UK medicines regulator issues its first authorisation under Project Orbis

A post-surgery treatment for lung cancer will be the first to receive an authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) under Project Orbis – only four months after the agency joined the scheme in January 2021.

Osimertinib (Tagrisso), a medicine made by AstraZeneca, is a licensed treatment for patients with mid and later stage non-small cell lung cancer (NSCLC) who test positive for a specific gene mutation called EGFR. EGFR mutations occur in approximately 12%* of lung cancer patients. The licence has now been extended to include a new population of patients in early-stage disease. The extended licence offers a novel treatment option for these patients, after their cancer has been surgically removed, in an area of significant unmet need.

Project Orbis is an innovative programme coordinated by the US Food and Drug Administration (FDA) with Canada, Australia, Switzerland, Singapore, Brazil and the UK as other participants. The programme has been set up to allow participating partners to review and approve applications for promising cancer treatments quickly and efficiently.

Prior to the UK joining, the scheme has already given the green light to many life-saving treatments for patients suffering from conditions such as breast cancer, lung cancer, liver cancer, endometrial cancer, and chronic lymphocytic leukaemia.

NHS England, NICE and AstraZeneca have reached an agreement to enable early access to osimertinib for early-stage lung cancer patients in England on a budget-neutral basis to the NHS while NICE undertakes its appraisal.

Health and Social Care Secretary Matt Hancock said:

> It is absolutely vital that NHS patients have access to the most promising, cutting-edge treatments at quickly as possible.
>
> Leaving the EU presented us with the opportunity to join Project Orbis – an international collaboration with the top regulators around the world – to speed up the time it takes to get these new medicines to patients.
>
> I am delighted that today we are able to see the first results of our involvement in this partnership, with a groundbreaking drug for lung cancer which will soon benefit hundreds of patients, and I look forward to seeing what further innovations it will bring to

the table.

Dr June Raine CBE, Chief Executive, Medicines and Healthcare products Regulatory Agency said:

> With Project Orbis, we are working to ensure that patients receive earlier access to promising, life-saving cancer treatments. We know that the earlier we can treat patients, the better their outcomes. Through international cooperation, innovation in regulation, and working with others across the whole health system, the MHRA is cementing the UK's global position at the centre of life sciences and healthcare access.

Tom Keith-Roach, President, AstraZeneca UK, said:

> Project Orbis is a powerful example of how collaboration between regulatory authorities around the world can accelerate the approval of life-changing treatments and we're delighted that osimertinib is the first medicine to undergo this innovative review process with the MHRA. It's fantastic news that NHS patients in England with this specific type of early-stage lung cancer will have early access to this medicine, which could significantly improve their chance of disease-free survival. We will continue our work to secure access for patients in the devolved nations at the earliest possible opportunity.

Notes to editors

- Project Orbis is a programme coordinated by the US Food and Drug Administration involving Canada, Australia, Switzerland, Singapore Brazil and the UK to review and approve promising cancer treatments. The scheme has already given the green light to many life-saving treatments for patients suffering from conditions such as breast cancer, lung cancer, liver cancer, endometrial cancer, and chronic lymphocytic leukaemia.

- The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.

- The Medicines and Healthcare products Regulatory Agency ('the agency') has three centres. The MHRA, the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The agency is an executive agency of the Department of

Health and Social Care.

- *Midha A, Dearden S, McCormack R. EGFR mutation incidence in non-small cell lung cancer of adenocarcinoma histology: a systematic review and global map by ethnicity (mutMapII). Am J Cancer Res. 2015;5;2892-2911.