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Roche's Eye Drug Scores First UK Approval Under Access Consortium

by Vibha Sharma

The UK MHRA has approved its first drug under an international work-sharing initiative that also includes regulators from Australia, Canada, Singapore and Switzerland.

Roche's ophthalmology drug Vabysmo (faricimab) has become the first product to be approved by the UK medicines regulator under the Access Consortium, an international work-sharing scheme that the agency joined post-Brexit to accelerate drug approvals.

The Medicines and Healthcare products Regulatory Agency joined the consortium in October 2020 to work with regulators from Australia, Canada, Singapore and Switzerland to promote greater regulatory collaboration and alignment of regulatory requirements. (Also see "*Brexit: MHRA Joins Second International Work-Sharing Scheme To Speed Up Drug Approvals*" - Pink Sheet, 15 Oct, 2020.)

The MHRA has approved faricimab, an anti-VEGF and anti-angiopoietin-2 bispecific antibody, for the treatment of neovascular or "wet" age-related macular degeneration (wet AMD) and visual impairment due to diabetic macular edema (DME).

The drug is designed to block two different pathways implicated in causing vision loss in patients with wet AMD and DME. It has been shown to be effective in improving vision or reducing vision loss in these patient groups, but has the added benefit in that it can be given less frequently in selected patients than other medicines currently available, the MHRA explained.

The treatment's UK approval was made possible through the Access Consortium's "New Active Substance Work Sharing Initiative," which allows companies to submit applications for a new chemical or biological entity or a new indication for joint review by two or more participating agencies.

Faricimab is approved in the US and Japan and is also under review in the EU, where it is in the later stages of the evaluation cycle. The European Medicines Agency's human medicines committee, the CHMP, was due to adopt a "list of outstanding issues" in relation to faricimab at its latest monthly meeting taking place from 16 to 19 May. (Also see "*Roche Seeks EU Marketing Approval For Novel Eye Disease Drug Faricimab*" - Pink Sheet, 19 Jul, 2021.)

Roche told the *Pink Sheet* that it had submitted applications for faricimab to health authorities worldwide, including all Access Consortium countries.

Quicker Access

The MHRA's first approval under the Access Consortium was touted by Health and Social Care Secretary Sajid Javid as one of the ways in which the MHRA might manage to get products approved faster since leaving the EU.

After Brexit, Javid said, the UK was "free to team up with other world-leading regulators to speed up the approval process for medicines, while maintaining the highest safety standards." Faricimab's UK approval, he said, was "fantastic news" and a "great example of UK patients getting quicker access to cutting-edge treatments."

MHRA chief executive June Raine said the approval highlighted the significant benefit that patients can get from the agency's "communication, collaboration and innovation with our international peers."

Since leaving the EU, the MHRA has also joined Project Orbis, the US-led scheme that enables international regulators to simultaneously review new cancer drugs and approve them faster. Last year, the UK regulator approved its first product under Project Orbis – an extended indication for AstraZeneca's lung cancer treatment Tagrisso (osimertinib). (Also see "*UK Pips EU To The Post With 'Project Orbis' Approval For Tagrisso*" - Pink Sheet, 7 May, 2021.)

Fewer Hospital Visits

The Macular Society, the UK-based sight loss charity, also welcomed the UK's approval of faricimab. Wet AMD and DME patients "face the burden of regular hospital visits to receive the vital treatment" and these trips can be "arduous and often rely on the support of friends and family, sometimes as often as every four weeks," explained society chief executive Cathy Yelf.

Faricimab has the potential to maintain vision and help minimize the number of hospital visits, which can make a "real difference to the lives of many people living with this devastating condition," said Yelf.

As for the drug's availability on the National Health Service, this will be decided by the National Institute for Health Excellence (NICE) and the Scottish Medicines Consortium (SMC), the health

technology assessment bodies for England and Wales, and for Scotland, respectively.

NICE is carrying out a fast-track appraisal (FTA) of the drug, and if a positive recommendation is made through the FTA process, NHS England/commissioners have committed to providing funding for the technology within 30 days of final guidance publication.