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Media and Public Relations

Press release

New treatment for patients with soft tissue sarcoma

Lartruvo recommended for conditional approval

The European Medicines Agency (EMA) has recommended granting a conditional marketing authorisation to Lartruvo (olaratumab) for the treatment of adults with soft tissue sarcoma, a rare type of cancer. Lartruvo is to be used in combination with doxorubicin (a chemotherapy medicine) in patients with advanced soft tissue sarcoma for whom surgery or radiotherapy is not suitable, and who have not been previously treated with doxorubicin.

Lartruvo is a monoclonal antibody, a type of protein that has been designed to recognise and attach to a protein called platelet-derived growth factor receptor alpha (PDGFRα). In soft tissue sarcoma this protein is present in high levels or is overactive, causing cells to become cancerous. When Lartruvo attaches to PDGFRα on sarcoma cells, it blocks its activity, thereby slowing down the growth of the cancer.

Soft tissue sarcoma can occur in muscles, blood vessels, fat tissue or in other tissues that support, surround and protect the organs. It is a long-term debilitating and life-threatening disease, particularly when the cancer has spread to other parts of the body. It has a high mortality rate and accounts for approximately 2% of all cancer-related deaths.

The most common treatment for soft tissue sarcoma in the early stages is surgery. In some instances, surgery is followed by radiotherapy and chemotherapy to kill any cancerous cells that are left behind. 40-60% of patients with soft tissue sarcoma will be in an advanced stage of the disease. Only half of these patients live longer than five years under currently available treatment and this prognosis has not improved over the last forty years. Therefore new medicines are needed for patients.

The Committee for Medicinal Products for Human Use (CHMP) reviewed Lartruvo under EMA's accelerated assessment program and recommended conditional approval for the medicine. These are two of the Agency's most important mechanisms to facilitate early access to medicines that fulfil unmet medical need. Conditional approval allows EMA to recommend a medicine for marketing authorisation in the interest of public health where the benefit of its immediate availability to patients outweighs the risk inherent in the fact that additional data are still required.

The recommendation from the CHMP is based on the results of a Phase II study in patients with advanced soft tissue sarcoma who had not been previously treated with doxorubicin. The study showed

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a significant improvement in the time patients survived with a combination of doxorubicin plus Lartruvo compared to doxorubicin alone (a median gain of 11.8 months).

The most common side effects of Lartruvo were nausea, musculoskeletal pain, neutropenia (low counts of infection-fighting white blood cells) and mucositis (inflammation and ulceration of the mucous membranes lining the digestive tract).

As part of the conditional marketing authorisation, the applicant for Lartruvo must provide results from an ongoing Phase III study in order to confirm the previous results. The study compares how long patients receiving doxorubicin plus Lartruvo survive compared with patients who only receive doxorubicin. The study is ongoing and the data will be provided by the applicant. The CHMP will review the benefits and risks of Lartruvo annually to determine whether the conditional marketing authorisation can be maintained until full data are available.

Because soft tissue sarcoma is rare, Lartruvo received an orphan designation from the Committee for Orphan Medicinal Products (COMP) in 2015. Orphan designation is the key instrument available in the European Union (EU) to encourage the development of medicines for patients with rare diseases. Orphan-designated medicines qualify for ten years' market exclusivity. In addition orphan designation gives medicine developers access to incentives, such as fee reductions for marketing authorisation applications and for scientific advice.

The applicant received scientific advice from the CHMP on clinical aspects of the dossier.

The opinion adopted by the CHMP at its September 2016 meeting is an intermediary step on Lartuvo's path to patient access. The CHMP opinion will now be sent to the European Commission for the adoption of a decision on an EU-wide marketing authorisation. Once a marketing authorisation has been granted, a decision on price and reimbursement will then take place at the level of each Member State considering the potential role/use of the medicine in the context of the national health system of that country.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The applicant for Lartruvo is Eli Lilly Nederland B.V.
3. Following this positive CHMP opinion, the COMP will assess whether the orphan designation should be maintained.
4. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

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