1 Category/product

Category of application: Best biotechnology product

Drug name: TALVEY™ (talquetamab-tgvs)

Technical name: Talquetamab-tgvs

Trade name: TALVEY™

Date of US approval: August 9, 2023

Date of EU/EAA approval: August 21, 2023

Therapeutic categories: Oncology: multiple myeloma (MM)

Indications: In the United States, TALVEY™ (talquetamab-tgvs) is a G protein-coupled receptor class C group 5 member D (GPRC5D)-directed CD3 T-cell engager approved in the United States of America as a monotherapy for the treatment of adult patients with relapsed or refractory MM (RRMM) who have received at least 4 prior lines of therapy including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody (mAb). This indication is approved under accelerated approval based on response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In the European Union, TALVEY™ is approved as a monotherapy for the treatment of adult patients with RRMM who have received at least 3 prior therapies including a PI, an IMiD, and an anti-CD38 mAb, and have demonstrated disease progression on the last therapy.

Table. Additional approvals and indications

Country	Indication
Australia	Provisional approval for the treatment of adult patients with RRMM who have previously received ≥4 prior therapies, including a PI, an IMiD, and an anti-CD38 mAb

Bahrain, Costa Rica, Dominican Republic, Hong Kong, Iceland, Israel, Mexico, Norway, Panama, Peru, Qatar, Singapore, Switzerland, Syria, Thailand, and the United Kingdom	Indicated as monotherapy for the treatment of adult patients with RRMM who have received ⩾3 prior therapies, including a PI, an IMiD, and an anti-CD38 mAb and have demonstrated disease progression on the last therapy
Brazil	Indicated for the treatment of adult patients with RRMM who have received ⩾3 prior therapies, including a PI, an IMiD, and an anti-CD38 mAb and have demonstrated disease progression on the last therapy
Canada	Indicated for the treatment of adult patients with RRMM who have received ⩾3 prior lines of therapy, including a PI, an IMiD, and an anti-CD38 mAb, and have demonstrated disease progression on or after the last therapy
China and Korea	Indicated as monotherapy for the treatment of adult patients with RRMM who have received ⩾3 prior therapies, including a PI, an IMiD, and an anti-CD38 mAb
Japan	Indicated as monotherapy for the treatment of adult patients with RRMM (limit the use to patients for whom standard treatment is difficult)
Kuwait, Oman, Saudi Arabia, Serbia, and United Arab Emirates	Indicated as monotherapy for the treatment of adult patients with RRMM who have received⩾3 prior therapies, including a PI, an IMiD, and an anti-CD38 mAb and have demonstrated disease progression or did not respond to the last therapy
Taiwan	Indicated for the treatment of adult patients with RRMM who have received ⩾4 prior lines of therapy, including an IMiD, a PI, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

TALVEY™ (talquetamab-tgvs) US Prix Galien submission. [June 30th, 2025]

Orphan drug designations: United States, European Union, Japan, and South Korea

Breakthrough therapy designations: United States and China