Ref: RXUKPOLA00026 April 2020

Direct Healthcare Professional Communication

POLIVY® ▼ (polatuzumab vedotin): 140 mg powder for concentrate for solution for injection
Important information on temporary plastic vial flip-off cap colour

Dear Healthcare Professional,

Roche Registration GmbH in agreement with the European Medicines Agency and the Medicines and Healthcare products Regulatory Agency (MHRA) would like to inform you of the following:

Summary

- **To avoid a potential shortage of Polivy in some European markets, one batch manufactured for clinical trial use will be repurposed for commercial supply. The shortage risk is not associated with any manufacturing or quality issue.**
- **From May 2020, Roche will be distributing POLIVY 140mg/vial with an aqua-coloured plastic vial flip-off cap, in addition to the approved dark blue plastic vial flip-off cap (photos below). Both are equivalent in terms of composition.**
- **For the time being, vials with both plastic vial flip-off cap colours (aqua and dark blue) will be on the market. After depletion or expiration of existing stock of vials with aqua plastic vial flip-off cap, Roche will return to distributing the dark blue plastic vial flip-off cap only.**
- **Prescribers and pharmacists should continue to use the existing stocks of POLIVY 140 mg/vial until depleted or expired.**

Product	Current (dark blue plastic vial flip-off cap)	Temporary (aqua plastic vial flip-off cap)	Change
POLIVY 140 mg/vial EU/1/19/1388/001			Aqua-coloured plastic vial flip-off cap to be temporarily available in addition to the dark blue plastic vial flip-off cap.

Background information

POLIVY (polatuzumab vedotin), a CD79b-directed antibody-drug conjugate, is an orphan medicinal product that received a conditional marketing authorization from the European Commission on 16 January 2020 with the following indication:

POLIVY in combination with bendamustine and rituximab is indicated for the treatment of adult patients with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) who are not candidates for haematopoietic stem cell transplant.

To prevent a potential shortage of Polivy and in order to ensure continuous supply for some European markets, one batch manufactured for clinical trial use will now be repurposed for commercial supply.

This batch is produced according to the commercially registered and validated manufacturing process in the commercial manufacturing facility at BSP PHARMACEUTICALS S.p.A but differs in color of the plastic vial flip-off cap as indicated above.

Call for reporting

Health Care Professionals should continue to 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 ▼

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, 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.

As Polivy is a biological medicine, healthcare professionals should report adverse reactions by brand name and batch number.

Company contact point

Should you have any questions about the information in this letter or require any further assistance, please contact Roche Medical Information by phone on +44(0)800 328 1629 or via e-mail medinfo.uk@roche.com

Yours faithfully,

Dr Rav Seeruthun MBBS BSc MRCGP MFPM MBA

UK Medical Director