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Health Technology Briefing
June 2025

Talquetamab with pomalidomide or with teclistamab for relapsed or refractory multiple myeloma previously treated with an anti-CD38 antibody and lenalidomide

Company/Developer	Johnson & Johnson Innovative Medicine

☐ New Active Substance ☒ Significant Licence Extension (SLE)

NIHRIO ID: 39926	NICE ID: Not available	UKPS ID: 675084

Licensing and Market Availability Plans

Currently in phase III clinical development

Summary

Talquetamab, in combination with pomalidomide (Tal+P) or with teclistamab (Tal+Tec), is in development for the treatment of relapsed or refractory multiple myeloma (RRMM) in patients who have previously received at least one prior therapy, including an anti-cluster of differentiation 38 (anti-CD38) antibody and lenalidomide therapy. Multiple myeloma (MM) is a type of blood cancer that is characterised by an abundance of abnormal immune cells, known as plasma cells, in the bone marrow (the spongy tissue at the centre of some bones that produces the body's blood cells). MM affects several areas of the body, such as the spine, skull, pelvis and ribs, and symptoms may include persistent bone pain, tiredness, weakness, shortness of breath, repeated infections, unusual bleeding, and kidney problems. Outcomes for patients with disease progression is poor, therefore there is a need to develop new treatment options for RRMM.

Talquetamab is a bispecific antibody (a type of protein) that has been designed to attach to two different targets: CD3, found on T cells (cells in the immune system), and GPRC5D, found mostly on myeloma cells. By attaching to these targets simultaneously, talquetamab brings the cancer cells and T cells together, activating the T cells to kill MM cells. In a clinical trial, teclistamab, also a bispecific antibody, and pomalidomide, a type of drug that helps regulate the immune system, are being used with talquetamab in patients with RRMM. Talquetamab and teclistamab are given through an injection under the skin (subcutaneous administration), and pomalidomide is taken orally. If licenced, Tal+P or Tal+Tec could provide an additional treatment option for patients with RRMM.

This briefing reflects the evidence available at the time of writing and a limited literature search. It is not intended to be a definitive statement on the safety, efficacy or effectiveness of the health technology covered and should not be used for commercial purposes or commissioning without additional information. A version of the briefing was sent to the company for a factual accuracy check. The company was available to comment.

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Proposed Indication

Treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least one prior therapy, including an anti-cluster of differentiation 38 (anti-CD38) antibody and lenalidomide, and have demonstrated disease progression on the last therapy.[1]

Technology

Description

Talquetamab (Talvey) is an immunoglobulin G4 proline, alanine, alanine (IgG4-PAA) bispecific antibody directed against G protein-coupled receptor class C group 5 member D (GPRC5D) and the CD3 receptor on T cells. Talquetamab promotes enhanced T cell-mediated cytotoxicity through recruitment of CD3-expressing T cells to GPRC5D-expressing cells. This leads to the activation of T cells and induces subsequent lysis of GPRC5D-expressing cells mediated by secreted perforin and various granzymes stored in the secretory vesicles of cytotoxic T cells. Based on the expression of GPRC5D on plasma cells with minimal to no expression detected on B cells and B cell precursors, talquetamab targets multiple myeloma (MM) cells particularly.[2]

Pomalidomide (Imnovid) has direct anti-myeloma tumoricidal activity, immunomodulatory activities, and inhibits stromal cell support for MM tumour cell growth. Pomalidomide binds directly to the protein cereblon (CRBN), which is part of an E3 ligase complex that includes deoxyribonucleic acid (DNA) damage-binding protein 1 (DDB1), cullin 4 (CUL4), and regulator of cullins-1 (Roc1), and can inhibit the auto-ubiquitination of CRBN within the complex.[3]

Teclistamab (Tecvayli) is a full-size, IgG4-PAA bispecific antibody that targets the CD3 receptor expressed on the surface of T cells and B cell maturation antigen (BCMA), which is expressed on the surface of malignant multiple myeloma B-lineage cells, as well as late-stage B cells and plasma cells. With its dual binding sites, teclistamab is able to draw CD3+ T cells in close proximity to BCMA+ cells, resulting in T cell activation and subsequent lysis and death of BCMA+ cells.[4,5]

Talquetamab in combination with pomalidomide (Tal+P) or with teclistamab (Tal+Tec) is currently in clinical development for the treatment of RRMM in patients who have previously received at least one prior therapy, including an anti-CD38 antibody and lenalidomide. In the phase III clinical trial (MonumenTAL-6, NCT06208150), participants are given talquetamab via subcutaneous injection either with pomalidomide (orally) or teclistamab (via subcutaneous injection).[1]

Key Innovation

Despite the range of approved therapies, clonal heterogeneity and acquired resistance leads to relapse and disease refractory to existing treatments in almost all patients with MM.[6,7] Patients who become refractory to lenalidomide have a poor survival prognosis, which generally worsens with each additional line of therapy, highlighting the need for new and effective treatments for this population.[8]

Bispecific antibodies (BsAbs) (talquetamab and teclistamab) have the advantage of being directly available for use, excluding the need for bridging therapy. Furthermore, the rates of grade three or worse cytokine release syndrome (CRS) or neurotoxicity are generally lower compared with some other types of treatment, and therapy can be discontinued if needed, allowing for the use of bispecific antibody treatments in patients with late-stage disease, and older patients.[9] Since cancer is a complex and multifactorial disease, dual

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targeting could be used to modulate two functional pathways in the tumour, thus avoiding resistance to the treatment.[10] Preliminary data using Tal+Tec (NCT04586426), or Tal+P (NCT05050097) have shown manageable safety profiles and promising efficacy in pretreated RRMM patients.[11,12] If licenced, Tal+Tec or Tal+P will offer an additional treatment option to patients with RRMM.

Regulatory & Development Status

Talquetamab currently has Marketing Authorisation in the EU/UK for the treatment of adult patients with RRMM, who have received at least three prior therapies, including an immunomodulatory agent (IMiD), a proteasome inhibitor (PI), and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.[2]

Pomalidomide has Marketing Authorisation in the EU/UK in combination with other technologies for the following indications: [3]

- The treatment of adult patients with MM who have received at least one prior treatment regimen including lenalidomide.
- The treatment of adult patients with RRMM who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

Teclistamab has Marketing Authorisation in the EU/UK for the treatment of adult patients with RRMM, who have received at least three prior therapies, including an IMiD, a PI, and an anti-CD38 antibody and have demonstrated disease progression on the last therapy. [4,5]

Talquetamab was previously awarded the following regulatory designations:

- PRIME (PRIority MEdicines) designation by the European Medicines Agency (EMA) in January 2021 for the treatment of RRMM[13]
- Orphan drug designation by the EMA in August 2021 for the treatment of MM.[14]
- Breakthrough Therapy by the US Food and Drug Administration (FDA) in June 2022 for the treatment of RRMM[13]

Pomalidomide was previously awarded the following regulatory designations:

- Orphan drug designation by the FDA in January 2003 for the treatment of MM.[15]
- Fast Track Status by the FDA in September 2012 for the treatment of RRMM.[16]

Tal+P or Tal+Tec is not in phase II/III clinical development for any other indications.[17]

Patient Group

Disease Area and Clinical Need

MM is a type of bone marrow cancer that develops when there is a change in the DNA of the plasma cells.[18,19] The exact cause of MM is unknown, however it is more common in men, adults over 60, black people, and people with a family history of monoclonal gammopathy of unknown significance or MM.[19] MM damages the bones and affects the production of healthy blood cells, and often affects several areas of the body, such as the spine, skull, pelvis and ribs.[18] RRMM is defined as MM that is non-responsive to therapy or progresses within 60 days of the last line of therapy, or previously treated MM that has progressed after prior therapy and requires new therapy.[20] MM may not cause any symptoms in the early stages, but eventually leads to a wide range of problems including bone pain, bone fractures and spinal cord compression, anaemia, repeated infections, raised calcium levels in the blood, unusual bleeding, thickened blood, and kidney problems.[21]

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Treatment can often help to control the condition for several years, but most cases of MM cannot be cured.[19]

MM is the 19th most common cancer in the UK, accounting for 2% of all new cancer cases (2017-2019).[22] The age standardised incidence of newly diagnosed cases of MM in England in 2022 was 12.6 and 8 per 100,000 amongst males and females respectively.[23] In England, 2023-24, there were 167,351 finished consultant episodes (FCEs) and 161,752 admissions for MM (ICD-10 code C90.0), which resulted in 99,531 FCE bed days and 154,272 day cases.[24] In England (2020), there were 2,709 deaths registered where MM and malignant plasma cell neoplasms was the underlying cause.[23] For patients diagnosed with myeloma between 2013 and 2017, followed up to 2018, the 1-year and 5-year age-standardised survival rates were 82.7% and 52.3% respectively.[25]

Recommended Treatment Options

The National Institute for Health and Care Excellence (NICE) currently recommends the following pharmacological treatment options for RRMM after **one** prior therapy:

- Bortezomib monotherapy.[26]
- Carfilzomib with dexamethasone.[27]
- Daratumumab with bortezomib and dexamethasone, if the previous treatment included lenalidomide, or where lenalidomide is unsuitable as a second-line treatment.[28]
- Selinexor with bortezomib and dexamethasone, if refractory to both daratumumab and lenalidomide.[29]
- Lenalidomide with dexamethasone, if prior treatment included bortezomib.[30]
- Carfilzomib with dexamethasone and lenalidomide, if prior treatment included bortezomib.[31]

After **two** prior therapies:

- Lenalidomide in combination with dexamethasone.[32]
- Panobinostat in combination with bortezomib and dexamethasone, if prior treatments included bortezomib and an immunomodulatory agent.[33]
- Ixazomib with lenalidomide and dexamethasone.[34]
- Selinexor with bortezomib and dexamethasone, if refractory to lenalidomide.[29]

After **three** prior therapies:

- Pomalidomide in combination with low-dose dexamethasone, if prior treatments included both lenalidomide and bortezomib.[35]
- Isatuximab with pomalidomide and dexamethasone, if previous treatments included lenalidomide and a proteasome inhibitor (available via Cancer Drugs Fund only).[36]
- Daratumumab monotherapy, if previous treatments included a proteasome inhibitor and immunomodulator.[28]
- Ixazomib with lenalidomide and dexamethasone.[34]
- Teclistamab monotherapy, if prior treatment included an immunomodulatory drug, a proteasome inhibitor and an anti-CD38 antibody.[37]
- Elranatamab monotherapy, if prior treatment included an immunomodulatory drug, a proteasome inhibitor and an anti-CD38 antibody (available via Cancer Drugs Fund only).[38]

After **four** prior therapies:

- Selinexor with dexamethasone, if prior treatment included at least two proteasome inhibitors, two immunomodulatory agents and an anti-CD38 monoclonal antibody.[39]

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Clinical Trial Information

Trial	**MonumenTAL-6,** NCT06208150, EudraCT 2022-502446-27-00; A Phase 3 Randomized Study Comparing Talquetamab in Combination With Pomalidomide (Tal-P), Talquetamab in Combination With Teclistamab (Tal-Tec), and Investigator's Choice of Either Elotuzumab, Pomalidomide, and Dexamethasone (EPd) or Pomalidomide, Bortezomib, and Dexamethasone (PVd) in Participants With Relapsed or Refractory Myeloma Who Have Received 1 to 4 Prior Lines of Therapy Including an Anti-CD38 Antibody and Lenalidomide **Phase III** – Recruiting **Locations(s):** 13 EU countries, UK, USA, Canada and other countries **Primary completion date (estimated):** April 2026
Trial Design	Randomised, parallel assignment, open label
Population	N = 795; subjects with RRMM; aged 18 years and older
Intervention(s)	• **Tal+P:** 0.8 mg/kg talquetamab subcutaneous (SC) injection, oral pomalidomide, and oral or intravenous (IV) dexamethasone[40] • **Tal+Tec:** 0.8 mg/kg talquetamab (SC), 3.0 mg/kg teclistamab (SC), and dexamethasone (orally or IV)[40]
Comparator(s)	• Elotuzumab (IV), pomalidomide (orally), and dexamethasone (orally or IV)[40] • Pomalidomide (orally), bortezomib (SC) and dexamethasone (orally or IV)[40]
Outcome(s)	Primary outcome: Progression Free Survival (PFS) [Time frame: up to 6 years 5 months] See trial record for full list of other outcomes
Results (efficacy)	-
Results (safety)	-

Estimated Cost

Talquetamab, pomalidomide and teclistamab are already marketed in the UK.

The NHS indicative cost of one 2mg/1ml solution for injection vial of talquetamab (3mg/1.5ml) is £326.41. The NHS indicative cost of one 40mg/1ml solution for injection vial of talquetamab (40mg/ml) is £4,352.00.[41]

The NHS indicative costs of pomalidomide are £7,995.60 and £8,884.00, depending on the brand, for 21 x 1, 2, 3 and 4 mg capsules.[42]

The NHS indicative cost of one 30mg/3ml solution for injection vial of teclistamab (10mg/ml) is £775.14. The NHS indicative cost of one 143mg/1.7ml solution for injection vial of teclistamab (90mg/ml) is £3,952.78.[43]

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Relevant Guidance

NICE Guidance

- NICE technology appraisal awaiting development. Elranatamab for treating relapsed or refractory multiple myeloma after 2 treatments (GID-TA11661). Expected date of issue to be confirmed.
- NICE technology appraisal awaiting development. Mezigdomide with dexamethasone and carfilzomib for treating relapsed or refractory multiple myeloma after at least 1 line of treatment (GID-TA11660). Expected date of issue to be confirmed.
- NICE technology appraisal awaiting development. REGN5458 for treating relapsed or refractory multiple myeloma (GID-TA11052). Expected date of issue to be confirmed.
- NICE technology appraisal awaiting development. Teclistamab with daratumumab for treating relapsed or refractory multiple myeloma after 1 or more therapies (GID-TA11162). Expected date of issue to be confirmed.
- NICE technology appraisal awaiting development. Idecabtagene vicleucel for treating relapsed or refractory multiple myeloma after 2 to 4 therapies (GID-TA11075). Expected date of issue to be confirmed.
- NICE technology appraisal in development. Ciltacabtagene autoleucel for treating relapsed and lenalidomide refractory multiple myeloma after 1 to 3 therapies (GID-TA10905). Expected date of issue to be confirmed.
- NICE technology appraisal in development. Belantamab mafodotin for treating relapsed or refractory multiple myeloma after 4 or more therapies (GID-TA10568). Expected date of issue to be confirmed.
- NICE technology appraisal in development. Belantamab mafodotin with pomalidomide and dexamethasone for treating relapsed or refractory multiple myeloma after 1 or more treatments (GID-TA11201). Expected date of issue to be confirmed.
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- NICE technology appraisal in development. Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma (review of TA658) (GID-TA10979). Expected October 2025.
- NICE technology appraisal in development. Talquetamab for treating relapsed or refractory multiple myeloma after 3 treatments (GID-TA10969). Expected October 2025.
- NICE technology appraisal. Elranatamab for treating relapsed and refractory multiple myeloma after 3 or more treatments (TA1023). December 2024.
- NICE technology appraisal. Teclistamab for treating relapsed and refractory multiple myeloma after 3 or more treatments (TA1015). November 2024.
- NICE technology appraisal. Selinexor with bortezomib and dexamethasone for previously treated multiple myeloma (TA974). May 2024.
- NICE technology appraisal. Selinexor with dexamethasone for treating relapsed or refractory multiple myeloma after 4 or more treatments (TA970). May 2024.
- NICE technology appraisal. Daratumumab with bortezomib and dexamethasone for previously treated multiple myeloma (TA897). June 2023.
- NICE technology appraisal. Ixazomib with lenalidomide and dexamethasone for treating relapsed or refractory multiple myeloma (TA870). February 2023.
- NICE technology appraisal. Daratumumab monotherapy for treating relapsed and refractory multiple myeloma (TA783). April 2022.

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- NICE technology appraisal. Isatuximab with pomalidomide and dexamethasone for treating relapsed and refractory multiple myeloma (TA658). November 2020.
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- NICE technology appraisal. Lenalidomide for the treatment of multiple myeloma in people who have received at least 2 prior therapies (TA171). June 2019.
- NICE technology appraisal. Lenalidomide plus dexamethasone for multiple myeloma after 1 treatment with bortezomib (TA586). June 2019.
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Other Guidance

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NB: This briefing presents independent research funded by the National Institute for Health and Care Research (NIHR). The views expressed are those of the author and not necessarily those of the NHS, the NIHR or the Department of Health.

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