October 25, 2022 02:41 PM EDT *Updated 07:05 PM* | Pharma, FDA+

FDA approves J&J's BCMA-targeted bispecific for multiple myeloma

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The FDA on Tuesday granted accelerated approval to Johnson & Johnson's Tecvayli (teclistamab), a BCMA-directed bispecific antibody, looking to head into an already crowded field of treatments aiming to help those with the blood cancer multiple myeloma.

The approval, which included a REMS due the risks of CRS and neurologic toxicity, follows promising early efficacy in 40 patients, with 65% of patients having a partial response or better, and further data from a Phase I/II trial, published in the New England Journal of Medicine earlier this month, known as MajesTEC-1. Those results showed that in a larger group of 165 patients, with median follow-up of 14.1 months (range of 0.3 to 24.4), responses occurred in 104 patients (63%; 95% confidence interval [CI], 55.2 to 70.4), as well as a partial response or better in 97 patients (58.8%), and a complete response or better in 65 (39.4%).

The FDA said it's the first bispecific BCMA-directed CD3 T-cell engager for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

Bernadette King, a J&J spokesperson, told Endpoints via email that in its clinical trial, the average patient was treated for 9 to 10 months. Based on this, the total cost of therapy ranges between a list price of $355,000 and $395,000 – or $39,500 per month.

The approval follows the launch of three other BCMA-targeted therapies — GSK's ADC Blenrep, Bristol Myers Squibb's CAR-T therapy Abecma, and J&J's CAR-T Carvykti — in myeloma for those who have received prior treatments including immunomodulatory agents, proteasome inhibitors, and anti-CD38 antibodies.

Vincent Rajkumar

"I think this is an important addition to treatment of relapsed refractory myeloma," Vincent Rajkumar, professor at the Mayo Clinic and editor-in-chief of the Blood Cancer Journal, told Endpoints News. "Currently there are long waiting periods for CAR-T and delays in administration. The other BCMA targeted agent belantamab has risks of keratopathy limiting use. Teclistamab will be therefore be very important as a treatment option for refractory disease."

But as cytokine release syndrome occurred in 72% of patients in the trial, and 45% of patients experienced grade 3 or 4 infections, Rajkumar added:

I am however concerned about prolonged weekly therapy and the risk of serious infections and other complications it can bring along. I do not think we know the optimal dosing schedule. I suspect for many patients we can reduce the frequency or stop therapy once a good response is achieved.

A Phase III trial is ongoing and comparing teclistamab in combo with daratumumab.

The NEJM publication also laid out the various response rates of the other therapies, noting, "In this heavily pretreated population, the overall response rate with belantamab mafodotin [Blenrep] is approximately 31%.5 Response rates are 67% for idecabtagene vicleucel [Abecma] and 83% for ciltacabtagene autoleucel [Carvykti] in patients who have undergone apheresis; however, CAR-T therapy has limitations regarding patient eligibility, safety, and access to treatment."

While J&J is first to the US market (EU approval came last week) with teclistamab, the BCMA T-cell engager space is crowded, according to Evaluate Pharma. Pfizer's elranatamab expects a final analysis from its pivotal MagnetisMM-3 later this year, while others in ongoing studies include AbbVie's ABBV-383, Regeneron's REGN5458 and Amgen's AMG 701.