Legend Biotech is a global, clinical-stage biopharmaceutical company with integrated end-to-end capabilities focused on discovery and development of novel cell therapies. The company’s lead product, LCAR-B38M, is in late-stage global clinical development for multiple myeloma in collaboration with Janssen Biotech, Inc.

Legend Biotech is uniquely positioned to enable accelerated global clinical development and commercialization of innovative cell therapies (Fig. 1). Legend is developing several proprietary technology platforms including chimeric antigen receptor-T cell (CAR-T), T cell receptor (TCR) and allogeneic cell-based therapies. The company’s lead product is a B cell maturation antigen (BCMA)-targeting CAR-T therapy, LCAR-B38M, which is in late-stage clinical development for advanced relapsed or refractory (R/R) multiple myeloma (MM). Legend has developed a robust pipeline that includes products targeting gastric cancer, pancreatic cancer, ovarian cancer, T cell lymphoma, acute myeloid leukemia and infectious diseases. Multiple first-in-human studies are underway or planned in China and the US.

**Advanced CAR-T collaboration for MM**

Legend’s lead product, LCAR-B38M, is a structurally differentiated CAR-T cell therapeutic containing a 4-1BB (also known as TNFRSF9 or CD137) costimulatory domain and two BCMA-targeting single-domain antibodies designed to confer high avidity, which distinguishes LCAR-B38M from other BCMA CAR constructs. LEGEND-2 (NCT03090659), a first-in-human and proof-of-concept study in 74 patients with R/R MM in China, demonstrated deep and durable responses to treatment with LCAR-B38M accompanied by a manageable and tolerable safety profile.1,2

These promising clinical data along with Legend’s innovative research and development (R&D) capabilities led to the successful execution of a worldwide collaboration and license agreement to develop, manufacture and commercialize LCAR-B38M with Janssen in December 2017. Under the terms of the worldwide agreement, Legend and Janssen are codeveloping and will cocommercialize LCAR-B38M/JNJ-4528. Legend will manufacture LCAR-B38M/JNJ-4528 for commercial distribution worldwide and act as Janssen’s contract manufacturing organization. LCAR-B38M/JNJ-4528 is currently in a phase 1b/2 global clinical study, CARTITUDE-1 (NCT03548207), in the US with plans to expand to Europe. In addition, a phase 2 registration clinical study, CARTIFAN-1 (NCT03758417), is actively enrolling patients in China.

In February 2019, JNJ-4528 was granted orphan drug designation by the US Food and Drug Administration. More recently, it was also granted a priority medicines (PRIME) designation from the European Medicines Agency. The PRIME program focuses on medicines that may offer a major therapeutic advantage over existing treatments or benefit patients without treatment options. It offers companies enhanced interaction and early dialogue in order to optimize development plans and speed up the evaluation so that medicines may reach patients earlier. In order to be accepted for PRIME designation, a medicine must show its potential to benefit patients with unmet medical needs based on early clinical data.

**Flexible partnership model for pipeline assets**

Legend is continuing to leverage its strong R&D engine to deliver innovative pipeline assets. Legend’s global network and strategy will facilitate accelerated clinical proof of concept for lead candidates. In addition, Legend’s worldwide manufacturing footprint enables rapid development and commercialization of novel cell therapies. Legend is building a best-in-class cell therapy company that has attracted top talent to advance pipeline assets.

“Improving patients’ lives is a core value at Legend,” said Yuan Xu, CEO of Legend. “We are excited and open to future collaboration agreements with companies that share the same vision and passion for innovative cell therapies to address high unmet medical needs.”


Yuan Xu, CEO, Legend

*Improving patients’ lives is a core value at Legend*

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