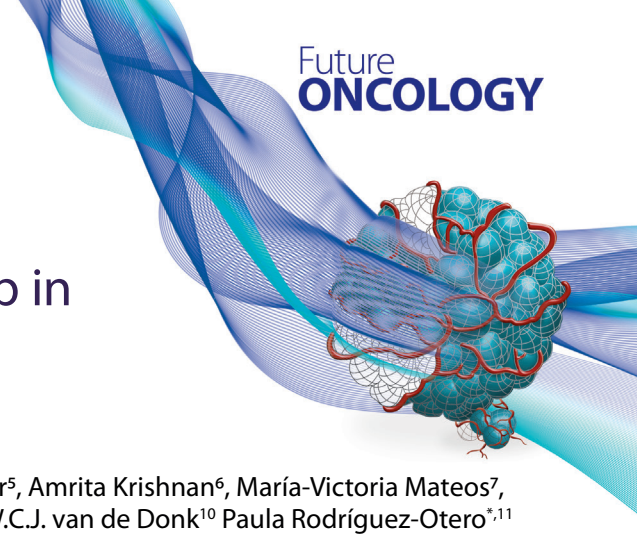
Plain Language Summary of Publication



Plain language summary of the MonumenTAL-1 study of talquetamab in people with relapsed or refractory multiple myeloma

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Summary

What is this summary about?
This plain language summary describes the results of a phase 1 research study (or clinical trial) called MonumenTAL-1 published in the *New England Journal of Medicine* in December 2022. A phase 1 study is an early clinical trial where researchers evaluate how safe a medicine is at different doses in a small number of people. In the MonumenTAL-1 study, researchers looked at a new medicine under development called talquetamab, for people living with multiple myeloma (a type of blood cancer) who did not respond (refractory), stopped responding (relapsed) or who had difficulty dealing with their previous treatments.

How to say (double click sound icon to play sound)...

- **Talquetamab:** tal-KWE-ta-mab
- **Multiple myeloma:** MUL-tih-pul MY-eh-LOH-muh
- **Cytokine release syndrome:** SY-toh-kine reh-LEES SIN-drome
- **Hypogammaglobulinemia:** HY-poh-GA-muh-GLAH-byoo-lih-NEE-mee-uh
- **Tocilizumab:** toh-sih-LIH-zoo-mab

How was the study conducted?
The phase 1 MonumenTAL-1 study was performed in 2 parts. Safety was the main focus of Part 1 in which side effects, and how serious they were, were assessed. The results of Part 1 were used to identify doses of talquetamab that were well tolerated, without a need to stop treatment or reduce the doses, for further study in Part 2. Part 2 of the study examined how well talquetamab worked to decrease signs of the cancer and what side effects, and their severity, people experienced at the doses identified in Part 1.

What were the results?
In Part 1 of the study, researchers identified 2 doses of talquetamab for further study: 405 micrograms for every kilogram of body weight (µg/kg) given weekly and 800 µg/kg every other week. All participants experienced at least one side effect of treatment at these 2 doses. Less than half of participants (43% at the 405-µg/kg weekly dose and 34% at the 800-µg/kg every-other-week dose) experienced serious side effects, which are those side effects that led to hospitalization, death or permanent or life-threatening damage. The most common side effects at both doses were a condition known as cytokine release syndrome (CRS); changes in blood cell levels (where different types of cells in the blood were measured); changes in skin such as itching, dry skin, eczema, ulcers or shedding; changes in nails such as discoloration or ridging (lines or dents); and changes in sense of taste such as food tasting sour or metallic. CRS is caused by the overactivation of the immune system (the body's natural defense system) and can result in fever, feeling sick (nausea), being tired (fatigue), low blood pressure, low blood oxygen levels and body aches. Most cases of CRS, as well as most other side effects, were mild or moderate. Most common serious events were CRS, fever and bone pain. Most people had fewer signs of the cancer after taking talquetamab, and the response was similar between the 2 doses. The median duration of response at the 2 identified doses was 8–10 months.

Future Medicine part of fsg

What do the results mean?
Most of the side effects people experienced when taking talquetamab were mild or moderate. Most people who took talquetamab responded to the treatment even though they hadn't responded or stopped responding to previous multiple myeloma treatments or stopped taking those treatments because they were unable to tolerate them. These results demonstrate the potential of talquetamab as a treatment option in people who have used up other available therapy options. The 2 doses of talquetamab identified here are being examined in a larger group of participants to further test for safety and to test how well people respond.

Who should read this article?

This summary may be helpful for people living with relapsed or refractory multiple myeloma (people living with multiple myeloma that have not responded or have stopped responding to previous treatments) and their caregivers. Healthcare professionals may also find this summary useful.

Where can I find the original article on which this summary is based?

The original article "Talquetamab, a T-Cell–Redirecting GPRC5D Bispecific Antibody for Multiple Myeloma" was published in the *New England Journal of Medicine* (Chari A, *et al. N Engl J Med.* 2022; 387:2232-2244).

You can read the full article for a fee at: https://www.nejm.org/doi/full/10.1056/NEJMoa2204591

What is multiple myeloma?

- Multiple myeloma is a form of cancer that affects a type of white blood cell known as a plasma cell. Normally, bone marrow (the soft, spongy tissue found in the center of most bones) does not contain many plasma cells, but in people with multiple myeloma, cancerous plasma cells build up and frequently cause damage to the bones
- Bone and/or back pain, feeling weak, being tired (fatigue), kidney problems, high calcium levels, low red blood cell levels and sometimes broken bones are common signs and symptoms of multiple myeloma. People who have multiple myeloma also tend to get infections more often, and more severely, than people without multiple myeloma
- For most people with multiple myeloma, treatment will work at first, but after some time the cancer starts growing again. This is known as a relapse. People can be treated after each relapse, but after a few relapses they may no longer respond, and this is known as being refractory. In addition, some people with multiple myeloma are unable to tolerate the side effects of treatment. In each of these cases, additional or different medicines are needed to manage the cancer
- Multiple myeloma treatments that are well tolerated and can reduce signs of cancer over time are needed

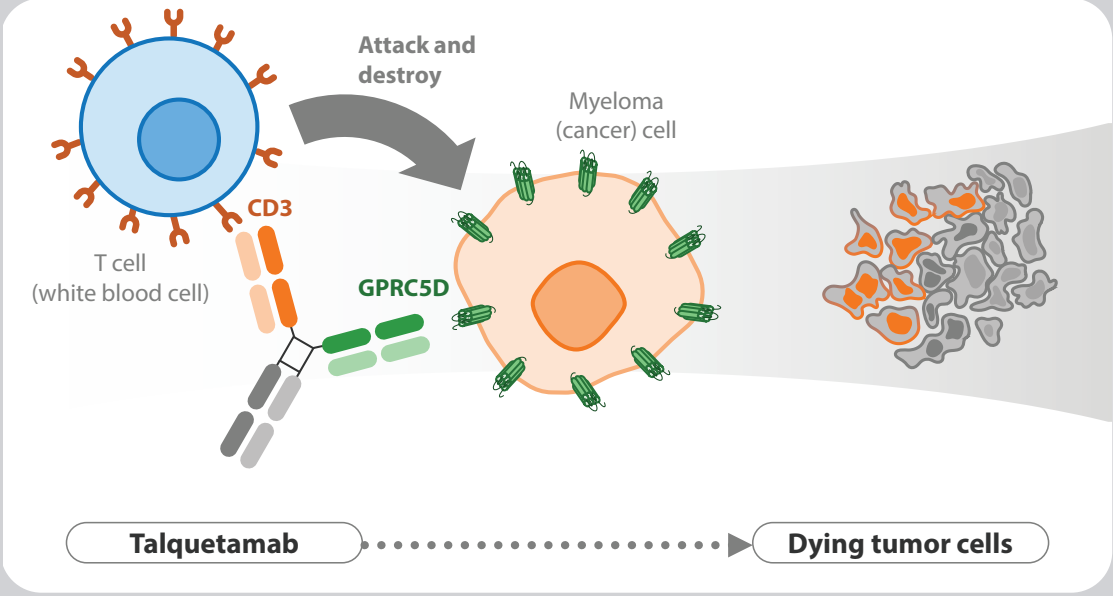
What is talquetamab?

- Talquetamab is a type of laboratory-made antibody known as a "bispecific" **antibody**. This is an antibody that attaches to 2 different targets at the same time. In the case of talquetamab, one target is a protein known as CD3 on the surface of T cells (a type of white blood cell) and the other target is GPRC5D, a protein on the myeloma (cancer) cell
- The United States Food and Drug Administration (FDA) has designated talquetamab as what is known as an orphan drug for the treatment of relapsed or refractory multiple myeloma in people who have received at least 4 previous therapies. Drugs that show promise in the treatment, prevention or diagnosis of rare diseases are given this status

Antibody:

An antibody is a protein found in the blood that recognizes a specific substance such as on the surface of a virus, bacteria or cancer cell, to help white blood cells destroy them.

How does talquetamab work?



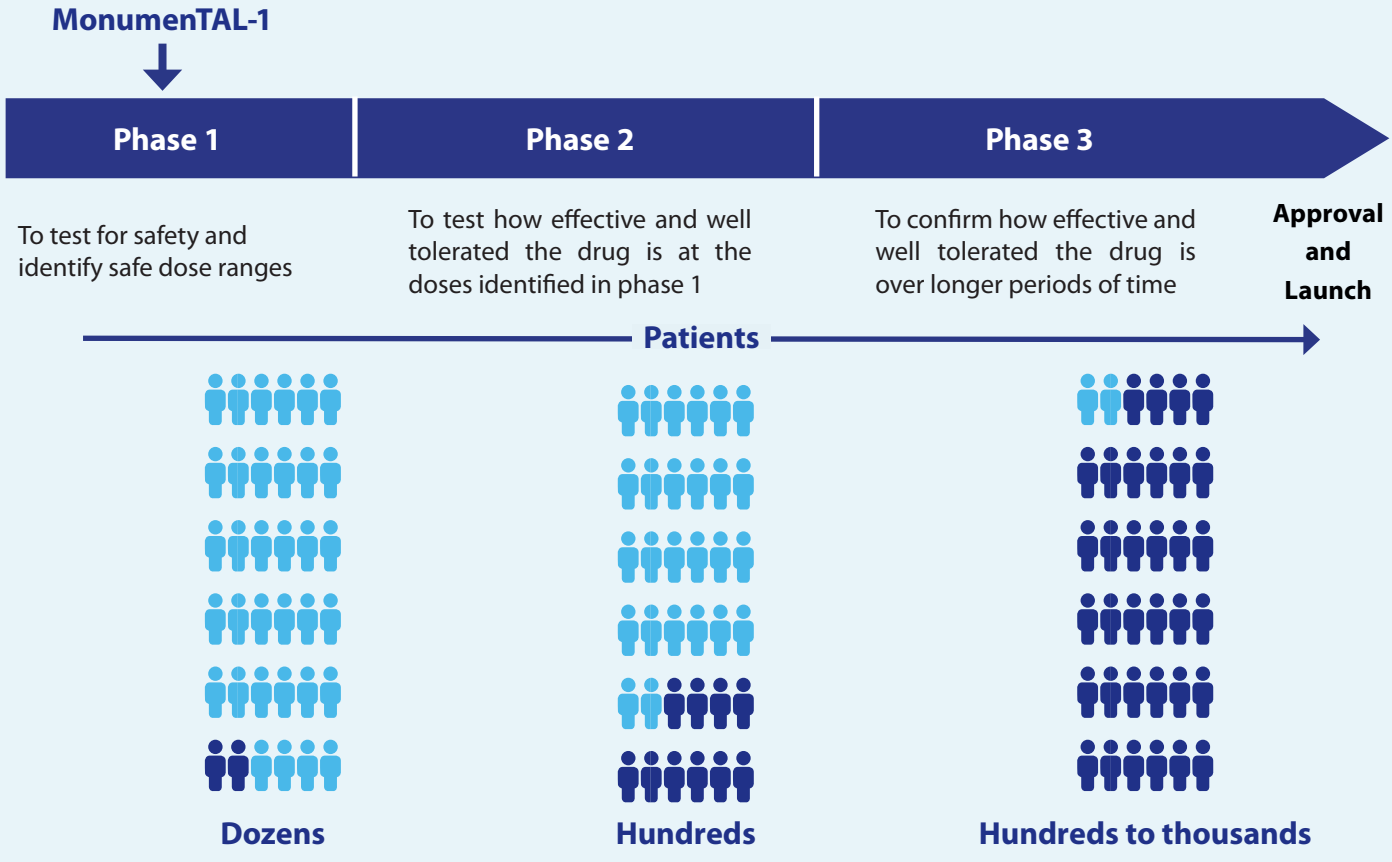
What are GPRC5D and CD3 and why are they important?

- GPRC5D is a receptor found in high amounts on the surface of multiple myeloma cells
  - A receptor is a protein found inside or on the surface of a cell. When a specific substance binds to a receptor, it results in an effect on the cell
- CD3 is a protein found on the surface of white blood cells known as T cells. T cells help protect the body from infection by targeting and destroying infected cells
- Talquetamab attaches to both GPRC5D and CD3 at the same time, bringing T cells close to the myeloma cells that have GPRC5D on their surface. This allows the T cells to target and destroy the myeloma cells
- Before entering the MonumenTAL-1 study, none of the participants had received a cancer drug that targets GPRC5D, such as talquetamab

Where is the MonumenTAL-1 study in the drug development timeline?

- MonumenTAL-1 is a phase 1 research study (clinical trial). A phase 1 study is an early clinical trial, often the first in humans, where researchers evaluate how safe a medicine is at different doses in a small number of people
- Results of phase 1 studies are used to determine appropriate doses of a treatment for further investigation in a greater number of people in phase 2 studies and beyond. An appropriate dose is one that has the best chance of having a response with manageable side effects. In cancer studies, phase 1 and phase 2 trials are sometimes combined to answer research questions quickly and with fewer participants
- More participants in phase 2 trials and beyond will add to the results of the phase 1 study

Phase of clinical trials



What did this study look at?

Researchers in the MonumenTAL-1 study examined how safe talquetamab is and how well it worked in people with multiple myeloma who had been treated previously with several multiple myeloma therapies and who stopped responding (relapsed), did not respond (refractory) or who could not tolerate these treatments.

Blood and urine tests were used to measure response, along with bone marrow analysis to determine the amount of cancer cells.

Who took part in this study?

Between January 3 2018, and November 15 2021,

232 people

entered and took part in the MonumenTAL-1 study.

All participants…

…were at **least 18 years of age**

…had a diagnosis of **multiple myeloma**

…were **not responding to** or **could not tolerate their previous treatments** for multiple myeloma.

How was the study carried out?

The MonumenTAL-1 study was a worldwide study (carried out in the United States, Belgium, Spain and the Netherlands) and was performed in **2 parts**.

PART 1

To reduce the risk for side effects, researchers started treating patients with a **low dose of talquetamab** given intravenously (into a vein) every other week

Safety was monitored, and if there were no concerning side effects, **then the dose was slowly increased** (this is known as **dose escalation**) and was given more often (weekly)

The same approach was also used to **investigate injections given under the skin** (subcutaneously) weekly, every other week and monthly

To reduce the risk of exaggerated side effects, participants were pretreated (treated before each step-up dose and before the first full dose) **with a glucocorticoid** (a steroid that reduces inflammation), **an antihistamine** (a drug that reduces the risk of allergic reactions) **and acetaminophen** (paracetamol, a pain killer that reduces fever)

Information from **Part 1** of the study was used to help design **Part 2** of the study and to decide on doses to be used in further studies with more participants

PART 2

Doses and dosing schedules were chosen **based on the results from Part 1**

Step-up dosing was used to **lower the risk of severe cytokine release syndrome (overactivation of the immune system)**

Participants were pretreated with a glucocorticoid, an antihistamine and acetaminophen (paracetamol) **before administration of all step-up doses and before the first full dose**

Safety **was monitored**

Response to treatment **was recorded** and was measured by looking for signs of the cancer in the blood and urine and the amount of cancer cells in the bone marrow

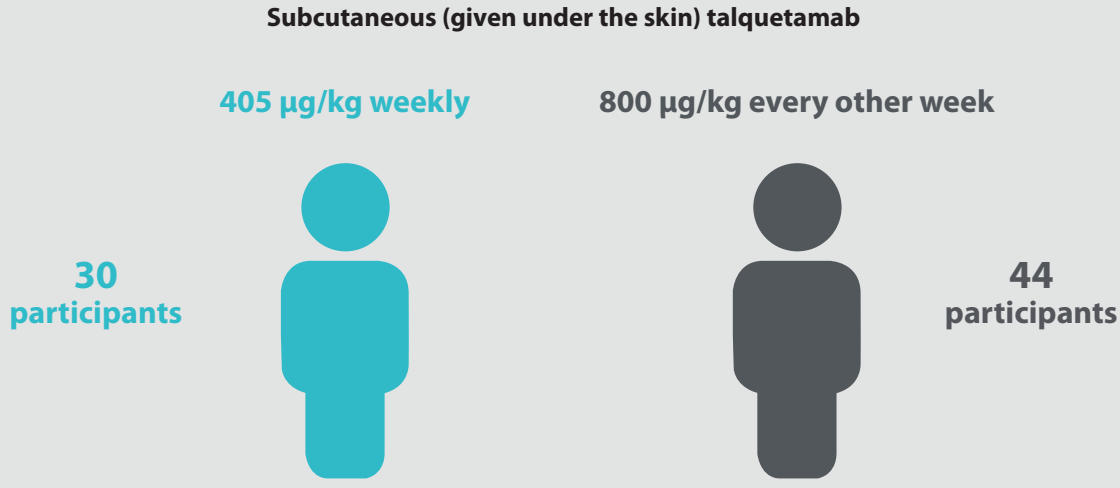
What were the main results of the study?

- In Part 1 of the study, 2 doses of talquetamab given subcutaneously (underneath the skin) were identified as most appropriate for further study in Part 2
  - One dose was 405 **micrograms** for every kilogram of body weight (µg/kg) given weekly (with step-up doses of 10 and 60 µg/kg)
  - The other dose was 800 µg/kg given every other week (with step-up doses of 10, 60 and 300 µg/kg)
  - 30 people received 405 µg/kg weekly and 44 people received 800 µg/kg every other week
- For Part 2, the 2 subcutaneous doses of talquetamab were chosen based on how safe they were in Part 1, along with how they were administered. A larger phase 2 study was designed using Part 1 and Part 2 results. Participants could stay on treatment until the disease progressed, they had unacceptable side effects or if they withdrew their consent to participate

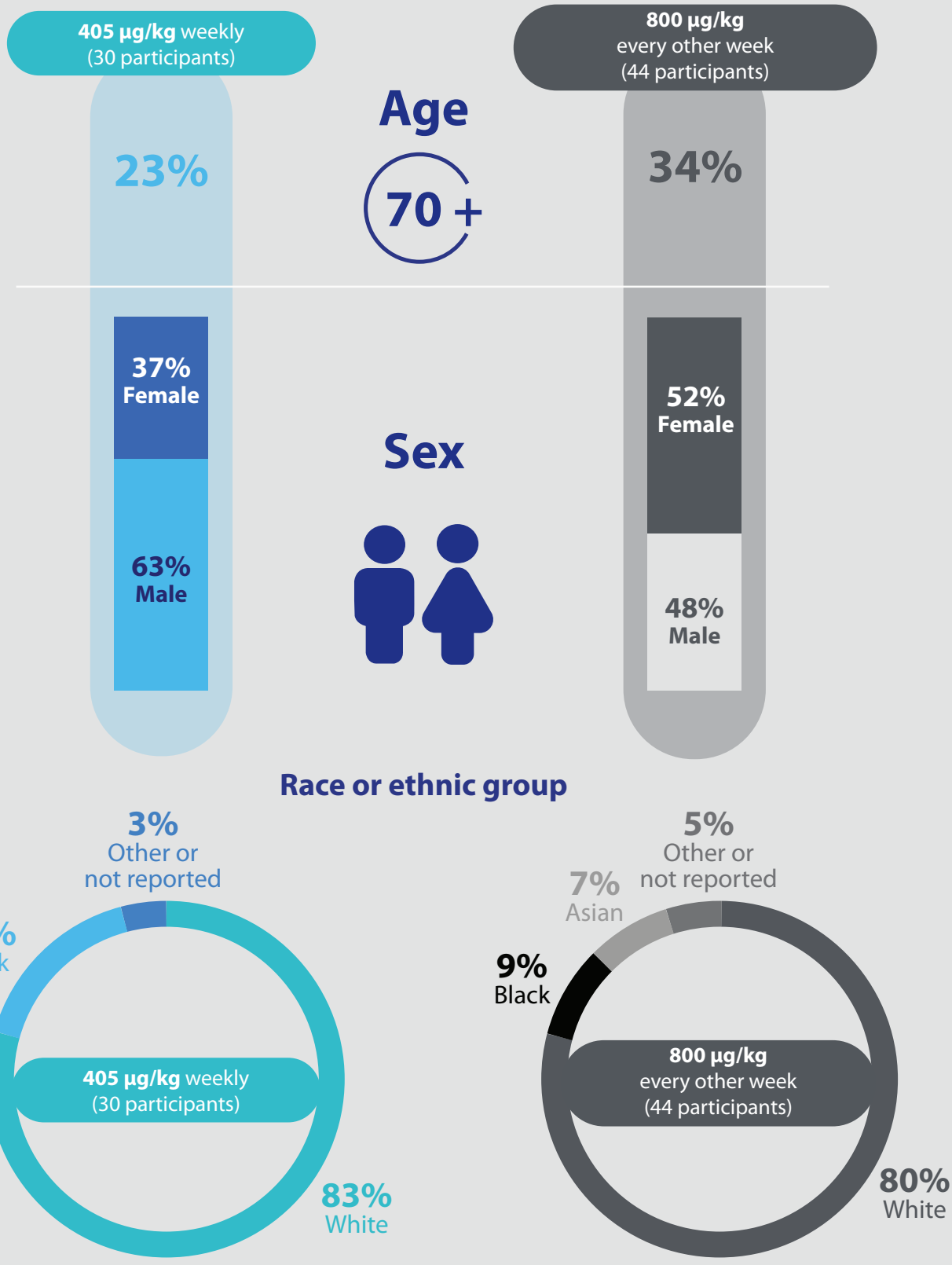
Microgram:

A microgram is one millionth of a gram.

Participants

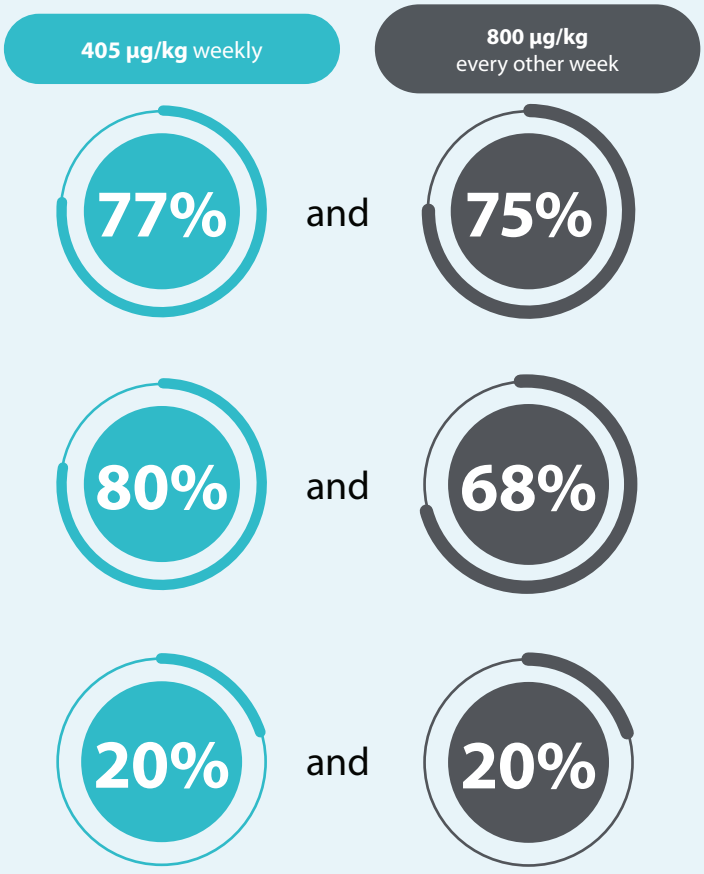


Participants' characteristics



Previous treatments

How did the participants respond to previous treatments?



Proteasome inhibitors (e.g., bortezomib, carfilzomib and ixazomib) are drugs that block the action of proteasomes. A proteasome is a large protein complex that helps destroy other proteins in the cell when they are no longer needed.

Immunomodulatory drugs (e.g., thalidomide, lenalidomide and pomalidomide) can regulate the immune system.

Anti-CD38 antibodies (e.g., daratumumab and isatuximab) bind to the CD38 protein which is found on some types of blood cells and in high levels on some cancer cells (including myeloma cells) and can help the immune system kill cancer cells.

- 30% of participants in the group receiving 405 µg/kg weekly and 27% of those receiving 800 µg/kg every other week had previously received therapies that help T cells target a receptor on the myeloma cells known as BCMA (B-cell maturation antigen)
- Participants who were treated with 405 µg/kg of talquetamab weekly had received a **median** of 6 previous treatments, and those treated with 800 µg/kg every other week had received a median of 5 previous treatments
- Median **follow-up** was approximately 12 months for participants receiving 405 µg/kg weekly and 4 months for those receiving 800 µg/kg every other week

Median:
Median is the middle value when all values are placed in order from smallest to largest.

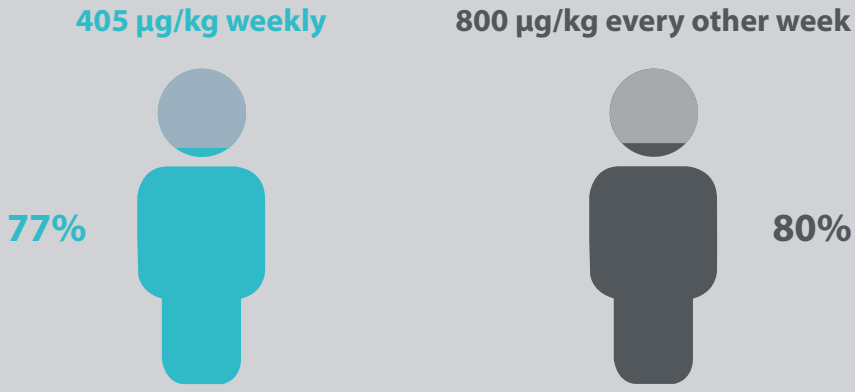
Follow-up:
Follow-up is how long the participants were monitored for.

What were the side effects in the MonumenTAL-1 study?

Cytokine release syndrome

- A condition known as cytokine release syndrome (CRS) was the most common side effect of talquetamab
- CRS occurs when the immune system is triggered and becomes overactive. This causes a large burst of small proteins (known as cytokines) to be released into the blood. This can happen when T cells, which are a key part of the immune system, are activated by therapies like talquetamab
- Fever, feeling sick (nausea), being tired (fatigue), low blood pressure, low blood oxygen levels and body aches are symptoms of CRS
- CRS is also a side effect of other therapies that activate the immune system

Participants experiencing CRS



Most of the cases of CRS were **mild** or **moderate**

CRS **usually happened soon after treatment** with talquetamab (starting a median of 2 days after treatment for both doses) and lasted for a **median of 2 days for both doses**

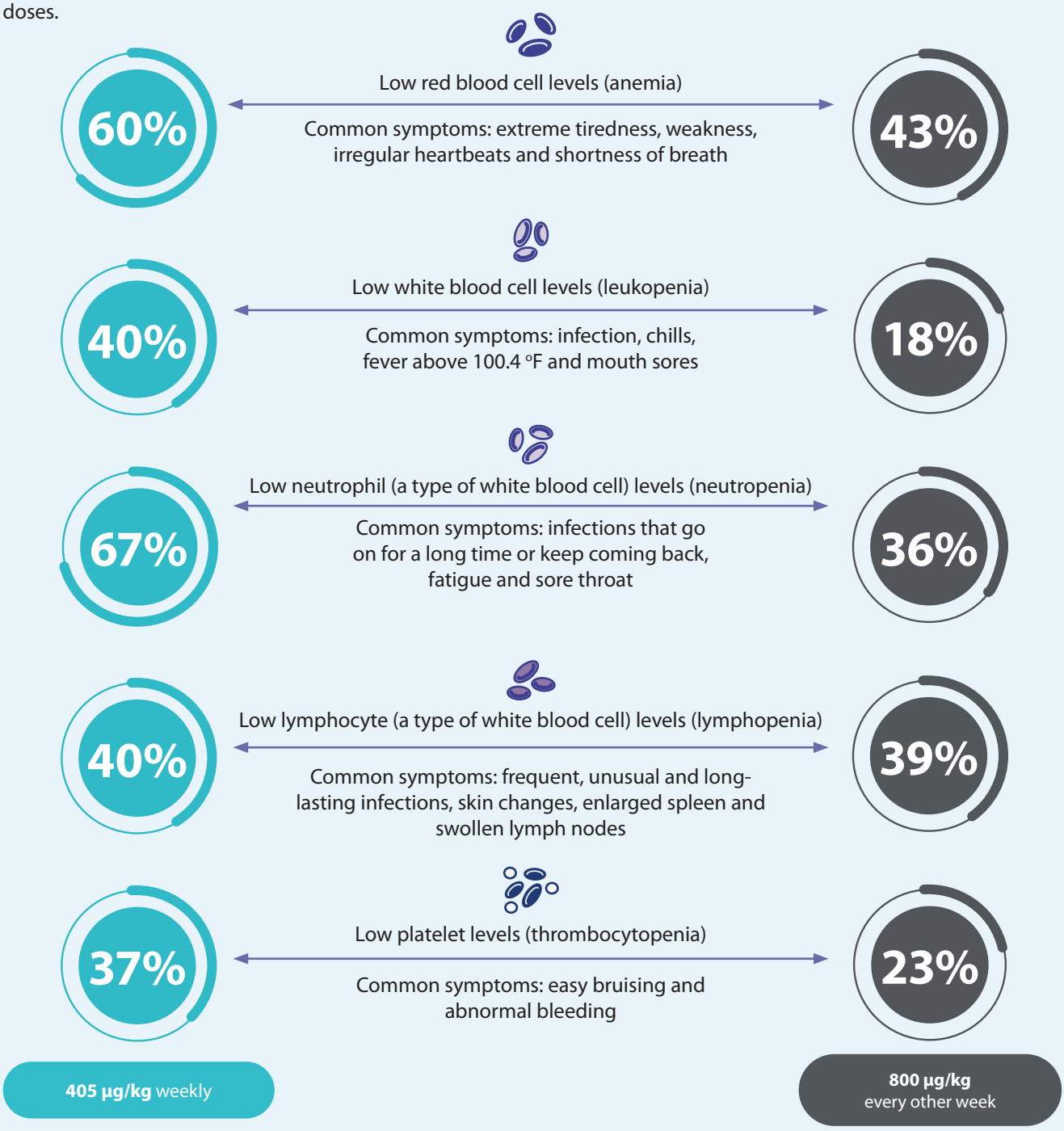
- Across all of the subcutaneous (under the skin) doses tested, most CRS events (82%) occurred during the step-up doses (when the dose of talquetamab is being increased) and the first full dose
- Less than one-third of participants who received talquetamab had more than 1 CRS event (30% of participants who received 405 µg/kg weekly and 27% of participants who received 800 µg/kg every other week)

Treatment of cytokine release syndrome

- All participants who had CRS received supportive treatment
- In total, 19 out of 30 participants (63%) who received talquetamab at 405 µg/kg weekly and 24 out of 44 (55%) of those who received 800 µg/kg every other week were treated for CRS with a drug known as tocilizumab
- Tocilizumab is a medicine that neutralizes one of the cytokines that contributes to CRS development
- Other treatments for CRS, such as steroids, drugs to increase blood pressure, supportive oxygen therapy, fever-reducing medicines and fluids were used less often

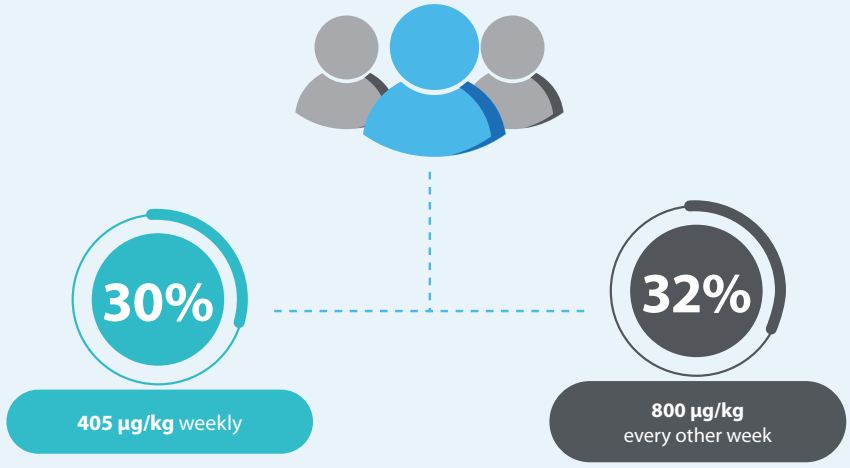
Changes in blood cell levels

There were also side effects related to blood cell levels. These were reversible and mostly limited to the step-up and early full doses.



Weight loss

About a third of participants who received talquetamab experienced weight loss.



Of the participants who experienced weight loss, all except 1 lost less than 20% of their starting weight.

There were side effects related to changes in skin such as itching, dry skin, eczema, ulcers or shedding; changes in nails such as discoloration or ridging (lines or dents); and changes in sense of taste such as food tasting sour or metallic.

Changes in skin

experienced skin-related side effects

Nearly **half** of skin events were resolved, and the events lasted for a **median of 39 days**

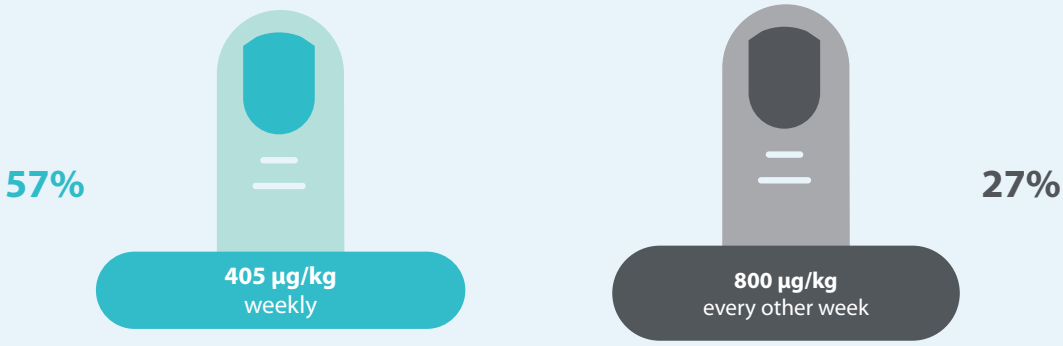
Most common skin-related side effects were mild or moderate…

… and included:

- ✓ Shedding of the surface of the skin
- ✓ Itching
- ✓ Dry skin

Across all subcutaneous (given under the skin) doses of talquetamab, the time from the first treatment until skin side effects were observed was a **median of 24 days**

Changes in nails



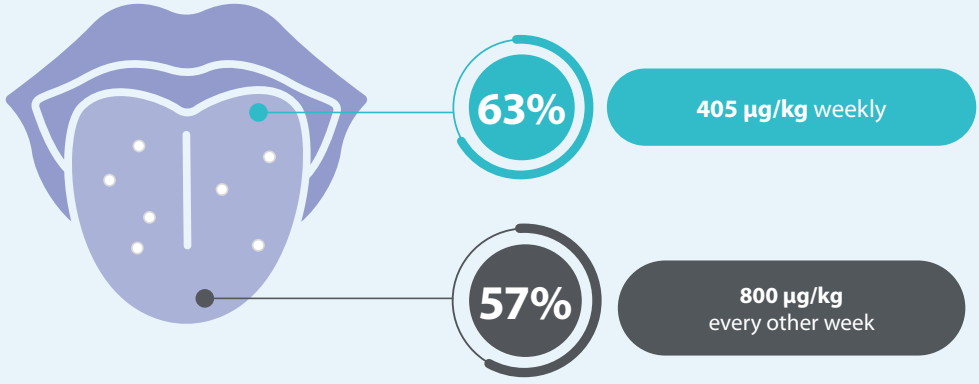
experienced changes in nails

Nail-related side effects included:

- ✓ Disorders of the nail bed
- ✓ Nail coming away from the nail bed
- ✓ Changes in nail color, shape, texture and growth
- ✓ Shedding of the nail
- ✓ Nail ridging (lines or dents in the nails)

Across all subcutaneous (given under the skin) doses of talquetamab, the **median time** until these nail side effects were seen was **51 days following the first subcutaneous administration** of talquetamab and **lasted for a median of 74 days**

Changes in sense of taste



Across all subcutaneous (given under the skin) doses of talquetamab, changes were first seen a **median of 14 days** after the first treatment and lasted for a **median of 48 days**

Several participants reported side effects related to the nervous system. The nervous system includes the brain, spinal cord and a system of nerves and is responsible for transferring messages between the brain and the body.

Nervous system side effects

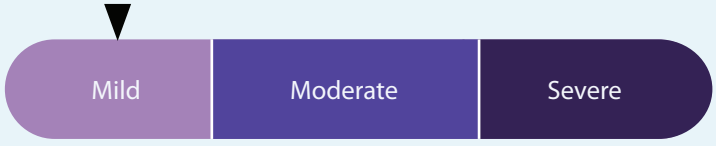
Some participants receiving talquetamab experienced **side effects** associated with the **nervous system.**

3 at **405 µg/kg** weekly

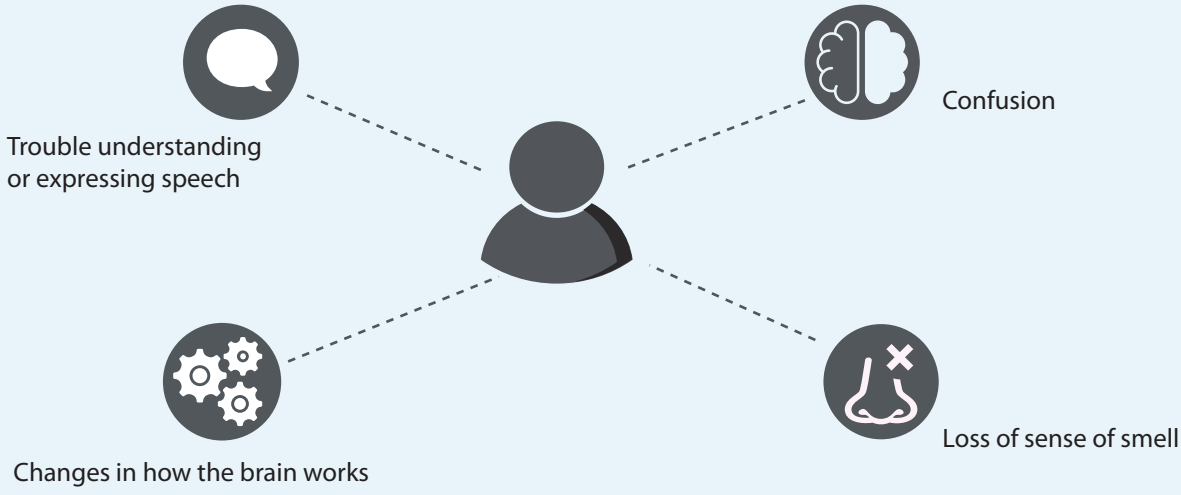
2 at **800 µg/kg** every other week

These were generally **mild**...

...and **resolved**

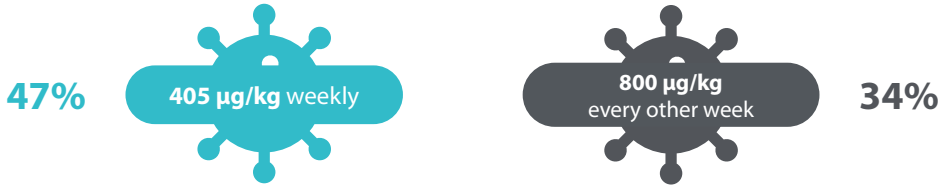


These included:



Nearly half of the participants who received talquetamab at the 405-µg/kg weekly dose and about one-third of those who received the 800-µg/kg every-other-week dose developed infections.

Infections



experienced infections

Most of the infections were **not considered severe**

Opportunistic infections (infections that happen more often and are more severe in people with a weakened immune system)…

…occurred in **2 participants** who received talquetamab at the **405-µg/kg** dose level…

…and in **2 participants** at the **800-µg/kg dose** level.

Covid-19 occured in

13%

of participants who received talquetamab at the **405-µg/kg** dose level…

...and in

2%

of those who received it at the **800-µg/kg** dose level.

No deaths from Covid-19 were reported

Hypogammaglobulinemia is a disorder of the immune system where there is lower than normal levels of antibodies in the blood. This makes it harder for someone to fight off infection.

87% of participants who received talquetamab at **405 µg/kg weekly**

71% of participants who received talquetamab at **800 µg/kg every other week**

Serious side effects are those that cause someone to be hospitalized, die or suffer permanent or life-threatening damage.

Serious side effects

405 µg/kg weekly

43%

of participants reported **serious side effects**

800 µg/kg
every other week

34%

of participants reported **serious side effects**

Most common serious side effects were:

Cytokine release syndrome

Fever

Pain in bones

3 participants

who received the 800-µg/kg dose died

None

deemed by investigators to be because of talquetamab

Stopping treatment or changing dosing of talquetamab due to side effects

One participant who received the 800-µg/kg dose of talquetamab stopped treatment because of side effects, although the researchers did not consider them to be related to talquetamab.

Researchers reduced the dose of talquetamab in 13.3% of participants who received the 405-µg/kg weekly dose and 13.6% of those who received the 800-µg/kg every-other-week dose because of side effects.

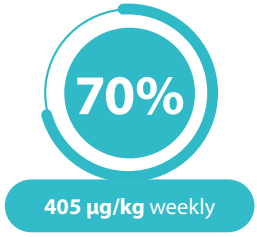
How many people responded to talquetamab?

Regular blood and urine tests were performed to check for signs of multiple myeloma, and cancer cells in the bone marrow were counted to measure the response to talquetamab.
Most people had less measurable multiple myeloma following treatment with talquetamab, and responses were similar between the 2 doses.
People can experience different levels of response to treatment, these are known as:

- **Stringent complete response**
- **Complete response**
- **Very good partial response**
- **Partial response**

Stringent complete response: Complete response plus normal levels of proteins known as 'light chains' in the blood and no detectable cancer cells in the bone marrow.
Complete response: No signs of myeloma in the blood or urine and less than 5% cancer cells in the bone marrow.
Very good partial response: A 90% or more decrease in signs of myeloma (measured by levels of a protein known as M-protein) in the blood and less than 100 mg per day in the urine.
Partial response: A 50% or more decrease in signs of myeloma (M-protein) in the blood and a 90% or more decrease in the urine.

Response



Overall, **21 of 30** participants who received talquetamab at **405 µg/kg**…

…and **28 of 44** at **800 µg/kg** responded to treatment

	405 µg/kg weekly	800 µg/kg every other week
Stringent complete response	23%	11%
Complete response	0%	11%
Very good partial response	33%	30%
Partial response	13%	11%

- The median time until responses were measurable was approximately 1 month with both doses
- To date, median duration of response was approximately 10 months in participants receiving 405 µg/kg weekly and 8 months in those receiving 800 µg/kg every other week
- Responses to talquetamab were similar in people who were triple-class refractory (did not respond or stopped responding to 3 different types of medications) and penta-drug refractory (did not respond or stopped responding to 5 different medications). Talquetamab also led to responses in people who had previously received therapies that help T cells target a receptor on the myeloma cells known as BCMA

What do the results of the MonumenTAL-1 study mean?

- The side effects reported with talquetamab treatment in the MonumenTAL-1 study were mostly mild or moderate and included CRS, changes in blood cell levels and changes in nails, skin and sense of taste
- Participants in this study with relapsed or refractory multiple myeloma responded equally well to treatment with talquetamab at the 2 subcutaneous (given under the skin) doses examined
- The study shows that talquetamab works in people who have tried many currently approved therapies including those that target a receptor known as BCMA on myeloma cells, and this will be of importance when choosing the right order of medications. The low rate of infections and changes in blood cell levels also make talquetamab an option well suited for combining with other multiple myeloma medicines that themselves may impact blood cell levels or have a risk of infection
- Talquetamab is the furthest along in clinical trials of the bispecific agents (agents that attach to 2 different targets at the same time) for multiple myeloma that does not target BCMA. There are ongoing studies looking at talquetamab in combination with other multiple myeloma medicines
- These results support the ongoing phase 2 study of talquetamab in a larger group of people with multiple myeloma that will make the results reported here more reliable
- The results of the phase 2 study have been presented and may be published soon and will provide further information on how safe talquetamab is and how well people respond at the 2 doses identified in this study

Who sponsored the study?

The MonumenTAL-1 study was sponsored by Janssen Research & Development, LLC. Janssen would like to thank all the people who took part in this study as well as their families and caregivers; the physicians, nurses and staff at the clinical sites and the scientific staff for their assistance.

Summary prepared by Karen Pemberton, PhD, of Eloquent Scientific Solutions, and funded by Janssen Research & Development, LLC. The original authors of the full article were involved in preparing this summary.

Where can readers find more information on this study?

The original article "Talquetamab, a T-Cell–Redirecting GPRC5D Bispecific Antibody for Multiple Myeloma" was published in the *New England Journal of Medicine* (Chari A, *et al. N Engl J Med.* 2022; 387:2232-2244). You can read the full article for a fee at: https://www.nejm.org/doi/full/10.1056/NEJMoa2204591

You can read more about the MonumenTAL-1 study (NCT03399799) on the following website: https://clinicaltrials.gov/study/NCT03399799

Financial & competing interests disclosure

A Chari (Mount Sinai School of Medicine, NY, USA) has served in a consulting or advisory role for AbbVie, Amgen, Antengene, Bristol-Myers Squibb, Celgene, Genentech, Genzyme, GlaxoSmithKline, Janssen Oncology, Karyopharm Therapeutics, Oncopeptides, Seattle Genetics, Secura Bio, Shattuck Labs and Takeda; and has received research funding from Amgen, Celgene, Janssen, Pharmacyclics, Seattle Genetics and Takeda. E Askari (Hospital Universitario Fundación Jiménez Díaz, Madrid, Spain) is a consultant for Amgen, Celgene, GSK, Janssen, Sanofi, and Takeda; has received research funding from Celgene and Janssen. J Caers (Centre Hospitalier Universitaire de Liège, Liege, Belgium) has received honoraria from Sanofi; has received research funding from Johnson & Johnson; is a consultant for Johnson & Johnson; and is a speakers' bureau member for Amgen. LJ Costa (University of Alabama at Birmingham, AL, USA) has received honoraria from Adaptive Biotechnologies, Amgen, Bristol-Myers Squibb, Janssen and Sanofi; has received research funding from AbbVie, Amgen, Bristol-Myers Squibb, Genentech and Janssen; and is a consultant for Adaptive Biotechnologies, Amgen, Bristol-Myers Squibb, Janssen and Sanofi. BW Hilder and K Pillarisetti (Janssen Research & Development, Spring House, PA, USA) are employees and/or shareholders of Janssen. A Krishnan (City of Hope Comprehensive Cancer Center, Duarte, CA, USA) has received research funding from Janssen; is a consultant for Adaptive, Artiva, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Janssen, Pfizer, Regeneron, Sanofi and Sutro; is a speakers' bureau member for Amgen, Bristol-Myers Squibb, GlaxoSmithKline, Sutro SAB and Takeda; owns stock in Bristol-Myers Squibb; and is a current equity holder in Bristol-Myers Squibb. M-V Mateos (University Hospital of Salamanca/IBSAL/CIC/CIBERONC, Salamanca, Spain) has served in a consulting or advisory role for AbbVie, Amgen, Celgene, GlaxoSmithKline, Janssen-Cilag, Pfizer, Regeneron, Roche-Genentech and Takeda; and has received honoraria from AbbVie, Amgen, Celgene, Genentech, GlaxoSmithKline, Janssen-Cilag, Sanofi and Takeda. MC Minnema (University Medical Center Utrecht University, Utrecht, Utrecht, Netherlands) has served in a consulting or advisory role for Alnylam, BMS, CDR-life, GSK, Janssen-Cilag and Kite/Gilead. A Oriol (Institut Català d'Oncologia and Institut Josep Carreras, Hospital Germans Trias i Pujol, Badalona, Barcelona, Spain) is a consultant for BMS, Celgene, GlaxoSmithKline, Janssen and Sanofi; is a speakers' bureau member for BMS, Celgene, GlaxoSmithKline and Sanofi. NWCJ van de Donk (Amsterdam University Medical Center, Vrije Universiteit Amsterdam, Cancer Center Amsterdam, Amsterdam, Netherlands) is a member of a board of directors or advisory committee for Amgen, Adaptive Biotechnologies, Bayer, Bristol-Myers Squibb, Celgene, Janssen Pharmaceuticals, Novartis, Roche, Servier and Takeda; has received research funding from Amgen, Bristol-Myers Squibb, Celgene, Cellectis, Janssen Pharmaceuticals and Novartis. P Rodríguez-Otero (Clínica Universidad de Navarra, Navarra, Spain) is an employee of the Hematology Clínica Universidad de Navarra; is a consultant for AbbVie, BMS, GSK, Janssen, Pfizer, Roche and Sanofi; is a speakers' bureau member for Amgen, BMS-Celgene, GSK, Janssen, Regeneron Pharmaceuticals, Inc and Sanofi.