Legend Biotech
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Advancing targeted cell therapies to meet unmet needs in oncology and beyond

Legend Biotech is advancing cell therapy platforms for hematologic malignancies, solid tumors, infectious and autoimmune diseases.

At the 2020 American Society of Hematology (ASH) meeting, there was much anticipation around the latest results of the phase 1b/2 CARTITUDE-1 clinical trial which assessed ciltacabtagene autoleucel (cilta-cel), the investigational B cell maturation antigen (BCMA)-targeted chimeric antigen receptor (CAR) T cell therapy being jointly developed by Legend Biotech and Janssen Biotech, Inc.

The results are encouraging. The trial, which included 97 patients with relapsed or refractory multiple myeloma who had received a median of six prior treatments, indicates that a single low-dose infusion of cilta-cel led to early, deep, and durable responses. The overall response rate was 97%, with 67% of patients achieving a stringent complete response at median follow up of 12.4 months. The 12-month progression free survival rate was 77% and the safety profile was manageable at the recommended phase 2 dose.

For Ying Huang, Chief Executive Officer and Chief Financial Officer of Legend Biotech, these strong results demonstrate the potential of cilta-cel to be an efficacious treatment option with a manageable safety profile for patients who have been previously treated and have stopped responding to the three well-established classes of current treatments for multiple myeloma—a proteasome inhibitor, an immunomodulatory drug and an anti-CD38 antibody.

Based on these results, Janssen Biotech, Inc. initiated a rolling submission of a Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for cilta-cel at the end of 2020. Plans to submit marketing authorization applications for cilta-cel in Europe, China and Japan are also underway. Further, a comprehensive clinical development program has been started to study the use of cilta-cel in earlier lines of treatment for multiple myeloma.

Targeting BCMA in multiple myeloma

Multiple myeloma is the third most common type of blood cancer and represents >13% of all hematologic malignancies. Despite the rapidly growing development of novel agents and available therapies in recent years, patients keep relapsing or stop responding to available treatments, leading to poor quality of life and prognosis.

In recent years, CAR-T therapies, in which a patient's T cells are modified to recognize and target a specific protein on cancer cells, have emerged as a promising therapeutic option for hematologic cancers. BCMA is highly expressed on myeloma cells and has been identified as a strong target for CAR-T therapies. Cilta-cel is a structurally differentiated CAR-T with two BCMA-targeting domains.

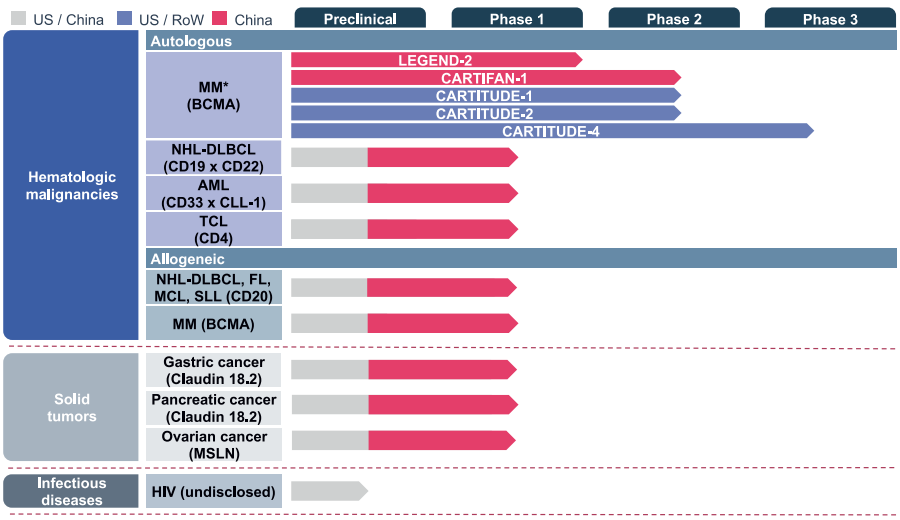

Fig. 1 | Legend Biotech's robust pipeline of next-generation cell therapies. The pipeline consists of both autologous and allogeneic therapies targeting hematologic malignancies, solid tumors, infectious diseases and autoimmune diseases. AML, acute myeloid leukemia; BCMA, B cell maturation antigen; DLBCL, diffuse large B cell lymphoma; FL, follicular lymphoma; HIV, human immunodeficiency virus; MCL, mantle cell lymphoma; NHL, non-Hodgkin lymphoma; MM, multiple myeloma; MSLN, mesothelin; RoW, Rest of World; SLL, small lymphocytic lymphoma; TCL, T cell lymphoma. *In collaboration with Janssen Biotech, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

A multicenter, first-in-human, investigator-initiated phase 1 clinical trial in patients with relapsed or refractory multiple myeloma in China (LEGEND-2) showed high response rates with a manageable safety profile. "The results observed in these patients were remarkable," said Huang. Presentation of early results by Legend at ASH and ASCO 2017 led to a subsequent worldwide collaboration and license agreement with Janssen Biotech, Inc., a global leader in pharmaceutical product development. Huang expressed excitement that in just three years, this collaboration has grown from signing the agreement to initiating a BLA submission for cilta-cel.

Advancing a robust pipeline

With an end-to-end R&D capability and an experienced global leadership team, Legend Biotech is growing an innovative pipeline of both autologous and allogeneic therapies for different indications including hematologic malignancies, solid tumors, infectious diseases and autoimmune diseases (Fig. 1).

The recent FDA clearance of its Investigational New Drug LB1901, an autologous CAR-T therapy being explored for the treatment of adults with relapsed or refractory T cell lymphoma (TCL), will allow the company to initiate a phase 1 study in the US. LB1901 targets CD4, a surface membrane glycoprotein that is expressed in most TCL subtypes.

Legend Biotech is also advancing allogeneic CAR-T therapies, designed as off-the-shelf treatments, targeting CD20 and BCMA, as well as autologous CAR-T therapies targeting Claudin 18.2 for advanced pancreatic and gastric cancer.

"Cell therapies hold a lot of promise for a wide range of hard-to-treat cancers. We look forward to exploring the full potential of CAR-T cell therapies and are working hard to provide physicians and patients with innovative treatment options," Huang concluded.

CONTACT
Jessie Yeung, Head of Corporate Finance and Investor Relations
Legend Biotech
Somerset, NJ, USA
Tel: +1-732-317-5050
Email: media@legendbiotech.com