First Innovation Passport awarded to help support development and access to cutting-edge medicines

A promising treatment for a cancer-causing rare disease will be the first to pass a significant milestone under a new UK approval process designed to bring medicines more rapidly to patients.

Belzutifan, a treatment developed by MSD (UK) for adults with von Hippel Lindau disease (a rare genetic disorder that causes cancer) has been awarded the first 'Innovation Passport' by the Medicines and Healthcare products Regulatory Agency, National Institute for Health and Care Excellence and the Scottish Medicines Consortium (SMC).

This means patients could benefit much sooner from this treatment and it will be accelerated through the approval process; the Innovative Licensing and Access Pathway (ILAP).

Launched in January this year, the ILAP combines the MHRA's globally recognised high standards of quality and safety with improved flexibility to reduce the time it takes innovative treatments to be available to NHS patients.

Medicines developed through the ILAP will have more focus on patient engagement than ever before. By incorporating patient views, both on the benefits and risks of medicines in the pathway, and on how to improve patient outcomes throughout the product lifecycle, medicines can be developed to meet patient requirements more successfully.

The award of this designation celebrates another first: the successful partnership between the MHRA, NICE and the SMC in making effective joint decisions and awarding Innovation Passports to products that will benefit patients.

The Innovation Passport is the first step in the ILAP and is open to developers of a wide range of medicines, including medicines for rare diseases, repurposed medicines and Advanced Therapy Medicinal Products. Since launch, companies have submitted 10 applications.

Innovation Passport holders, the MHRA and partners will next work together to create a product-specific Target Development Profile (TDP) for the new medicine. The TDP will define key regulatory and development features, identify potential pitfalls, offer access to specialist toolkits and create a roadmap for delivering early patient access.

The TDP will also outline how the Innovation Passport holder can work together with other UK stakeholders to achieve coordinated, efficient evidence generation and evaluation, and address considerations regarding

patient access.

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

> We’re transforming the MHRA to make the regulator an enabler of innovation. I’m very pleased to announce the first Innovation Passport designation demonstrating that this process is well underway.
>
> Our Innovative Licensing and Access Pathway is already working to deliver new and innovative treatments to patients through strong and effective partnerships.
>
> Patients are our top priority and are involved at every stage of this process. Together, we look forward to bringing more Innovation Passport holders on board to deliver earlier access to these products, better outcomes for patients and to continue our transformation.

Prof Gillian Leng CBE, Chief Executive of NICE said:

> I am delighted that our partnership with the MHRA and the SMC has delivered on this important milestone so quickly. Our contribution to the ILAP is one of the ways NICE is delivering tangible benefits to patients, the NHS and life sciences industry. We look forward to working with our ILAP partners and the company to explore the opportunities for efficient and timely development, regulation and access processes.

Mark MacGregor, Chairman of the Scottish Medicines Consortium, said:

> This important milestone has helped to underscore our pivotal role in ILAP and as a key partner in ensuring patients in Scotland can benefit from the best, most clinically effective and cost-effective treatments that are available, as early as possible.

David Peacock, Managing Director of MSD (UK) Ltd, said:

> We are excited to be the first company to receive an Innovation Passport as part of the new Innovative Licensing and Access Pathway (ILAP). We welcome the opportunity to participate in any approach that recognizes the potential value of innovative medicines and seeks to accelerate access for patients who might benefit. We look forward to continuing to play our role as an engaged partner in our

efforts to improve the lives of patients in the UK and around the world.

Notes to editor

- Information about the Innovative Licensing and Access Pathway
- Von Hippel-Lindau (VHL) disease is a rare genetic disorder caused by mutations in the VHL tumour suppressor gene. Patients commonly suffer from a kidney cancer called renal cell carcinoma that often spreads to other parts of the body. Approximately 1 in 33,000 people have Von Hippel-Lindau (VHL) disease.
- The Medicines and Healthcare products Regulatory Agency 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 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.
- The Scottish Medicines Consortium (SMC) is the national source of advice on the clinical and cost-effectiveness of all new medicines for NHS Scotland. As part of Healthcare Improvement Scotland, the SMC aims to ensure that people in Scotland have timely access to beneficial new medicines.
- The Innovation Passport does not replace the Promising Innovative Medicine (PIM) Designation of the Early Access to Medicines Scheme (EAMS) and applicants can apply for both. An applicant is required to submit an Innovation Passport application for each separate medicinal product (different active substances).