

EU approval for Roche's cervical cancer drug

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Roche has announced that the European Commission (EU) has approved Avastin (bevacizumab) in combination with standard chemotherapy (paclitaxel and cisplatin or, alternatively, paclitaxel and topotecan in patients who cannot receive platinum therapy) for the treatment of adult patients with persistent, recurrent or metastatic carcinoma of the cervix.

Avastin's EU approval in persistent, recurrent or metastatic carcinoma of the cervix is an important development in a disease area where, until now, treatment options were limited to chemotherapy.

"We are pleased that women in Europe now have a much needed new treatment option that is proven to help them live longer lives compared to chemotherapy alone," said Dr Sandra Horning, chief medical officer and head of global product development. "Currently, fewer than one in six women with this disease are alive five years after diagnosis. Avastin's approval is a welcome advance for women with persistent, recurrent or metastatic carcinoma of the cervix".

The EU approval was based on the significant survival benefit in the pivotal GOG-0240 study, which showed that women who received Avastin plus chemotherapy had a statistically significant 26 percent reduction in the risk of death, representing a median improvement in survival of nearly four months, compared to women who received chemotherapy alone (median overall survival: 16.8 months vs. 12.9 months; Hazard Ratio (HR)=0.74, p=0.0132).

Also based on the GOG-0240 data, Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan chemotherapy was approved in the US in August 2014, in Switzerland in December 2014, and in six other countries worldwide, for the treatment of women with persistent, recurrent or metastatic carcinoma of the cervix.