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Japan approves CAR-T therapy for relapsed or refractory multiple myeloma

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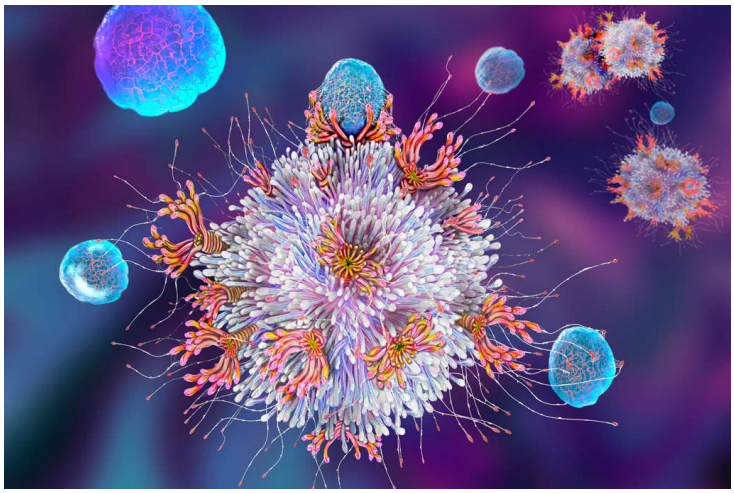
CARVYKTI (ciltacabtagene autoleucel) receives approval from Japan's Ministry of Health, Labour and Welfare (MHLW) for the treatment of patients with relapsed or refractory multiple myeloma



US-based Legend Biotech Corporation has announced that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved CARVYKTI (ciltacabtagene autoleucel), a B-cell maturation antigen (BCMA)-directed chimeric antigen receptor T cell (CAR-T) therapy, for the treatment of adults with relapsed or refractory multiple myeloma, limited to cases meeting both of the following conditions:

- Patients have no history of CAR-positive T cell infusion therapy targeting BCMA
- Patients who have received three or more lines of therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody, and in whom multiple myeloma has not responded to or has relapsed following the most recent therapy

The New Drug Application was submitted by Legend Biotech's collaboration partner, Janssen Pharmaceuticals (Janssen). Legend entered into an exclusive worldwide license and collaboration agreement with Janssen to develop and commercialize ciltacabtagene autoleucel (cilta-cel) in December 2017.

CARVYKTI features two BCMA-targeting single domain antibodies, is specifically developed for each individual patient and is administered as a single infusion.