FOR USE IN IRELAND

Columvi▼(glofitamab)

Healthcare Professional Guide

Important Safety Information to Minimise the Risk of Tumour Flare and a reminder of the Patient Card

▼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.
See box on page 6 for details on how to report.

This educational material is provided by Roche Products (Ireland) Limited as a condition of the Columvi marketing authorisation and has been approved by the HPRA

This material should be read in conjunction with the Summary of Product Characteristics (SmPC) which is available on www.medicines.ie and www.ema.europa.eu

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1. Important Safety Information

All patients who are treated with glofitamab should be provided with a copy of the Patient Card.

Please complete the relevant contact information and give a copy of the Patient Card to your patient.

The objective of the card is to inform patients of the main symptoms of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) and the need to seek medical attention immediately in case of their occurrence.

Patients should also be advised to keep the Patient Card with them at all times and show it to any healthcare professional involved in their care.

Alert Health Care providers to have on-site immediate access to tocilizumab.

2. What is glofitamab?

Glofitamab is a "2:1" T-cell bispecific humanised monoclonal antibody that binds to human CD20 on B cells through two fragment antigen-binding (Fab) domains, and to the human CD3 epsilon subunit (CD3e) of the T-cell receptor (TCR) complex on T cells through a single Fab domain. The molecule is based on the human IgG1 isotype but contains an Fc-part devoid of Fc gamma receptor (FcγR) and complement (C1q) binding.

3. Important risks associated with glofitamab use

- Cytokine release syndrome (CRS)*
- Tumour flare
- Immune effector cell-associated neurotoxicity syndrome (ICANS)**

The aim of the HCP Guide is to inform physicians of the risk of tumour flare and its manifestations. The aim is also to inform physicians to provide each patient with the Patient Card and educate the patient on its content, that includes a list of symptoms of CRS and ICANS.

* Information on the occurrence, prevention and management of CRS associated with glofitamab is provided in the glofitamab prescribing information. CRS is a known risk among healthcare professionals; however, the signs/symptoms of CRS may not be well understood by patients (please refer to the Patient Card).

** Information on the management of ICANS associated with glofitamab is provided in the glofitamab prescribing information.

4. Guidance on minimising the risk of tumour flare

4.1 What is tumour flare?

Tumour flare is typically characterised by localised responses, which can manifest as tumour pain, volumetric enlargement of tumour sites, swelling or inflammation, usually in early cycles of treatment. Tumour flare is a phenomenon whereby symptoms present due to effects of influx of immune cells in response to treatment with glofitamab. Tumour pseudoprogression is primarily a radiological diagnosis, in contrast to the clinical manifestations that characterise tumour flare (Taleb 2019)[1].

Depending on tumour size and anatomic location, events associated with tumour flare may potentially result in mass effects on surrounding structures that can compromise organ function, e.g., dyspnea as a result of airway compression, pleural or pericardial effusion, and bleeding or perforation if major blood vessels or highly vascularised areas are involved.

Consistent with the mechanism of action of glofitamab, tumour flare is likely due to the influx of T cells into tumour sites following glofitamab administration and may mimic progression of disease. Tumour flare does not imply treatment failure or represent tumour progression.

4.2 Tumour flare and glofitamab

Tumour flare was reported in 11.7% of patients, including Grade 2 tumour flare in 4.8% of patients and Grade 3 tumour flare in 2.8% of patients. Adverse reactions of tumour flare involving lymph nodes in the head and neck presenting with pain and involving lymph nodes in the thorax with symptoms of breathlessness due to development of pleural effusion have been reported with glofitamab. Most tumour flare events occurred during Cycle 1, and no tumour flare events were reported beyond Cycle 2. The median time to onset of tumour flare of any grade was 2 days (range: 1 to 16 days), and the median duration was 3.5 days (range: 1 to 35 days).

Tumour flare has been reported in patients receiving glofitamab (see section 4.8 of the SmPC). Manifestations included localised pain and swelling.

4.3 Patient monitoring

Specific risk factors for tumour flare have not been identified, however, there is a heightened risk of compromise and morbidity due to mass effect secondary to tumour flare in patients with bulky tumours located in close proximity to airways and/or a vital organ. Patients with tumours at critical anatomic locations are at most risk of serious sequelae, as tumour flare reactions may affect surrounding structures. Therefore, evaluation of lymphoma distribution is important prior to treatment initiation to anticipate the potential spectrum of clinical manifestations of tumour flare after glofitamab administration.

Patients with tumours involving critical anatomic locations (e.g., major vessels, tracheobronchial tree and upper airway, heart and pericardium) should be closely monitored for tumour flare, and prospective preventive or interventional measures may need to be considered or planned prior to dosing.

Proactive monitoring of vital signs, physiological parameters, or implementing prophylactic procedures (e.g., tracheostomy) may be required.

Depending on the clinical manifestation of tumour flare, further medical and/or surgical management may be necessary (e.g., anti-inflammatory agents, airway management, decompression, tracheostomy, stenting, prolonged hospitalisation). Corticosteroids and analgesics should be considered to treat tumour flare.

Reporting of suspected adverse events or reactions

▼ 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 (see details below). Reporting suspected adverse events or reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.

Where possible, healthcare professionals should report adverse events or reactions by brand name and batch number.

In the event of a suspected adverse event, please report it to:
The Drug Surveillance Centre
Roche Products (Ireland) Limited
3004 Lake Drive, Citywest, Naas Road, Dublin 24
Telephone: (01) 4690700
Email: ireland.drug_surveillance_centre@roche.com

Alternatively, suspected adverse reactions should be reported to:
HPRA Pharmacovigilance
Website: www.hpra.ie

Further Information

For electronic copies of this risk minimisation material, refer to www.hpra.ie and download the required material (enter 'Columvi' or 'glofitamab' in the search box and click on 'EdM' next to any of the medicines that appear). Alternatively if you would like hard copies, please contact Roche Products (Ireland) Limited, 3004 Lake Drive, Citywest, Naas Road, Dublin 24 by mail, telephone (01 4690700) or email (ireland.drug_surveillance_centre@roche.com).

For further information about this medicine, please contact Medical Information at Roche Products (Ireland) Limited by telephone (01 4690700) or email (Ireland.druginfo@roche.com).

5. References

1. Taleb BA. Tumour flare reaction in cancer treatments: a comprehensive literature review. Anticancer Drugs 2019;30(9):953-958.

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