

Avastin Receives Positive Opinion in Europe for First-Line Treatment of Patients With Advanced Kidney Cancer

Basel, Switzerland, November 16 (ots/PRNewswire) -

- Avastin Offers Patients the Chance to Live Twice as Long Without Their Disease Advancing

Roche announced today that the European Committee for Medicinal Products for Human Use (CHMP) has issued a positive recommendation for Avastin (bevacizumab) for the first-line treatment of patients with the most common form of advanced kidney cancer, renal cell carcinoma (RCC)(1). The CHMP's decision is based on data from the pivotal phase III AVOREN trial, which showed that adding Avastin to interferon gave patients with advanced RCC the chance to live twice as long without their disease progressing ("progression free survival") compared with interferon (IFN) alone.

"The AVOREN study has shown us that Avastin is an effective and safe treatment for patients with kidney cancer," said Professor Bernard Escudier, Head of Immunotherapy and Innovative Therapy Unit, Institut Gustave-Roussy, Paris, France and Principal Investigator of the pivotal AVOREN study. "This announcement is very significant because this drug offers new therapeutic options in advanced kidney cancer, where chemotherapy and radiotherapy are not as effective as in other cancers."

On an annual basis, in excess of 200,000 people worldwide will receive a diagnosis of kidney cancer and more than 100,000 people worldwide will lose their lives to the disease(i). These figures can be expected to increase as the number of people suffering from cancer in general rises by 50%, as recently estimated by the WHO(ii).

Avastin Approval Status

Kidney cancer is the fourth cancer type in which Avastin has demonstrated survival benefits. Data from the comprehensive Avastin cancer clinical development programme have resulted in approvals in colorectal, breast, and lung:

- February 2004 (US) and January 2005 (EU) - first-line

treatment in patients with metastatic colorectal cancer

- June 2006 (US) - second-line treatment in patients with metastatic colorectal cancer

- October 2006 (US) - first-line treatment in patients with advanced non-small cell lung cancer (NSCLC)

- March 2007 (EU) - first-line treatment in patients with metastatic breast cancer

- April 2007 (Japan) - recurrent or advanced treatment in patients with advanced colorectal cancer

- August 2007 (EU) - first-line treatment in patients with advanced NSCLC

About the AVOREN Study

The AVOREN study is a randomised, controlled, double-blind phase III study that included 649 patients from 101 study sites across 18 countries. In the study patients received treatment with either Avastin and interferon alpha-2a or placebo and interferon alpha-2a, a standard of care in advanced kidney cancer.

The results of the AVOREN trial showed that by adding Avastin to IFN (a current standard of care):

- Progression free survival was almost doubled from a median of 5.4 to 10.2 months

- Tumour response was significantly increased from 12.8% with interferon alone to 31.4% when Avastin was added

- Dose-reduction of IFN did not appear to affect the efficacy of the combination of Avastin (based on PFS event free rates over time, as shown by a sub-group analysis)

The study also showed a trend towards improved overall survival; however, the survival data are still pending. No new or unexpected adverse events were observed.

An interim analysis of AVOREN was performed in December 2006 and

the benefits provided by Avastin were so positive that the Drug Safety Monitoring Board (DSMB) recommended that the trial was unblinded and all patients were offered treatment with Avastin. The study demonstrated, for the first time that Avastin also benefits patients in combination with an immunotherapeutic, the class of drugs to which IFN belongs.

About Kidney Cancer

Kidney cancer is more common in men than women (approximately 62% of patients with RCC are male) and incidence increases with age(i).

As the most common type of kidney cancer, RCC accounts for nine out of ten cases of the disease. Within this cancer type, there are several sub-types of cancer based on looking at the cells under a microscope. Clear cell renal cell cancer is the most common type. If RCC is diagnosed at an early stage when the cancer is still confined to the kidney, the 5 year survival rates are relatively good at 60 to 75%. However, if diagnosis is made at a later stage and the cancer has already spread to distant sites the 5 year survival rate is less than 5%(iii). Unfortunately, because kidney cancer is often asymptomatic, the majority of patients are diagnosed at later disease stages.

Treatment options for patients with kidney cancer are limited. Surgical removal of part or the entire kidney forms the mainstay of treatment but is only really successful in early stage disease. In later stage disease, treatment is more often employed with a view of controlling the cancer and improving associated symptoms.

Additional information

- Roche in Oncology:

http://www.roche.com/pages/downloads/company/pdf/mboncology05e_b.pdf

- Roche Health Kiosk, Cancer:

http://www.health-kiosk.ch/start_krebs

- Avastin: <http://www.avastin-info.com>

(1) The positive opinion is for the use of Avastin in patients

with advanced clear cell RCC in combination with interferon, the current standard of care.

(i) Parkin DM, Bray F, Ferlay J and Pisani P. Global cancer statistics 2002. CA Cancer J Clin 2005; 55; 74 - 108.

(ii) WHO Information sheet on cancer
<http://www.who.int/dietphysicalactivity/publications/facts/cancer/en/>
(accessed 24 May 2007)

(iii) Medline Plus
<http://www.nlm.nih.gov/medlineplus/ency/article/000516.htm#Causes,%20incidence,%20and%20risk%20factors> (accessed 15 August 2007) (copy and paste this URL into your browser)

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