

Basel, 3 August 2009

Avastin approved in US for the most common type of kidney cancer

Roche today announced that the U.S. Food and Drug Administration (FDA) has approved Avastin (bevacizumab) plus interferon alpha for people with metastatic renal cell carcinoma, the most common type of kidney cancer. According to the American Cancer Society, kidney cancer is the eighth most commonly diagnosed cancer in the United States. In 2009, approximately 13,000 Americans will die from the disease.

Commenting on the approval, William M. Burns, CEO of Roche's Pharmaceuticals Division said, "Avastin has now been approved for five different types of cancer in the USA. This underscores our belief in the important clinical benefits that Avastin delivers as we push forward with our ongoing research programs in more than 30 tumour types."

The FDA approval is based on data from the pivotal phase III study (AVOREN) in patients with advanced, previously untreated metastatic renal cell carcinoma. The study showed that patients who received Avastin plus interferon alpha lived nearly twice as long without their disease getting worse compared to those who received interferon alpha alone; 10.2 months versus 5.4 months respectively.

Avastin is designed to block the vascular endothelial growth factor (VEGF) protein to address a key underlying cause of cancer growth. Avastin works differently than other approved medicines for renal cell carcinoma because it specifically binds to the VEGF protein, which is produced in elevated amounts in most kidney cancers.

"We hope that researchers someday find a cure for kidney cancer," said William P. Bro, chief executive officer of the Kidney Cancer Association. "Until then, each new medicine, like Avastin, offers patients an opportunity to find a treatment best suited for them."

In Europe, Avastin has been available since the end of 2007 for the first-line treatment of patients with advanced and/or metastatic renal cell cancer in combination with interferon alpha.

Kidney cancer is the uncontrolled growth of cancerous cells that originate in the kidneys with no known cause. Nine out of ten people with kidney cancer have renal cell carcinoma.

Avastin in Metastatic Kidney Cancer

This FDA approval is based on data from a global, randomised, double-blind, placebo-controlled Phase III study (AVOREN) of 649 patients with previously untreated metastatic renal cell carcinoma. The study showed patients who received Avastin plus interferon alpha had a 67% increase in the time patients lived without their disease worsening (progression-free survival or PFS), compared to those who received interferon alpha alone (hazard ratio=0.60, 95% CI=0.49, 0.72). In AVOREN median PFS was 10.2 months for patients who received Avastin plus interferon alpha compared to 5.4 months for patients who received interferon alpha alone corresponding to an 89% improvement in median PFS.

The study was originally designed to measure an improvement in overall survival (OS). However, in prior consultation with the U.S. FDA and European regulatory authorities, the PFS endpoint was accepted as the basis for regulatory approval.

Secondary analysis endpoints included objective response rate and OS. In this study, tumour size decreased in 30% of patients in the Avastin plus interferon alpha group, compared to 12% of patients who received interferon alpha alone. There was no improvement in overall survival based on the final analysis after 444 deaths, with a median overall survival of 23 months in the Avastin plus interferon alpha arm and 21 months in the interferon alpha plus placebo arm (hazard ratio=0.86, 95% CI=0.72 , 1.04).

Adverse events in this study were consistent with those previously reported for Avastin or interferon alpha.

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 (NSCLC) 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 five tumour types: colorectal cancer, non-small cell lung cancer, breast cancer, glioblastoma, and renal cell carcinoma.

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 cancers and others) and different settings (advanced or early stage disease).

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2008, Roche had over 80'000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com.

All trademarks used or mentioned in this release are protected by law.

Roche Group Media Relations

Phone: +41 -61 688 8888 / e-mail: basel.mediaoffice@roche.com

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