Early Access continues during the coronavirus pandemic

The MHRA is committed to speeding up access to innovative new medicines for patients. The Early Access to Medicines Scheme (EAMS) gives patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need. The scheme has remained fully operational throughout the coronavirus pandemic, ensuring that patients with serious conditions can still be offered new treatment options for their conditions.

As an example, the MHRA issued a positive scientific opinion for Roche's atezolizumab (Tecentriq) in a new combination regimen for patients with unresectable hepatocellular carcinoma (HCC) in June 2020. Atezolizumab is a monoclonal antibody that directly binds programmed death-ligand 1 (PD-L1). PD-L1 may be expressed on tumour cells and/or tumour-infiltrating-immune cells and can contribute to the inhibition of the anti-tumour immune response in the tumour microenvironment.

Through EAMS, MHRA has been able to work with Roche since 2017 to ensure that over 600 UK patients with limited treatment options, have been among the first in the world to benefit from 8 breakthrough treatments prior to licence. This has paved the way for accelerated routine access in the NHS. To date, this working collaboration between MHRA and Roche has represented roughly a quarter of all EAMS run in the UK, including patients benefiting from receiving Tecentriq in five new cancer indications.

The Challenge

Cases of primary liver cancer are rising in the UK. HCC is the most common form of primary liver cancer and tends to be diagnosed at an advanced stage, often in cirrhotic livers, when very limited treatment options are available. For these patients, there is a high unmet need for alternative treatment options as their prognosis is poor, with rapid progression and short overall survival.

Role of the MHRA

EAMS

Roche benefitted from the MHRA validating the evidence generated at an early stage during the first step of the EAMS, the PIM (Promising Innovative Medicine) designation. The PIM designation gave an early indication from the MHRA that atezolizumab in combination with bevacizumab, was a potential candidate for EAMS. This enhanced opportunities for Roche to work with other stakeholders in the UK around patient access. Subsequently, Roche presented their positive Phase III clinical data at a pre-submission meeting with MHRA. This provided the company with an opportunity to discuss the dossier of

evidence and consider data collection aspects with the MHRA in advance of a formal application. At this point, the MHRA recommended Roche submit an application for step II of EAMS, the Scientific Opinion (SO). During the SO assessment, the MHRA fully assessed the data generated for atezolizumab to ensure that the EAMS criteria were met and the benefits outweighed the risks. A resultant positive SO was issued.

Post-EAMS pilot

There often is a time period between granting of a marketing authorisation (when EAMS closes) and NICE reimbursement, during which new patients may be unable to access the innovative medicine. Following a partnership between Roche, NHS England and NHS Improvement and the MHRA, the first Post-EAMS pilot was created to enable new patients to gain access to atezolizumab and bevacizumab during this time period.

The Outcome

During the EAMS period, 63 patients with HCC were able to access atezolizumab (in combination with bevacizumab) after discussions with their doctor. Submission through EAMS accelerated patient access to the treatment by around 4 months.

The Post-EAMS pilot has enabled Trusts in England to order medicine for patients using the same processes that were used for EAMS, saving capacity and NHS resources. During the relatively short duration of this pilot, 13 more eligible HCC patients were able to access treatment with atezolizumab and bevacizumab.

Tecentriq, in combination with Avastin, is now the first cancer immunotherapy treatment recommended by NICE for HCC.

Milestone dates include:

- May 2019: PIM designation awarded
- June 2020: MHRA issued positive Scientific Opinion for atezolizumab through EAMS
- October 2020: NICE appraisal committee meeting
- November 2020: European Commission (EC) granted an EU licence for Atezolizumab triggering closure of EAMS to new patients – existing EAMS patients continued to gain access to the medicine until FAD, and new patients gained access via PEAMS
- November 2020: NICE Final Appraisal Determination (FAD) was recommended marking closure of the PEAMS in England and transition of patients to NHS funding.

Reflections

Tim Meyer, Professor of Experimental Cancer Medicine in UCL,

said:

> The IMbrave150 trial was published in New England Journal of Medicine in May 2020 and established the superiority of atezolizumab and bevacizumab for advanced hepatocellular carcinoma compared to the existing standard of care. The Roche EAMS allowed us to offer this new standard of care to our patients within 8 weeks of the publication and the Post-EAMS pilot facilitated seamless transition to NHS provision.
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> The close collaboration between Roche and regulators has enabled the translation of research, partly conducted in the UK, into patient benefit with minimal delay and great efficiency.

Matt Whitty, Chief Executive of the Accelerated Access Collaborative said:

> Roche’s EAMS journey with atezolizumab (in combination with bevacizumab) is a good example of the NHS continuing to support patient access to innovative treatment throughout the coronavirus pandemic.
>
> Thanks to the partnership working between Roche, NHS England and NHS Improvement, and the MHRA, access continued through the Post-EAMS pilot, allowing clinicians to choose this treatment to support their patients and demonstrating the potential for this collaborative approach to be expanded for an enhanced EAMS programme.

Gemma Boni, Head of Liver Cancer, Roche Products Limited said:

> Raising awareness of EAMS, especially during the coronavirus pandemic is important to ensure patients with high unmet medical needs such as these HCC patients, do not miss out on potentially life-changing new treatments.
>
> The MHRA and Roche have been steadfast in their commitment to the assessment of the EAMS Scientific Opinion, ensuring no delay to early access for HCC patients even amidst all the challenges presented by the pandemic.

> The addition of the Post-EAMS pilot to EAMS demonstrates that UK health agencies in collaboration with industry partners may be able to feasibly offer a more streamlined process to enable equitable early access to innovative treatments in the UK. Learnings from this pilot will help to refine the process for future EAMS programs.

How to apply for EAMS and supporting innovation

EAMS aims to give patients with life threatening or seriously debilitating conditions access to medicines that do not yet have a marketing authorisation when there is a clear unmet medical need. Visit EAMS to find out more.

You may also find help to expedite your medicines to patients by visiting the MHRA Innovation Office which provides free and confidential expert regulatory information and advice. Find out more about how the innovation office has helped support innovation; read our case studies.