SANOFI

# Press Release

Source: Sanofi (EURONEXT: SAN) (NASDAQ: SNY)

UNITED KINGDOM

For UK Consumer Health Media Only

## Sarclisa® ▼ (isatuximab) approved in EU for hard to treat blood cancer, multiple myeloma[1]

- Almost 18,000 people in the UK live with the incurable blood cancer, multiple myeloma[2]
- Despite current treatments relapse is common, creating an urgent need for new therapies[3]
- Isatuximab showed significant improvement in disease control when used with an existing treatment[4] – the first approved combination of its kind in Europe

**READING, UK – June 2, 2020** – Sanofi today announced that Sarclisa® (isatuximab) has been approved by the European Commission (EC) to be used in adults in combination with an existing treatment for people with an incurable blood cancer, known as relapsed/refractory* multiple myeloma (RRMM).[1] Multiple myeloma occurs within the bone marrow and is the second most common blood cancer in the UK.[2] Sanofi is working closely with healthcare providers and organisations in the UK to make isatuximab available to patients as quickly as possible.

> *"Multiple myeloma is an incurable blood cancer, with a high death rate that affects thousands of people in the UK every year. It can affect your body in several ways, including bone pain and fractures, fatigue, kidney failure and frequent infections. Patients experience great emotional distress and a decline in quality of life as a result of repeated relapses," said Professor Kwee Yong, Consultant of Haematology, University College Hospital, London. "New treatments, like isatuximab, are needed to help control the disease, relieving symptoms and complications, therefore improving care and quality of life for myeloma patients."*

It is estimated that 5,700 people in the UK are diagnosed with multiple myeloma each year,[2] equivalent to 15 people each day.[5] There are approximately 3,000 myeloma deaths

*Relapsed refers to those who have their cancer return after receiving treatment. Refractory refers to patients who have had little-to-no response to treatment, which can be common for those who relapse after initial treatment.[6]

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. See yellowcard.mhra.gov.uk for how to report side effects.

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each year, with half of patients dying within five years of diagnosis.[5] Patients experience frequent relapses and the cancer can become resistant to treatment, making it much harder to control.

Isatuximab has been approved for use in combination with existing standard of care treatments, pomalidomide and a low dose of the steroid, dexamethasone (pom-dex), to extend the length of time a patient can live without their cancer progressing.[1] In the ICARIA-MM trial, isatuximab in combination significantly reduced the risk of disease progression or death in adults by 40%, extending the length of time a patient can live without their cancer progressing (progression-free survival) to 11.5 months, compared to 6.5 months when treated with pom-dex alone. Overall, isatuximab showed an additional five months of progression-free survival.[4]

> *"Multiple myeloma is a complex and progressive disease that contributes to an increasing number of deaths in the UK each year," said Dr Marc Moodley, Medical Director, Sanofi Genzyme. "Our hope is that isatuximab will improve progression-free survival and maintain quality of life for those living with this debilitating disease here in the UK."*

## About ICARIA-MM

The approval of isatuximab is based on the results of the key clinical trial, ICARIA-MM, the first trial to report results evaluating a combination of this kind. ICARIA-MM evaluated isatuximab in combination with pom-dex, in patients with RRMM.[4] This was compared to treatment with pom-dex alone.[4] The study involved 307 patients with RRMM across 24 countries, including the UK.[4] All patients had received approximately three previous anti-myeloma therapies.[4]

## About isatuximab

Isatuximab is a monoclonal antibody (also known as a mAb) that binds to a specific site on a protein called CD38, a high amount of which is present on the surface of multiple myeloma cells.[4] By binding to the CD38 protein, isatuximab helps the body's immune system to target and destroy the cancerous cell.[4]

**About Sanofi**

Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions.

With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.

Sanofi, Empowering Life.

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## References

[1] European Medicines Agency, 2020. Available at: https://www.ema.europa.eu/en. Accessed June 2020.
[2] About Myeloma booklet. Myeloma UK. Available at: https://www.myeloma.org.uk/documents/myeloma-an-introduction/. Accessed May 2020.
[3] Clinical Pathways to Address the Challenges of Treatment Resistance and Relapse in Multiple Myeloma. *Journal of Clinical Pathways*. 2017;3(7):49–55.
[4] Attal M, Richardson PG, *et al.* Isatuximab plus pomalidomide and low-dose dexamethasone versus pomalidomide and low-dose dexamethasone in patients with relapsed and refractory multiple myeloma (ICARIA-MM): a randomised, multicentre, open-label, phase 3 study. *Lancet*. 2019;394(10214):2096–2107.
[5] Cancer Research UK. Statistics by cancer type. Myeloma. Available at: https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/myeloma#heading-Two. Accessed May 2020.
[6] Infopack for relapsed and/or refractory myeloma patients. Myeloma UK. Available at: https://www.myeloma.org.uk/wp-content/uploads/2018/05/Myeloma-UK-Infopack-for-relapsed_refractory-myeloma-patients.pdf. Accessed May 2020.

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