FDA provides accelerated approval of Talvey for multiple myeloma

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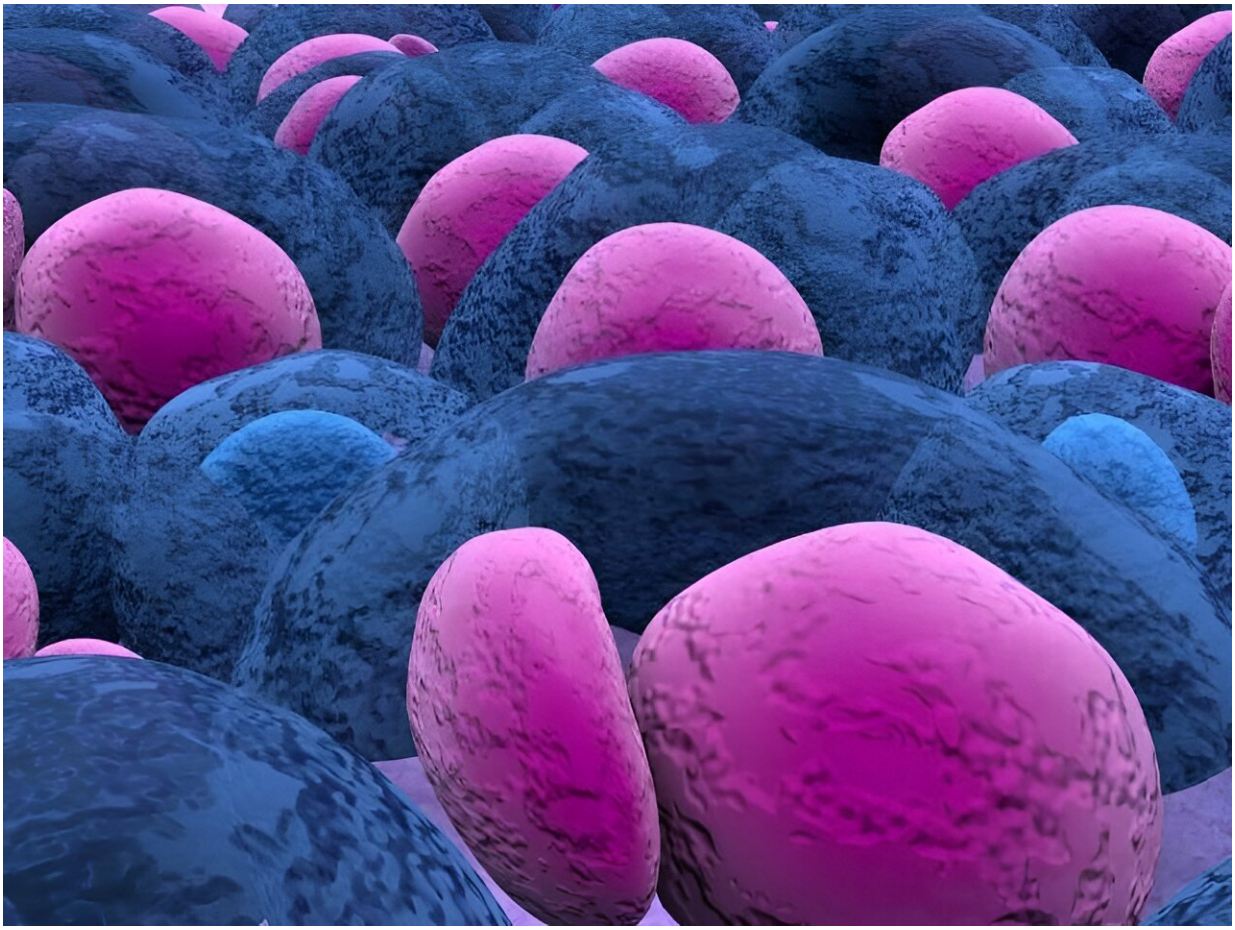

The U.S. Food and Drug Administration has approved Talvey

(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