IDRE Innovative Drugs Regulatory Europe

DEVELOPING NEWS

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Innovative Research Meets and Overcomes Milestones

BMS announced FDA and EC approvals for their innovative CAR T Cell Therapy for R/R Multiple Myeloma earlier this year. A ground-breaking achievement that gives many people new hope.

In August 2021 Bristol Myers Squibb (BMS) announced that the European Commission (EC) has granted Conditional Marketing Authorization for Abecma (idecabtagene vicleucel; ide-cel), a first-in-class B-cell maturation antigen (BCMA)-directed chimeric antigen receptor (CAR) T cell immunotherapy, for the treatment of adult patients with relapsed and refractory multiple myeloma. Patients must have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody, and have demonstrated disease progression on the most recent therapy.

Abecma is the first and only CAR T cell therapy approved that is directed to recognize and bind to BCMA, a protein that is nearly universally expressed on cancer cells in multiple myeloma, leading to the death of BCMA-expressing cells. Abecma is approved for use in all European Union (EU) member states.

Abecma was earlier approved by U.S. Food and Drug Administration (FDA) in March 2021.

Chimeric antigen receptor (CAR)-T cell therapy is a new multiple myeloma treatment. It is a class of immunotherapy that may improve outcomes for people with advanced myelomas.

Other CAR-T cell treatments are also currently in various stage of clinical trial, focusing on targeting BCMA, a TNF receptor superfamily. Most current CAR-T cell therapy trials for solid tumours are being conducted in China, with 34 trials out of a total of 52 trials registered in the ClinicalTrials.gov database. Of the remaining trials, 14 are being conducted in the US, 2 in Europe and 2 in Southeast Asia and the Pacific region (as of January 2021).

We are exploring opportunities partnering a company that has developed a CAR, based on the scFv of an antibody recognizing stage specific embryonic antigen-4 (IDA17) on cancer cell surface. The investigational treatment in this trial, IDA17-A, consists of a single infusion of patient-derived T cells which have been transduced with an anti-IDA17 expressing lentivirus. They are currently poised to kick-off a Ph.I open-label, single-centre, study designed to investigate the safety and tolerability of a single infusion of autologous peripheral blood T-lymphocytes transduced with the anti-IDA17 lentivirus vector.

The primary aim of the trial is to evaluate the safety and tolerability of CAR-IDA17 in patients with advanced solid tumours.

Please call us for further information (Investigator's Brochure (IB), Investigational Medicinal Product Dossier (IMPD) both available), or to express an interest in investment.

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