other proprietary intellectual property protection, including the uncertainties involved in the US 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 April 2, 2021. 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. Legend Biotech specifically disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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