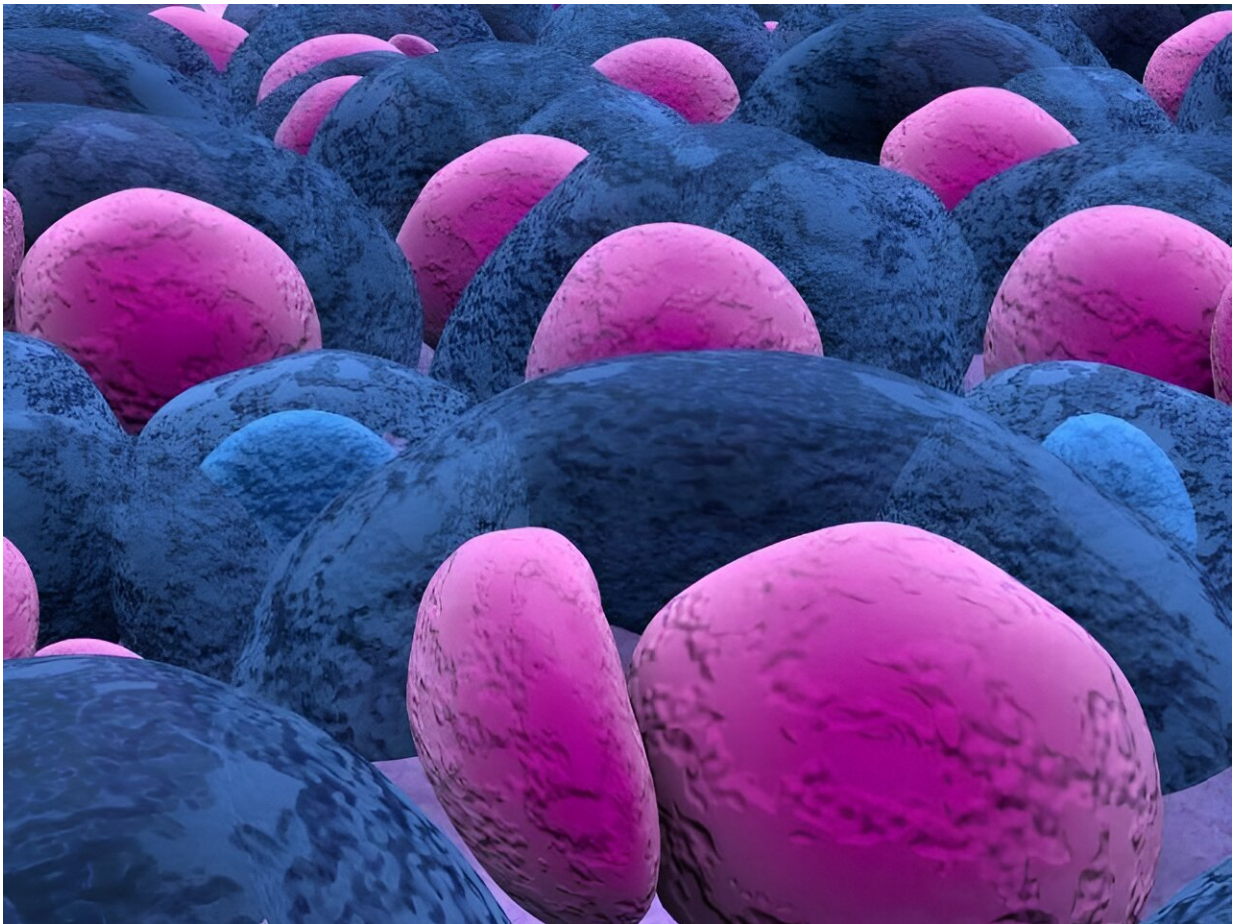


FDA provides accelerated approval of Talvey for multiple myeloma

August 16 2023, by Lori Solomon



The U.S. Food and Drug Administration has approved [Talvey](#)

(talquetamab-tvgs) for patients with relapsed or refractory multiple myeloma.

The [accelerated approval](#) is for individuals who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody. Talvey is a bispecific antibody targeting CD3 on T cells and G protein-coupled receptor class C group 5 member D, expressed on the surface of multiple myeloma cells.

Findings from the phase 2 MonumentAL-1 study showed both a positive response rate and durability of response. At a biweekly dose of 0.8 mg/kg, 73.6 percent of patients achieved an overall response rate. Over a median of six months from first response among responders, 58 percent of patients achieved a very good partial response or better, including 33 percent of patients achieving a complete response or better. For a weekly dose of 0.4 mg/kg, 73.0 percent of patients achieved an overall response rate, and over a median of nearly 14 months from first response among responders, 57 percent of patients achieved a very good partial response or better, including 35 percent of patients achieving a complete response or better. In the 0.8 mg/kg biweekly dose group, an estimated 85 percent of responders maintained response for at least nine months.

The most common nonhematologic adverse effects were oral toxicities (80 percent of [patients](#)), [weight loss](#) (62 percent), and serious infections (16 percent).

Approval of Talvey was granted to Janssen.

More information: [More Information](#)

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