

Avastin plus commonly used chemotherapies improves the time breast cancer patients live without their disease getting worse

RIBBON-1 study confirms benefit of Avastin in treating HER2-negative breast cancer

Basel, 29 May 2009 - Results from the phase III RIBBON-1 study presented today at ASCO showed that patients with advanced HER2-negative breast cancer who were treated with Avastin® (bevacizumab) plus the most commonly used chemotherapies lived longer without their disease worsening (progression free survival or PFS), compared to those being treated with chemotherapies alone. RIBBON-1 confirms that Avastin can be safely and effectively combined with a range of chemotherapies for first line treatment of HER2-negative metastatic breast cancer, offering patients and physicians more treatment options.

This is the first study to show clinical benefit for patients when combining Avastin with an anthracycline-containing regimen and Xeloda® (capecitabine), and the third trial (following E2100 and AVADO) to confirm the efficacy and safety of Avastin in combination with standard chemotherapies for the treatment of advanced breast cancer in the first line setting.

Key results from RIBBON-1 included:

- Up to 55% increase in the chance of the patient living without the disease getting worse.
- A significant increase in tumour shrinkage in patients that received Avastin (response rate = 51% vs. 37.9% for Avastin + anthracycline or taxane chemotherapy vs. chemotherapy alone).
- There were no new safety signals for Avastin in RIBBON-1, confirming the safety and tolerability profile seen in previous studies.

‘These results are further proof that Avastin based therapy is part of the armamentarium of treatment for patients with advanced breast cancer’ said Dr Nicholas Robert, M.D, Co-chair Breast Cancer Research Committee, U.S. Oncology, Inc., investigator of the RIBBON-1 study. ‘The growing body of evidence supporting the combination of Avastin with commonly used chemotherapy regimens, gives physicians more flexibility to tailor the most appropriate course of Avastin based therapy for their patients.’

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

About the RIBBON-1 study

RIBBON-1 is a global double blind, placebo-controlled, randomised phase III trial including 1,237 patients who did not receive previous chemotherapy for their HER2-negative locally recurrent or metastatic breast cancer.

- The primary objective of RIBBON-1 was to demonstrate superiority in PFS of Avastin containing treatment arms compared to the control arms.
- Secondary endpoints for the study included independently reviewed PFS, response rate, overall survival, 1-year survival, safety and tolerability.

RIBBON-1 comprised of two independently powered treatment groups investigating either Avastin or placebo in combination with 7 distinct chemotherapy regimens:

- Taxanes - docetaxel or protein bound paclitaxel
- Anthracyclines - doxorubicin- or epirubicin-based regimen

Standard anthracycline-based regimens included the following:

- FEC (Fluorouracil (5FU), epirubicin and cyclophosphamide),
- EC (epirubicin and cyclophosphamide),
- AC (doxorubicin and cyclophosphamide),
- FAC (Fluorouracil (5FU), doxorubicin and cyclophosphamide)
- Xeloda (capecitabine)

Avastin yielded superior PFS in both treatment groups.

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 (metastasise) 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, 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).

About Xeloda (capecitabine)

Xeloda, capecitabine, is a highly effective targeted oral chemotherapy offering patients a survival advantage when taken on its own or in combination with other anticancer drugs. Xeloda uniquely activates the cancer-killing agent 5-FU (5-fluorouracil) directly inside the cancer cells so avoiding damage to healthy cells. Xeloda tablets can be taken by patients in their own home, reducing the number of hospital visits.

Licensed and marketed by Roche in more than 100 countries worldwide, Xeloda has more than ten years of proven clinical experience providing an effective and flexible treatment option to over 1.8 million people with cancer. Xeloda is currently approved in metastatic colorectal cancer, metastatic breast cancer, adjuvant colon cancer, advanced gastric cancer, metastatic pancreatic cancer.

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For more information please contact:

Irina Berechet
Roche
+41 79 865 98 50

Dominic Elliston
Galliard Healthcare
+44 7717 502 860

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