



Teclistamab: First Approval

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Abstract

Teclistamab (TECVAYLI[®]), a bispecific antibody that targets CD3 and B cell maturation antigen (BCMA), is being developed by Janssen Research and Development for the treatment of relapsed or refractory multiple myeloma. Teclistamab was recently granted conditional approval in the EU for the treatment of adult patients with relapsed and refractory multiple myeloma who have received three or more prior therapies (including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody) and have demonstrated disease progression on the last therapy. Teclistamab was subsequently approved in the US for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy (including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody). This article summarizes the milestones in the development of teclistamab leading to this first approval for relapsed or refractory multiple myeloma.

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Teclistamab (TECVAYLI[®]): Key Points

A CD3xBCMA bispecific antibody is being developed by Janssen Research & Development for the treatment of relapsed and refractory multiple myeloma.

Received its first conditional approval on 24 Aug 2022 in the EU.

Conditionally approved for use in adults with relapsed and refractory multiple myeloma who have received three or more prior therapies (including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody) and have demonstrated disease progression on the last therapy.

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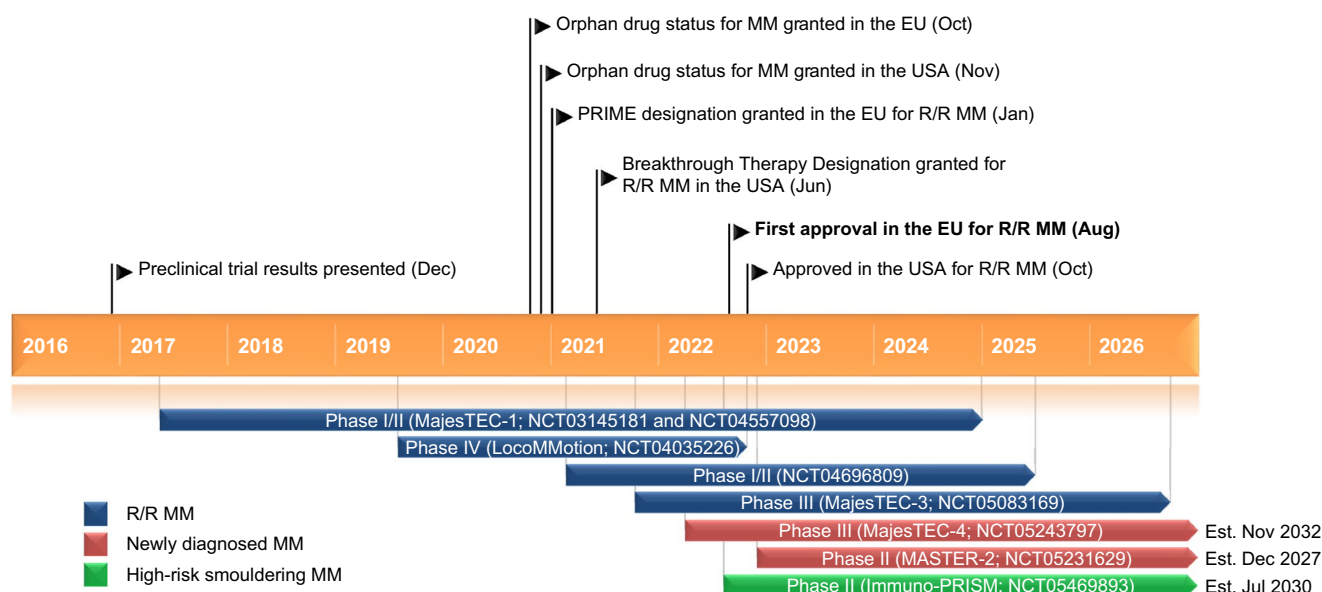
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1 Introduction

Teclistamab (TECVAYLI[®]), a bispecific antibody that targets CD3 and B cell maturation antigen (BCMA), is being developed by Janssen Research and Development for the treatment of relapsed or refractory (R/R) multiple myeloma (MM). Patients with MM who relapse after multiple lines of standard treatment (anti-CD38 antibodies in particular) are especially difficult to treat, as each subsequent line of treatment proves less effective [1]. Teclistamab is the first T-cell-redirecting bispecific antibody to be approved for MM [2].

Teclistamab received its first conditional approval on 24 Aug 2022 in the EU for the treatment of adult patients with R/R MM who have received three or more prior therapies (including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody) and have demonstrated disease progression on the last therapy [2]. The approved initial step-up dosing schedule is subcutaneous (SC) injections of teclistamab on day 1 (0.03 mg/kg), day 3 (0.06 mg/kg) and day 5 (1.5 mg/kg), followed by the maintenance dose of 1.5 mg/kg/dose once weekly [3]. Pre-treatment during the step-up schedule (with a corticosteroid, antihistamine and antipyretic) must be administered 1–3 h prior to each teclistamab dose to reduce the risk of adverse reactions such as cytokine release syndrome (CRS), infections, or neurological or haematological toxicities. Treatment with teclistamab is to be continued until unacceptable toxicity or disease progression [3]. Teclistamab was subsequently approved on 25 Oct 2022 in the US for the treatment



Key milestones in the development of teclistamab for the treatment of relapsed or refractory multiple myeloma. *Est.* estimated, *MM* multiple myeloma, *PRIME* Priority Medicines, *R/R* relapsed or refractory

of adult patients with R/R MM who have received at least four prior lines of therapy (including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody) [4]. Teclistamab is also being developed in MM after 1–3 prior lines of therapy (at phase III) [5].

1.1 Company Agreements

In July 2012, Genmab and Janssen Biotech, Inc. entered a research and development collaboration agreement for up to ten DuoBody® programmes (bispecific antibodies for multiple disease targets) [6]. Genmab received an upfront fee from Janssen Biotech, Inc. for this agreement, with entitlement to milestone and license payments for each product, as well as sales royalties and funding for research [6]. The agreement was updated in December 2013, where Janssen Biotech, Inc. was able to develop ten more programmes [7].

In October 2013, Janssen entered into an agreement with Ligand Pharmaceuticals, in which Janssen could develop fully human antibodies using Ligand Pharmaceuticals' OmniAb® technology platform, and Ligand Pharmaceutical would receive development milestone payments and royalties [8]. An affiliate of Janssen Pharmaceuticals, Inc. filed an Investigational New Drug application in March 2017, resulting in a milestone payment to Ligand Pharmaceuticals [8].

In September 2020, Janssen Biotech, Inc. and SpringWorks Therapeutics, Inc. entered into a clinical collaboration and supply agreement to investigate nirogacestat, a gamma secretase inhibitor, in combination with teclistamab

in patients with R/R MM [9]. Nirogacestat blocks the cleavage of BCMA from the cell surface, where circulating BCMA can bind to the anti-BCMA binding site [10]. This can lead to increased efficacy as has been reported with chimeric antigen receptor T cell therapy in MM [10].

2 Scientific Summary

2.1 Pharmacodynamics

Teclistamab works by redirecting CD3-positive T cells to MM cells that express BCMA to induce cytotoxicity and tumour cell death [3]. This targeting of BCMA is effective as BCMA is overexpressed and activated in MM [11], and is mediated by the secretion of perforin and certain granzymes from cytotoxic T cells [3]. This process is non-specific and does not involve major histocompatibility complex class I molecules on antigen-presenting cells [3].

Treatment with teclistamab for less than one month resulted in the activation and redistribution of T cells, a reduction in B cells and the induction of serum cytokines [3]. Reductions in soluble BCMA levels were also seen within one month of treatment [3]. The extent of the reduction was correlated to the depth of patient response, as patients who had achieved complete response (CR) or stringent CR had the greatest reductions from baseline in soluble BCMA levels [11].

Results from an ex vivo cytotoxicity assay demonstrated 1.5 mg/kg once weekly of SC teclistamab was the first

Features and properties of teclistamab

Alternative names	BCMAxCD3-Genmab/Janssen Research & Development; JNJ 7957; JNJ-64007957; TECVAYLI
Class	Antineoplastics; Bispecific antibodies; Immunotherapies
Mechanism of action	Antibody-dependent cell cytotoxicity; cytotoxic T lymphocyte stimulants
Route of administration	Intravenous, parenteral, subcutaneous
Pharmacodynamics	Binds to CD3 receptors on both T cells and B cell maturation antigen (BCMA; expressed on malignant multiple myeloma B cells), bringing CD3+ T cells and BCMA+ cells together and activating T cells; results in BCMA+ cell lysis and death Majority of teclistamab recipients had reduced soluble BCMA levels within 1 month of treatment
Pharmacokinetics	Steady-state C_{max} 25.3 µg/mL and AUC_{τ} 3905 µg·h/mL; mean volumes of distribution 4.13 L (central compartment) and 1.34 (peripheral compartment); mean clearance 0.449 L (time-independent)
Adverse reactions	
Most frequent (all-cause)	Hypogammaglobulinaemia, cytokine release syndrome, neutropenia, anaemia musculoskeletal pain, fatigue, thrombocytopenia (≥ 40% of patients)
Adverse reactions of special interest	Cytokine release syndrome, neurological toxicities (including immune effector cell-associated neurotoxicity syndrome), infections
ATC codes	
WHO ATC code	L01X-C (Monoclonal antibodies)
EphMRA ATC code	L1G (Monoclonal Antibody Antineoplastics)
Chemical name	Immunoglobulin G4 (233-proline, 239-alanine, 240-alanine, 410-leucine)

dosage level to have teclistamab exposure levels above target with no significant effects on the safety profile [12].

2.2 Pharmacokinetics

Following SC administration in a phase I/II trial (MajesTEC-1) in patients with R/R MM [1], teclistamab showed approximately dose-proportional pharmacokinetics (PKs) at a dose range of 0.08–3.0 mg/kg/dose [3]. Steady state was reached at the seventh weekly maintenance dose of teclistamab. At steady state, the maximum drug concentration (C_{max}) was 25.3 µg/mL and the area under the plasma concentration-time curve during the weekly dosing interval was 3905 µg·h/mL; the accumulation ratios were 2.71- and 3.05-fold, respectively. Time to reach C_{max} was 48.9 h. Compared to intravenous teclistamab, administration of SC teclistamab resulted in a mean bioavailability of 69% [3].

Based on a two-compartment population PK model, the mean volume of distribution for the central compartment was 4.13 L (and 1.34 L for the peripheral compartment) [3]. The mean time-independent clearance of teclistamab was 0.449 L/day; time-dependent clearance was ≈ 43% of total baseline clearance, and reduced to < 10% at week 8 of treatment. The population PK model showed the serum concentration of teclistamab was not significantly affected by soluble BCMA levels [3].

While formal studies in special populations are lacking, population PK analyses show teclistamab PKs were not affected by sex, age (24–84 years), mild-to-moderate kidney dysfunction or mild hepatic impairment. PK data in patients with severe kidney dysfunction or moderate-to-severe hepatic impairment are lacking [3].

2.3 Therapeutic Trials

Conditional approval of teclistamab was based on an ongoing, first-in-human, open-label, single-arm, multi-centre, phase I/II trial (NCT03145181, NCT04557098; MajesTEC-1) in which deep and durable responses to teclistamab were seen in patients with R/R MM [1, 13]. In phase 1 of the study (during the dose-escalation portion), different patient cohorts received either intravenous teclistamab (0.3–19.2 µg/kg once every 2 weeks or 19.2–720 µg/kg once weekly; $n = 84$) or SC teclistamab (80–3000 µg/kg once weekly; $n = 73$), with step-up titration for doses ≥ 38.4 µg/kg [1]. The purpose of this phase was to establish the recommended phase 2 dose (RP2D; 1.5 mg/kg once weekly of SC teclistamab after 0.06 mg/kg and 0.3 mg/kg step-up doses); 40 patients were treated at this dose [1]. Results from cohorts who received intravenous teclistamab or SC teclistamab at doses other than the RP2D are not discussed further.

Key clinical trials of teclistamab in multiple myeloma

Drug(s)	Phase	Status	Location(s)	Identifier	Sponsor(s)
Teclistamab	IV	Completed	USA		Janssen Research & Development
Teclistamab	IV	Active, no longer recruiting	Global	NCT04035226, LocoMMotion	Janssen-Cilag Ltd., Legend Biotech
Teclistamab, bortezomib, daratumumab/hyaluronidase, dexamethasone, pomalidomide	III	Recruiting	Global	NCT05083169, EudraCT2020-004742-11, MajesTEC-3	Janssen Research & Development
Teclistamab, lenalidomide	III	Not yet recruiting	Global	NCT05243797, EudraCT2021-002531-27, MajesTEC-4	Janssen Pharmaceutica, European Myeloma Network
Teclistamab	II	Recruiting	USA	NCT05469893, Immuno-PRISM	Janssen Research & Development
Teclistamab, daratumumab, dexamethasone	II	Not yet recruiting	USA	NCT05231629, MASTER-2	Janssen Scientific Affairs, University of Alabama at Birmingham
Teclistamab	I/II	Recruiting	Global	NCT03145181, NCT04557098, EudraCT2016-002122-36, MajesTEC-1	Janssen Research & Development
Teclistamab	I/II	Recruiting	Japan	NCT04696809	Janssen Pharmaceutical K.K.
Teclistamab, daratumumab, pomalidomide, talquetamab	Ib	Recruiting	Global	NCT04108195, EudraCT2019-000330-19, TRIMM-2	Janssen Research & Development
Teclistamab, bortezomib, daratumumab, lenalidomide, nirogacestat, pomalidomide	Ib	Recruiting	Global	NCT04722146, EudraCT2020-004404-33, MajesTEC-2	Janssen Research & Development, Spring-Works Therapeutics
Teclistamab, talquetamab	Ib	Recruiting	Global	NCT05338775, EudraCT2021-005073-22, TRIMM-3	Janssen Research & Development
Teclistamab, daratumumab, talquetamab	Ib	Recruiting	Global	NCT04586426, EudraCT2019-004124-38, RedirecTT-1	Janssen Research & Development

After a median follow up of 6.1 months, patients who received the RP2D achieved an overall response rate (ORR) of 65% [1]. Forty percent of patients who received the RP2D achieved a CR or better, and the 6-month progression-free survival (PFS) rate was 67%. The ORR was 61% in patients who were triple-class refractory and received the RP2D of teclistamab ($n = 33$). The median time to first confirmed response was 1 month, and 3 months to first confirmed CR or better [1].

Eligibility criteria into this phase of the trial included age ≥ 18 years, a diagnosis of MM that was R/R or intolerant to established therapies, previous treatment with a proteasome inhibitor and immunomodulatory drug but no BCMA-targeted therapy, had measurable disease and an Eastern Cooperative Oncology Group performance status (ECOG PS) of 0 or 1 [1].

In phase 2 of the study, treatment with teclistamab (at the RP2D established in phase 1) resulted in deep and durable response in patients with triple-class-exposed R/R

MM ($n = 125$) [13]. At primary analysis (median follow up 14.1 months), the primary efficacy endpoint of overall response was achieved by 63.0% of patients; CR or better was achieved by 39.4%. The median duration of response was 18.4 months [13]. Updated phase 2 efficacy results (data cutoff 9 Nov 2021) were consistent with the primary analysis; the ORR was 64%, and 30% of patients achieved a CR or better [14]. The 12-month duration of response rate was 66% [14].

This second phase of the trial enrolled patients aged ≥ 18 years with R/R MM who had previously received ≥ 3 lines of treatment (including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody) with no prior exposure to a BCMA-targeted therapy, had measurable and progressive disease and an ECOG PS of 0 or 1 [13].

Overall, treatment with teclistamab in MajesTEC-1 improved patient health-related quality of life (HR-QOL), consistent with the clinical outcomes in the study [15]. Patient-reported outcomes from baseline to cycle 8 of

treatment showed improvements in global health status scores, overall health (as assessed by a visual analogue scale), physical function and symptoms of pain and fatigue [15].

Clinical data from an ongoing open-label, multicentre, multicohort, phase Ib trial (NCT04108195; TRIMM-2) indicates SC teclistamab may be effective when used in combination with SC daratumumab in patients with R/R MM who have received ≥ 3 prior lines of treatment ($n = 37$); the ORR was 78%, with 73% of patients achieving very good partial response (VGPR) or better [16].

2.3.1 Real world studies

As MajesTEC-1 did not have a control arm, several real world studies have evaluated the efficacy of teclistamab in comparison to standard treatments. Compared to patients who received real-world treatments in a national de-identified electronic health record-derived Flatiron Health MM cohort database, teclistamab recipients had significantly ($p < 0.0001$) longer PFS [hazard ratio (HR) 0.43] and time to next treatment (HR 0.42). Patients in this database had triple-class exposed R/R MM, had received ≥ 3 prior lines of treatment and recently started a new line of therapy [17].

In the first prospective, multicentre, real-life standard of care, phase IV trial (NCT04035226; LocoMMotion) in triple-class exposed patients with R/R MM ($n = 248$), patients who met MajesTEC-1 eligibility criteria were used as an external control arm for MajesTEC-1. SC teclistamab demonstrated superior efficacy over treatments used in real-world clinical practice with regards to ORR, VGPR rate or CR or better rate (response-rate ratios 2.31–91.50; all $p < 0.0001$) [18]. Duration of response and PFS were both significantly improved in teclistamab recipients (HR 0.17 and 0.47, respectively; both $p < 0.0001$) [18]. However, improvements in HR-QOL were limited in LocoMMotion patients, particular in the reduction of pain [19].

2.4 Adverse Events

Treatment with SC teclistamab was generally tolerable in patients with R/R MM, as demonstrated in the phase I/II MajesTEC-1 trial [1, 13]. In the dose-expansion portion of phase 1 of MajesTEC-1, the safety and tolerability of teclistamab were investigated and found to be well tolerated [1]. In patients who received the RP2D, the most common treatment-emergent adverse events (AEs) were cytokine release syndrome (CRS; 70% of patients) and neutropenia (65% of patients) [1].

In phase 2 of the study ($n = 165$ for the safety population), all patients experienced AEs and 94.5% of patients experienced grade 3–4 AEs [13]. The most common any-grade AEs ($\geq 40.0\%$ of patients) were infections (76.4%),

hypogammaglobulinemia (74.5%), CRS (72.1%), neutropenia (70.9%), anaemia (52.1%) and thrombocytopenia (40.0%). Grade 3–4 AEs were most commonly ($> 20\%$ of patients) neutropenia (64.2%), infections (44.8%), anaemia (37.0%), lymphopenia (32.7%) and thrombocytopenia (21.2%) [13].

Serious AEs occurred in 64.8% of patients; these were most commonly ($> 5\%$ of patients) Covid-19 (14.5%), pneumonia (10.3%), CRS (8.5%), general deterioration in physical health (5.5%) and pyrexia (5.5%) [13]. Treatment discontinuation was reported in two patients (1.2%) due to grade 3–4 AEs (adenoviral pneumonia and progressive multifocal leukoencephalopathy). Treatment was skipped or reduced due to AEs in 63.0% and 0.6% of patients, respectively. Death was reported for 68 patients (41.2% of safety population), mostly due to progressive disease (60.3% of deaths). Death due to an AE was reported for 19 patients (27.9% of deaths); five deaths were considered treatment-related (due to progressive multifocal leukoencephalopathy, Covid-19, hepatic failure, streptococcal pneumonia) [13].

AEs of special interest (AESIs) include CRS and neurological toxicities [3]. Of the patients who developed CRS, the most common ($> 10\%$ of patients) signs and symptoms were fever (72%), hypoxia (13%), chills (12%) and hypotension (12%). These occurred mostly during the first three doses of teclistamab. Only 0.6% of CRS events were grade 3. Median time to onset and median duration were both 2 days. CRS was most commonly managed with tocilizumab and/or corticosteroids. The most common neurological toxicity in MajesTEC-1 was headache (8% of patients) [3]. Immune effector cell-associated neurotoxicity syndrome (ICANS) was reported in 3% of patients and almost all cases (77.8%) were concurrent with CRS (during or ≤ 7 days after resolution of CRS) [3, 13]. Median time to onset of ICANS was 4 days following a dose, with a median duration of 3 days [3]. Other AESIs include infections, hypogammaglobulinaemia, hepatitis B virus reactivation, vaccine efficacy and neutropenia [3].

The tolerability profile of teclistamab after ≈ 9 months of follow up in MajesTEC-1 was consistent with earlier analyses, and no new safety signals were seen [14].

Immunogenicity was assessed in 238 patients from MajesTEC-1; one patient (0.4%) developed low-titre neutralizing antibodies to teclistamab treatment [3].

In the safety population of the TRIMM-2 trial ($n = 46$), most (91%) patients experienced at least one AE, which were most commonly infections (63% of patients), CRS (61%), neutropenia (54%), anaemia (46%), thrombocytopenia (33%) and diarrhoea (33%) [16]. Grade 3–4 AEs were reported in 78% of patients; the most frequent included neutropenia (50% of patients), anaemia, thrombocytopenia and infections (all 28%). One case of ICANS was fully resolved [16].

2.5 Ongoing Clinical Trials

A multicentre, randomized, open-label, phase III trial (NCT05243797; MajesTEC-4) will be investigating the efficacy and safety of teclistamab plus lenalidomide, compared with lenalidomide alone, as maintenance therapy following autologous stem cell transplantation in patients with newly diagnosed MM. An ongoing, randomized, open-label, multicentre, phase III trial (NCT05083169; MajesTEC-3) is assessing the efficacy of teclistamab plus daratumumab, compared with investigator's choice of daratumumab plus pomalidomide plus dexamethasone or bortezomib plus dexamethasone, in patients with R/R MM [20]. The primary efficacy endpoint is progression-free survival [20].

A multiple arm, randomized, phase II platform study (NCT05469893; Immuno-PRISM) is currently recruiting to evaluate the efficacy of teclistamab compared with lenalidomide plus dexamethasone in patients with high-risk smouldering MM. A randomized, open-label, sequential assignment, phase II trial (NCT05231629; MASTER-2) will assess the efficacy of teclistamab plus autologous hematopoietic cell transplantation (AHCT) plus daratumumab compared with AHCT plus lenalidomide plus daratumumab in patients with newly diagnosed MM.

A phase I/II trial (NCT04696809) is currently recruiting Japanese patients with R/R MM to evaluate teclistamab at the recommended phase 2 dose (previously identified in phase 1 of MajesTEC-1).

Several phase Ib trials are ongoing to investigate the efficacy and safety of teclistamab as part of combination therapy for patient with R/R MM. A non-randomized, open-label, multicentre, phase Ib trial (NCT04722146; MajesTEC-2) is investigating the optimal dose(s) of teclistamab in combination with bortezomib, daratumumab, lenalidomide, nirogacestat and/or pomalidomide. The open-label, sequentially-assigned, multicentre, phase Ib TRIMM-3 trial (NCT05338775) is identifying the optimal safe dose(s) of a programmed cell death protein 1 inhibitor in combination with teclistamab or talquetamab. An open-label, multicentre, phase Ib, dose-escalation trial (NCT04586426; RedirecTT-1) is assessing the recommended dosages and safety of teclistamab plus talquetamab, with or without daratumumab.

All trials summarized in Sects. 2.3 and 2.4 are ongoing.

3 Current Status

Teclistamab received its first conditional approval on 24 Aug 2022 for R/R MM in the EU [2]. Teclistamab was subsequently approved on 25 Oct 2022 for R/R MM in the US [4].

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Declarations

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