Sevabertinib approved to treat adults with HER2-positive lung cancer that has spread or cannot be removed by surgery

2.4.2026 - | Her Majesty's Revenue and Customs

As with any medicine, the MHRA will keep the safety and effectiveness of sevabertinib under close review.

The Medicines and Healthcare products Regulatory Agency (MHRA) has approved sevabertinib (Hyrnuo) to treat adults with advanced non-small cell lung cancer (NSCLC) with HER2 mutations, that has spread to other parts of the body or cannot be removed by surgery.

Sevabertinib is indicated for patients whose cancer has progressed following prior treatment and whose tumours have specific changes in the HER2 gene. Patients should be tested for these mutations before starting treatment to ensure the medicine is suitable for them.

Sevabertinib is a protein kinase inhibitor that works by blocking abnormal HER2 protein which drives the growth of cancer cells. By targeting this protein, the medicine can help to slow or stop the cancer from growing and, in some cases, shrink the tumour. Clinical trial evidence shows sevabertinib produced positive responses in 71% of previously treated patients with advanced HER2 mutations, with many positive responses lasting six months or longer.

Julian Beach, Interim Executive Director of Healthcare Quality and Access at the MHRA, said:

> The approval of sevabertinib (Hyrnuo) provides a new treatment for adults with HER2-positive lung cancer that has spread or cannot be removed by surgery.
>
> As with all licensed medicines, we will continue to monitor its safety closely as it becomes more widely used.

The most common side effects of sevabertinib include diarrhoea, skin reactions, stomatitis (inflammation of the mouth) and paronychia (inflammation of skin surrounding toenails). Patients should speak to their healthcare professional if they experience any side effects.

As with any medicine, the MHRA will keep the safety and effectiveness of sevabertinib under close review. Anyone who suspects they are having a side effect from this medicine are encouraged to talk to their doctor, pharmacist or nurse and report it directly to the Yellow Card scheme, either through the website (https://yellowcard.mhra.gov.uk/) or by searching the Google Play or Apple App stores for MHRA Yellow Card.

Sevabertinib has been approved through Project Orbis, a global partnership between the MHRA, the Therapeutics Goods Administration in Australia, Health Canada, the Health Sciences Authority in Singapore, Swissmedic, Agência Nacional de Vigilância Sanitária in Brazil and Israel’s Ministry of Health, coordinated by the US Food and Drug Administration. This programme reviews and approves promising cancer drugs, helping patients to access treatments more quickly.

Notes to editors

1. The marketing authorisation was granted to Bayer PLC on 1 April 2026.

2. The aim of Project Orbis is to deliver faster patient access to innovative cancer treatments with potential benefits over existing therapies. For more information, see: Project Orbis

3. For more information about lung cancer, visit: https://www.nhs.uk/conditions/lung-cancer

4. More information can be found in the Summary of Product Characteristics and Patient Information leaflets which will be published on the MHRA Products website within 7 days of approval.

5. The Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgments to ensure that the benefits justify any risks.

6. The MHRA is an executive agency of the Department of Health and Social Care.

7. For media enquiries, please contact the newscentre@mhra.gov.uk, or call on 020 3080 7651.

https://www.gov.uk/government/news/sevabertinib-approved-to-treat-adults-with-her2-positive-lung-cancer-that-has-spread-or-cannot-be-removed-by-surgery