Category

Best Biotechnology Product

General Information

Company Name *

Johnson & Johnson Services, Inc.

Product/Solution Name *

TECVAYLI™ (teclistamab-cqyv)

Compound/Tech Name*

Teclistamab-cqyv

Trade Name *

TECVAYLI™

Corporate Name *

Johnson & Johnson

Date of Approval *

2022-10-25

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). 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.

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Therapeutic Areas *

Oncology - multiple myeloma (MM)

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Attached Files:

- Prix Galien_TECVAYLI_1_CategoryProduct.pdf

Background information and need for drug / device
(please be as specific as possible in your description; limit 500 words)

Multiple myeloma (MM) is a hematologic cancer with an incidence of ~2% in the United States alone and a 5-year survival rate of just 59.8%. MM is characterized by uncontrolled proliferation of malignant plasma cells and overproduction of monoclonal immunoglobulin in the bone marrow. The infiltration of these malignant cells into various organ systems gives rise to diverse clinical manifestations including bone disease, blood disorders, infections, fatigue, neurological effects, and renal impairment, resulting in painful symptoms that can severely impact patients' quality of life. The therapeutic landscape of MM is rapidly evolving, and the past few decades have given rise to several major treatment advancements, forming the foundation for current standard-of-care (SOC) therapy. Despite these advancements, MM remains a devastating disease, and most patients continue to experience cycles of remission and relapse, requiring further treatment. Outcomes are particularly poor for those who are triple-class exposed, having previously received at least one of the 3 main drug classes comprising current SOC: an immunomodulatory drug, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Improved therapeutic options that are well-tolerated and produce deeper and more durable responses at any point in a patient's treatment course are urgently needed. TECVAYLI offers a novel therapeutic approach, with a response rate of 63.0% (59.4% with very good partial response or better and 46.1%% with complete response or better) in patients with relapsed and/or refractory MM. TECVAYLI led to deep and durable responses with manageable toxicity, demonstrating significantly improved outcomes over current SOC treatments.

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- Prix Galien_TECVAYLI_2_Background.pdf

History of the development of the solution/product *
(please be as specific as possible in your description; 500 words)

TECVAYLI is a full-size bispecific antibody that induces T-cell-mediated cytotoxicity by recruiting CD3-expressing T cells to B-cell maturation antigen (BCMA)-expressing cells, leading to T-cell activation and subsequent cell lysis via secretion of perforin and granzymes. BCMA regulates B-cell proliferation, survival, and plasma cell differentiation. It is preferentially expressed on plasmablasts and differentiated plasma cells, is highly expressed on myeloma cells compared with normal plasma cells, and is a recognized target for therapeutic intervention in RRMM. In preclinical studies, TECVAYLI induced robust T-cell activation and selective lysis of myeloma cells. The pivotal phase 1/2 MajesTEC-1 study demonstrated high rates of deep and durable responses with a predictable, clinically manageable safety profile in heavily pretreated patients with RRMM. TECVAYLI is being developed across a range of disease and treatment settings, including RRMM for patients who have received one

or more prior lines of therapy, newly diagnosed MM for patients who are either eligible or ineligible for stem cell transplant, and early or smoldering MM. The full clinical development program also includes studies of TECVAYLI as monotherapy, in combination therapies, and as maintenance therapy. This accelerated development plan was designed to bring TECVAYLI to as many MM patients as possible at any stage of disease or treatment course.

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- Prix Galien_TECVAYLI_3_History.pdf

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition *

TECVAYLI is the first approved B-cell maturation antigen (BCMA) × CD3 bispecific antibody, with weight-based dosing and longest study follow-up of any bispecific antibody in MM. TECVAYLI demonstrated rapid, deep, and durable responses with a manageable safety profile in the MajesTEC-1 study. These clinical results are supported by rapid reductions in soluble BCMA (sBCMA) levels; as elevated sBCMA is associated with increased disease burden and poor prognosis, these data further validate BCMA as an effective target in MM therapy and solidify TECVAYLI as the BCMA-targeting therapy of choice. In addition, several indirect treatment comparisons have demonstrated substantially improved outcomes with TECVAYLI over current off-the-shelf SOC treatments. The clinical efficacy of any therapeutic is of utmost importance, but it is essential for a treatment to also be available and convenient in order to be truly effective for patients. TECVAYLI delivers on all 3 aspects with exceptional efficacy, immediate availability, and subcutaneous administration. TECVAYLI's novel mechanism of action has the potential to yield synergistic efficacy to enhance anti-myeloma effects when combined with complementary therapeutic agents. Several ongoing and future studies are exploring the use of TECVAYLI in combination with various SOC therapies and novel agents. TECVAYLI represents a new SOC for MM that has the potential to revolutionize the therapeutic landscape by expanding treatment options across all lines of therapy, both as a monotherapy and in a variety of combination treatments, giving rise to potentially curative regimens for patients with MM.

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- Prix Galien_TECVAYLI_4_5_Innovation_Conc.pdf

Please provide appropriate references (PubMed, Abstract, Website) *

Please see attached PDF for full list of references.

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Attached Files:

- Prix Galien_TECVAYLI_6_References.pdf