

Pomalidomide (Pomalidomide Celgene/Pomalyst®) for the 3rd-line therapy of patients with relapsed and refractory multiple myeloma
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Pomalidomide, an analogue of thalidomide, is a new immunomodulatory antineoplastic agent. It was licensed in Europe in August 2013 in combination with dexamethasone for the treatment of adult patients with relapsed and refractory multiple myeloma (MM) who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy. Since few therapeutic options exist for heavily pre-treated patients who -despite undergoing established therapies- have relapsed and refractory MM, new treatments are needed for this indication.

In the U.S., pomalidomide was licensed under the accelerated approval regulations based on the results of two phase II studies, whereas EMA's decision rested already on a phase III study. This phase III study comprised overall 455 patients and compared pomalidomide in combination with low dose dexamethasone with high dose dexamethasone. Progression-free survival, the primary study outcome, was prolonged by 2.1 months for patients treated with pomalidomide in comparison with the control group. Improved results were also found for overall survival, overall response rate and preliminary results for quality-of-life also indicated improvements for these patients.

Since therapy for MM is currently undergoing substantial changes, questions as to the optimal sequences and combination of regimens are raised. Also, long-term data on safety are needed to better characterise the role of pomalidomide for the treatment of MM.

The full English version is available

under

http://eprints.hta.lbg.ac.at/1010/1/DSD_HSO_Nr.39.pdf