16 September 2016
EMA/CHMP/608772/2016
Media and Public Relations

Press release

New treatment for breast cancer

Ibrance provides novel treatment option for women with advanced or metastatic disease

The European Medicines Agency (EMA) has recommended granting a marketing authorisation in the European Union (EU) for Ibrance for the treatment of women with locally advanced or metastatic breast cancer. It is to be used for cancer that is hormone receptor (HR) positive and human epidermal growth factor receptor 2 (HER2) negative.

Breast cancer is the most common cancer in women worldwide, with nearly 1.7 million new cases diagnosed in 2012. In Europe, there were an estimated 464,000 new cases of breast cancer in 2012 and an estimated 131,000 deaths from the disease. Hormone receptor positive breast cancer accounts for 65% of tumours in women aged 35 to 65 years and 82% of tumours in women older than 65 years.

Ibrance (palbociclib) works by blocking the activity of proteins known as cyclin-dependent kinases (CDK) 4 and 6. This inhibits the division of cancer cells and helps to stop growth of the tumour.

In postmenopausal women, Ibrance is to be used in combination with an aromatase inhibitor or with fulvestrant in cases where the patient has undergone prior hormone therapy. For women in stages preceding menopause, the hormone therapy should be combined with a luteinizing hormone releasing hormone (LHRH).

The recommendation from EMA's Committee for Medicinal Products for Human Use (CHMP) is based on two main studies. One is a Phase III trial comparing treatment with palbociclib and letrozole, an aromatase inhibitor, with letrozole treatment alone. 444 patients who received palbociclib in this trial lived on average 24.8 months without their disease getting worse, compared to 14.5 months in the group of 222 patients that received letrozole alone.

The other study is a Phase III trial which compared treatment of fulvestrant together with palbociclib to treatment with only fulvestrant. 521 women were enrolled in this trial, regardless of their menopausal status. Preliminary results showed that 347 patients who received palbociclib had an average of 11.2 months without their disease getting worse compared to 4.6 months for 174 patients who only received fulvestrant.

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

An agency of the European Union

© European Medicines Agency, 2016. Reproduction is authorised provided the source is acknowledged.

The most frequently reported side effects are associated with myelosuppression, a condition in which the patient's bone marrow produces fewer blood cells than normal. Other side effects included infections, fatigue, nausea and vomiting, inflammation of the lining of the mouth (stomatitis), diarrhoea and hair loss (alopecia).

The opinion adopted by the CHMP at its September 2016 meeting is an intermediary step on Ibrance'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 about 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 Ibrance is Pfizer Limited.
3. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officer

Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News