1 Category/Product

Category of application:	Best Biotechnology Product
Drug name:	TECVAYLI® (teclistamab-cqyv)
Technical name:	Teclistamab-cqyv
Trade name:	TECVAYLI®
Date of US approval:	October 25, 2022
Date of EU approval:	August 23, 2022
Therapeutic categories:	Oncology – multiple myeloma (MM)
Indications:	TECVAYLI® is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager approved in the United States 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. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).[1] In the EU, TECVAYLI 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.[2]