

Basel, 29 July 2009

## **European commission approves broader label for Avastin allowing combination with docetaxel for the first-line treatment of advanced (metastatic) breast cancer**

### **Physicians will be able to offer more patients Avastin-based treatment options**

More patients with advanced breast cancer could benefit from Avastin as a result of a broader label allowing Avastin to be combined with both docetaxel or paclitaxel chemotherapy, Roche announced today. In March 2007, Avastin was approved in Europe for the first-line treatment of patients with advanced breast cancer, in combination with paclitaxel. This broader label, approved today by the European Commission, means Avastin can also be combined with docetaxel, another commonly used chemotherapy, giving both patients and physicians more Avastin based therapy options. The standard dose of Avastin for the treatment of metastatic breast cancer remains at 10 mg/kg every 2 weeks or 15 mg/kg every 3 weeks.

'Avastin is changing the way cancer is treated, and it has already demonstrated significant benefits across multiple tumour types including breast cancer,' said William M. Burns, CEO of Roche's Pharmaceuticals Division. 'This approval is positive news as more patients with advanced breast cancer could benefit from Avastin since physicians will now have more treatment options.'

Despite the treatment improvements that have already been made, breast cancer continues to be the leading cause of cancer death in women under age of 55 and more than one million women are diagnosed each year, this leading to more than 500,000 deaths from the disease worldwide.<sup>1,2</sup>

### **About AVADO (BO17708)**

AVADO is an international phase III trial where 736 patients who did not receive previous chemotherapy for their metastatic breast cancer were randomised to one of three treatment groups:

- Avastin 15 mg/kg every 3 weeks in combination with docetaxel 100 mg/m<sup>2</sup>
- Avastin 7.5 mg/kg every 3 weeks in combination with docetaxel 100 mg/m<sup>2</sup>
- Placebo in combination with docetaxel 100 mg/m<sup>2</sup> as control arm

The primary objective of the study was to demonstrate superiority in progression free survival in one or both

of Avastin containing treatment arms compared to the control arm. Secondary endpoints for the study included response rate, duration of response, time to treatment failure, overall survival, 1-year survival, quality of life, safety and tolerability. Based on the updated analysis the combination of Avastin and docetaxel resulted in:

- Up to 49% increase in patient's chance of being alive without their disease progressing ('progression free survival') when treated with Avastin plus docetaxel compared to docetaxel alone.
- Over half the patients were alive without their disease progressing for more than 10 months when treated with Avastin plus docetaxel.
- In the 1-year survival analysis there were significantly more patients alive when treated with Avastin + docetaxel (84%) compared to docetaxel (76%).
- Overall survival data, reflecting ~ 45% of events, show no difference between the treatment arms.
- Up to two thirds of patients (64%) receiving Avastin based therapy experienced major shrinkage in their tumour.
- No new safety signals, confirming the safety and tolerability profile seen in previous studies. Furthermore, Avastin had only a limited impact on the known toxicity profile of docetaxel.

### **About Avastin**

Avastin is an antibody that specifically binds and blocks VEGF (vascular endothelial growth factor). VEGF is the key driver of tumour angiogenesis – an essential process of development and maintenance of blood vessels which is required for a tumour to grow and to spread (metastasize) to other parts of the body. Avastin's precise mode of action helps control tumour growth and metastases with only a limited impact on side effects of chemotherapy.

Avastin has proven survival benefits across multiple tumour types. Avastin is approved in Europe for the treatment of the advanced stages of four common types of cancer: colorectal cancer, breast cancer, non-small cell lung cancer and kidney cancer. These types of cancer collectively cause nearly 3 million deaths each year. In the US, Avastin was the first anti-angiogenesis therapy approved by the FDA and is now approved for the treatment of four tumour types: breast, colorectal, glioblastoma, and non-small cell lung cancer (NSCLC).

More than 500,000 patients have been treated with Avastin so far. A comprehensive clinical programme with more than 450 clinical trials is investigating the use of Avastin in various tumour types (including colorectal, breast, lung, brain, gastric, ovarian, prostate and others) and different settings (advanced or early stage disease).

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## **Roche Group Media Relations**

Phone: +41 -61 688 8888 / e-mail: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)

- Daniel Piller (Head)
- Alexander Klauser
- Martina Rupp
- Claudia Schmitt
- Nina Schwab-Hautzinger

## **References**

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2. WHO Cancer Factsheet N° 297 – updated July 2008. Last accessed 24 March 2009 at <http://www.who.int/mediacentre/factsheets/fs297/en/index.html>