29/02/2024

Direct Healthcare Professional Communication (DHPC)

GAVRETO®▼(pralsetinib): Planned transition of Market Authorisation Holder from Roche Products Ltd to BluePrint Medicines resulting in discontinuation of supply from Roche Products Ltd

Dear Healthcare professional,

Roche Products Ltd, in agreement with the Medicines and Healthcare Products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- Due to the transition of marketing authorisation for GAVRETO ® (pralsetinib) from Roche Products Ltd to BluePrint Medicines (BPM), and BPM's decision to discontinue marketing of GAVRETO in the UK, it is recommended that prescribers seek alternative treatment options for newly identified metastatic non-small cell lung cancer (NSCLC) patients with rearranged during transfection (RET)-driven tumours. There is a licensed alternative treatment option available in the UK.

- A transition plan is in place to manage interim access to GAVRETO ® (pralsetinib) in the United Kingdom for patients currently receiving treatment with GAVRETO.

- If you have patients currently undergoing treatment with GAVRETO ® (pralsetinib), including post-trial access and Free of Charge patients, a representative of Roche Products will contact you directly.

- These activities are not a result of any new clinical efficacy or safety information, and the known and established benefit-risk profile of the medicine in its approved indications remains unchanged.

Background

In February 2023, Roche Products Ltd informed BPM of its decision to terminate a global collaboration agreement to develop and commercialise GAVRETO® (pralsetinib). Ownership of GAVRETO will soon be transitioned back to a company named Blueprint Medicines, the original owner of GAVRETO, which will serve as the new Market Authorisation Holder in the United Kingdom.

On 8 January 2024, BPM announced their decision to discontinue global marketing and development of GAVRETO in all territories excluding the United States and Greater China. This decision has not been taken for any efficacy, safety or quality reasons. Discontinuation of development will also mean that ongoing clinical trials will be closed.

As part of the transition to BPM, Roche Products Ltd will be transferring the marketing authorisation of GAVRETO in the United Kingdom to BPM. Based on BPM's recent public update

on their decision to discontinue global marketing and development of GAVRETO in all territories excluding the US and Greater China, BPM is currently planning on deregistering GAVRETO in the United Kingdom and therefore GAVRETO will no longer be available in the United Kingdom. The precise timeline for the transition of the marketing authorisation by BPM is not yet confirmed.

Patients are Roche's top priority and we remain committed to continuously working with BPM to ensure GAVRETO continues to be accessible to RET+ metastatic NSCLC patients currently on treatment. For any newly identified NSCLC patients with RET-driven cancers, Roche Products Ltd are asking healthcare providers to explore other treatment options where available. Another RET-targeted treatment option is licensed in the UK.

Call for reporting

GAVRETO®▼(pralsetinib) is subject to additional monitoring. This will allow quick identification of new safety information.

Please report ANY suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle▼

You can report via:

- the Yellow Card website: www.mhra.gov.uk/yellowcard
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

Adverse events should also be reported to Roche Products Ltd. Please contact Roche Drug Safety Centre by emailing welwyn.uk_dsc@roche.com or calling +44 (0)1707 367554.

Company contact point

Should you have any questions regarding the use of Gavreto, please feel free to contact:

Roche Medical Information by phone on +44(0)800 328 1629 or via e-mail

medinfo.uk@roche.com

Dr Marius Scholtz

Medical Cluster Lead/Chief Medical Officer

Annexes

Press release: https://ir.blueprintmedicines.com/news-releases/news-release-details/blueprint-medicines-regain-global-rights-GAVRETOr-pralsetinib

Press release: https://ir.blueprintmedicines.com/news-releases/news-release-details/blueprint-medicines-highlights-2024-corporate-strategy-and

Thank you in advance for your understanding and cooperation in this additional information.

Yours faithfully,

Roche Products Limited

DocuSigned by:
Marius Scholtz
AB2CA8841CD144B...

Marius Scholtz

Medical Cluster Lead, Roche UK

04 March 2024