US FDA approves ciltacabtagene autoleucel (CARVYKTI) for relapsed or refractory myeloma

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Manufactured by Janssen, it is specifically approved for the treatment of patients with relapsed or refractory myeloma after four or more prior lines of therapy, including a proteasome inhibitor (like bortezomib), an immunomodulatory agent (like lenalidomide), and an anti-CD38 monoclonal antibody (like daratumumab or isatuximab). You can find the full Janssen press release here.

Cilta-cel is the second anti-BCMA CAR-T cell therapy the FDA has approved for myeloma, following the positive recommendation of idecabtagene vicleucel (Abecma) in March 2021.

The approval of cilta-cel is based on data from the phase Ib/II CARTITUDE-1 clinical trial, which showed deep and long-lasting responses in patients who were heavily pre-treated. 98% of patients responded to therapy, with 78% of these patients experiencing a stringent complete response (sCR), a very deep response to treatment. Follow up data presented at ASH 2021 also found that responses deepened over time.

Kate Morgan, Head of Policy and Access at Myeloma Patients Europe (MPE) commented:

"Whilst we are still awaiting approval in Europe, the FDA approval of cilta-cel in myeloma is good news as it has shown significant response rates in the heavily pre-treated myeloma population. MPE will be working with Janssen to understand the regulatory timelines in Europe and to understand how it will become available to patients. There are several challenges we face in making CAR-T therapies widely available in Europe, which we hope to work with relevant stakeholders to address – such as manufacturing and reimbursement challenges."

What is CAR-T? Where can I find further information?

CAR-T cell treatment genetically programmes, through a complex manufacturing process, immune cells (known as T cells) to find a specific protein (such as BCMA) on myeloma cells. When reintroduced into patients' bodies, CAR-T boosts the ability of the T-cells to find and destroy myeloma cells.

MPE has followed the development of CAR-T in recent years, see the materials below to find out more:

- Interview with Dr Hermann Einsele, Director of the Department of Internal Medicine II at the Würzburg University Hospital to summarise the main CARTITUDE-1 data and highlights on CAR-T in myeloma presented at American Society of Clinical Oncology (ASCO) 2020.
- Interview with Dr Marivi Mateos, Director of the Myeloma Unit at the University Hospital of Salamanca-IBSAL in Spain, to summarise the most important myeloma highlights presented at European Hematology Association's annual congress (EHA25 Virtual) in 2020 in which she talks about CARTITUDE-1 and other CAR-T clinical trials.

- Animated video “How does CAR-T cell therapy work?
- Q&A CAR-T cell therapy in myeloma
- The Reality of CAR T-cell Therapy: Am I Eligible?