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Public Summary SwissPAR dated 15 March 2024

Columvi® (active substance: glofitamab)

First authorisation in Switzerland: 7 November 2023

Medicinal product (concentrate for solution for infusion) for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) after 2 or more lines of systemic therapy

About the medicinal product

Columvi, containing the active substance glofitamab, is used to treat adults with a specific type of cancer called "diffuse large B-cell lymphoma" (DLBCL).

DLBCL is a malignant disorder of the lymphatic system[1] that originates from mature B lymphocytes (white blood cells). It is an aggressive and rapidly growing form of non-Hodgkin lymphoma (NHL).

Columvi is used to treat recurrent (relapsed) or refractory[2] DLBCL. Patients have previously received at least 2 lines of systemic[3] therapy, including 1 with an antibody and an anthracycline. The DLBCL continued to progress despite previous specific CAR T-cell therapy[4] or the patients were unsuitable for this treatment.

Since DLBCL is a rare, life-threatening disease, Columvi has been authorised as an orphan drug. The term "orphan drug" is used to refer to important medicines for rare diseases.

Mode of action

The active substance glofitamab is a "bi-specific monoclonal antibody" (an immunologically effective protein). Glofitamab binds both to the tumour cells, by binding to the CD20 receptor (binding site) on the surface of B cells, and to the CD3 receptor on the surface of T cells (cells of the immune system). By binding simultaneously to CD20 on

[1] Lymphatic system: The lymphatic system includes all the lymph pathways in the body plus the lymphatic organs, including the lymph nodes, the spleen, the lymphatic tissues in the gastrointestinal tract and throat, and the thymus gland.

[2] In the context of cancer, refractory means that the cancer does not respond to the treatment and fails to regress, or even progresses, despite the treatment.

[3] Systemic therapy: In contrast to local therapy (treatment at the site of the disorder), systemic therapy involves treatment of the entire body to eliminate a disorder.

[4] CAR T-cell therapy is a specific immunotherapy for cancer in which the patients' own immune cells are taken and modified using gene technology so that they recognise cancer cells and specifically destroy them. The modified CAR T cells are administered to the patient via an infusion.

B cells and CD3 on T cells, there is direct contact between the tumour cells and T cells, leading to replication and activation of the T cells. Specific proteins that play a key role in immune defence are excreted as a result.

Thanks to this mechanism of action, the immune system can kill the target B cells, thereby inhibiting the growth of the cancer.

Administration

Columvi, containing the active substance glofitamab, is a prescription-only medicine. The concentrate is available in vials containing 2.5 mg of the active substance in 2.5 mL or 10 mg of the active substance in 10 mL.

Columvi is administered as an infusion into a vein (intravenously) after dilution. The dose administered is adjusted gradually. A treatment cycle lasts 21 days. Columvi is administered for a maximum of 12 cycles.

Before treatment with Columvi, patients also receive another cancer medicine containing the active substance obinutuzumab.

Treatment with Columvi is initiated and monitored by a healthcare professional with experience in the administration of cancer treatments. It is administered in a setting with appropriate medical facilities for treating possible severe reactions.

At the start of treatment with Columvi and if severe reactions such as cytokine release syndrome (CRS[5]) or neurological side effects occur, patients are treated and monitored in an inpatient setting.

The doctor will also ask the patient to seek medical attention immediately in the event of a severe reaction.

Prior to treatment with Columvi, preliminary treatment (premedication) is given to reduce the risk of these severe reactions.

Efficacy

The efficacy of monotherapy with Columvi in patients with relapsed or refractory lymphoma was evaluated on the basis of the pivotal NP30179 trial. Participants had previously received at least 2 lines of systemic therapy. All patients had also previously received chemotherapy, treatment with a monoclonal CD20 antibody, and a specific CAR T-cell therapy.

Prior to treatment with Columvi, the patients received the monoclonal antibody obinutuzumab. They also received another medicinal product prior to treatment to relieve the symptoms of side effects.

In patients who received at least 1 dose of Columvi and had previously received CAR T-cell therapy, the overall response rate was 55% and median survival without further spread of the cancer was 6.8 months.

Precautions, undesirable effects, & risks

Columvi must not be used in those who are hypersensitive to the active substance or any of the excipients.

Columvi may cause serious or life-threatening reactions such as cytokine release syndrome and neurological toxicity including

[5] CRS: Cytokine release syndrome is a systemic inflammatory response to the massive secretion of cytokines (proteins), which activate the white blood cells.

immune effector cell-associated neurotoxicity syndrome (ICANS)[6].

All precautions, risks, and other possible undesirable effects are listed in the Information for healthcare professionals.

Why the medicinal product has been authorised

The study showed that patients with relapsed or refractory DLBCL who received Columvi benefited from the treatment. The study was able to demonstrate that Columvi delayed the progression of DLBCL.

The efficacy of Columvi in patients who had previously received at least 2 lines of systemic therapy and CAR T-cell therapy is therefore very promising. However, additional data are required, including for further parameters, to confirm the results.

The medicinal product Columvi was authorised temporarily in Switzerland (in accordance with Art. 9a TPA) since not all clinical trials were available or had been concluded at the time of authorisation.

The temporary authorisation is contingent on the timely submission of the data requested by Swissmedic. Once these authorisation conditions have been met, the temporary authorisation can be converted into an ordinary authorisation in the event of a positive benefit-risk assessment of the results.

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals Columvi®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Public Summary SwissPAR.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.

[6] ICANS: Immune effector cell-associated neurotoxicity syndrome is a complex of diverse neurological symptoms of varying intensity, such as impaired consciousness.