EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Press Office

Press release

European Medicines Agency recommends approval of pomalidomide for the treatment of multiple myeloma

CHMP recommends measures to minimise risk of exposure to unborn babies

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has recommended marketing authorisation for Pomalidomide Celgene (pomalidomide) to treat patients with multiple myeloma.

Multiple myeloma is a rare and incurable cancer of the bone marrow that primarily affects older adults. In Europe, approximately 27,800 new cases are diagnosed each year.

The CHMP concluded that the benefits of Pomalidomide Celgene in combination with dexamethasone, an anti-inflammatory medicine, outweigh its risks in patients who have received at least two prior therapies, including both lenalidomide and bortezomib, and whose disease progressed after treatment with these medicines. This group of patients has very limited treatment options.

Pomalidomide is a new active substance. When used in combination with dexamethasone it stimulates the patient's immune system to attack cancerous cells and stops the formation of blood vessels supplying these cells.

Pomalidomide has a chemical structure that resembles that of thalidomide, a substance that led to the birth of babies with malformed, short or missing limbs, and other severe, life-threatening deformities in the late 1950s and early 1960s. At that time it was used as a sleeping pill and a treatment for morning sickness. Thalidomide was banned in 1962. In 2008, thalidomide was re-introduced to the European Union (EU) market, with risk-minimisation measures, as a treatment for multiple myeloma, following extensive consultation with representatives of patients and thalidomide stakeholder organisations.

Optimising the benefit-risk balance

Pomalidomide is expected to have a similar teratogenic profile to that of thalidomide. Because of this, during the assessment of Pomalidomide Celgene, the CHMP consulted representatives of patients and thalidomide stakeholder organisations from across the EU to develop measures to effectively minimise foetal exposure to the medicine.

The CHMP has approved a risk-management plan that includes a number of actions intended to prevent pregnancies in women being treated with Pomalidomide Celgene and exposure of unborn

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children to the medicine. For example, all women of child-bearing potential who are treated with the medicine must undergo pregnancy tests before, during and after treatment, in addition to using selected and effective contraception.

Before the medicine can be marketed, the marketing-authorisation holder should put a programme in place to inform doctors and pharmacists about special measures they will need to take when prescribing and dispensing Pomalidomide Celgene. An information pack will be available for doctors prescribing the medicine, and treatment will only be initiated under the supervision of doctors who have experience in the treatment of multiple myeloma.

Educational brochures and patient cards will also be provided to patients. In addition, a clear warning will be printed on boxes containing the medicine, indicating that Pomalidomide Celgene carries a risk of severe birth defects.

The marketing-authorisation holder is also required to implement a pregnancy prevention programme (PPP) in each Member State. A post-authorisation registry study of patients treated with the medicine will be conducted to monitor the incidence of any adverse effects of the medicine and the implementation of the PPP.

The CHMP opinion on Pomalidomide Celgene will now be sent to the European Commission for adoption of a marketing-authorisation decision.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. Pomalidomide Celgene was designated as an orphan medicinal product in October 2009 because it is intended to treat a rare disease or condition.
3. The marketing-authorisation applicant for Pomalidomide Celgene is Celgene Europe Limited.
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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