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Pomalidomide Celgene gets EU nod for multiple myeloma

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

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.

Pomalidomide when used in combination with dexamethasone 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. 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 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.