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Roche

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Study of Avastin in combination with standard chemotherapy, followed by continued use of Avastin,met primary endpoint of improving progression-free survival in women with ovarian cancer

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that a second large, phase III, international study showed that the combination of Avastin (bevacizumab) and chemotherapy followed by the continued use of Avastin alone, increased the time women with previously untreated ovarian cancer lived without the disease worsening (progression-free survival or PFS, the primary endpoint), compared to chemotherapy alone. Adverse events were consistent with those observed in pivotal trials of Avastin. Data from the study, known as ICON7, will be submitted for presentation at an upcoming medical meeting.

â??With few advances in ovarian cancer and a need to improve outcomes for women with this disease, it is encouraging that a second phase III study showed that Avastin in combination with chemotherapy followed by the continued use of Avastin alone helped women live longer without their disease getting worse,â? said Hal Barron, M.D., executive vice-president Global Development and Chief Medical Officer for Roche. â??ICON7 is part of our continued commitment to understand the full potential of Avastin in ovarian cancer which includes several phase III studies in combination with other agents and in various stages of the disease.â?

The ICON7 study is sponsored by the Medical Research Council (MRC) in the United Kingdom, led by the MRC Clinical Trials Unit and conducted through an international network of researchers in the Gynaecologic Cancer InterGroup (GCIG). In the study, 1,528 women with newly diagnosed ovarian cancer who had already had surgery were randomised to receive one of the following:

- ARM 1: Chemotherapy (carboplatin and paclitaxel) for 6 cycles

- ARM 2: Avastin (7.5mg/kg every three weeks) in combination with chemotherapy (carboplatin and paclitaxel) for 6 cycles followed by Avastin alone (for a total of 18 cycles, up to 12 months)

Another phase III study of Avastin (known as GOG 0218) in women with previously untreated advanced ovarian cancer presented in June at ASCO also met its primary endpoint of progression-free survival, or PFS. The GOG 0218 study used an Avastin dose of 15mg/kg (every three weeks) in combination with carboplatin and paclitaxel, followed by the continued use of Avastin alone for a total duration of up to 15 months. In ICON7 the majority of patients had advanced stage ovarian cancer, however the trial also included patients with earlier stage disease. The ICON7 study used an Avastin dose of 7.5mg/kg (every three weeks) in combination with the same chemotherapy regimen, followed by the continued use of Avastin alone for a total duration of up to 12 months.

About the ICON7 study

ICON7 is an international, multicenter, randomised, open-label, phase III study in 1,528 women with previously untreated epithelial ovarian, primary peritoneal or fallopian tube carcinoma. The trial evaluates Avastin plus standard of care chemotherapy (carboplatin and paclitaxel) followed by the continued use of Avastin alone, compared to chemotherapy alone.

The primary endpoint of the study is PFS as assessed by trial investigators. Secondary endpoints of the study include overall survival, response rate, duration of response, quality of life and safety.

About ovarian cancer

Ovarian cancer is the sixth most commonly diagnosed cancer in women and the eighth leading cause of cancer death among women worldwide. Annually, an estimated 230,000 women will be diagnosed with ovarian cancer around the world and approximately 140,000 will die from the disease[1]. Currently, treatment options for women with this disease are limited to surgery, and chemotherapy. Ovarian cancer is associated with high concentrations of vascular endothelial growth factor (VEGF), a protein associated with tumour growth and spread. Studies have shown a correlation between a high concentration of VEGF and a poorer prognosis in women with ovarian cancer.

About Avastin: Over 5 Years of Transforming Cancer Care

With the initial approval in the USA for advanced colorectal cancer in 2004, Avastin became the first anti-angiogenic therapy made widely available for the treatment of patients with an advanced cancer.

Today, Avastin is continuing to transform cancer care through its proven survival benefit (overall survival and/or progression free survival) across several types of

cancer. Avastin is approved in the US and Europe for the treatment of advanced stages of colorectal cancer, breast cancer, non-small cell lung cancer and kidney cancer, and Avastin is also available in the US and 24 other countries for the treatment of patients with glioblastoma (advanced brain cancer). Avastin is the only anti-angiogenic therapy available for the treatment of these numerous advanced cancer types, which collectively cause over 2.5 million deaths each year.

Avastin has made anti-angiogenic therapy a fundamental pillar of cancer treatment today â?" over three quarters of a million patients have been treated with Avastin so far. A comprehensive clinical programme with more than 500 ongoing clinical trials is investigating the use of Avastin in over 50 tumour types (including colorectal, breast, non-small cell lung, brain, gastric, ovarian and others) and different settings (advanced or early stage disease).

About Avastin: Mode of Action

Avastin is an antibody that specifically binds and blocks the biological effects of VEGF (vascular endothelial growth factor). VEGF is the key driver of tumour angiogenesis â?" a fundamental process required for a tumour to grow and to spread (metastasise) to other parts of the body. Avastinâ??s precise mode of action allows it to be combined effectively with a broad range of chemotherapies and other anti-cancer treatments. Avastin helps to control tumour growth and extend survival with only a limited impact on the side effects of chemotherapy.

About the Medical Research Council

For almost 100 years the Medical Research Council has improved the health of people in the UK and around the world by supporting the highest quality science. The MRC invests in world-class scientists. It has produced 29 Nobel Prize winners and sustains a flourishing environment for internationally recognised research. The MRC focuses on making an impact and provides the financial muscle and scientific expertise behind medical breakthroughs, including the first antibiotic penicillin, the structure of DNA and the lethal link between smoking and cancer. Today MRC funded scientists tackle research into the major health challenges of the 21st century. www.mrc.ac.uk [1]

About GCIG

The Gynaecologic Cancer InterGroup (GCIG) is an organisation of representatives from international and national research groups performing clinical trials in gynaecological cancer. It aims to promote international collaboration on clinical research by performing high quality clinical trials.

GCIG groups who participated in ICON7 included:

- AGO-OVAR (Arbeitsgemeinschaft Gynaekologische Onkologie Studiengruppe

Ovarialkarzinom Germany)
- ANZGOG (Australia and New Zealand Gynecological Oncology Group)
- GINECO (Group dâ??Investigateurs Nationaux pour lâ??Etude des Cancers Ovariens)
- GEICO (Grupo Espanol de Investigacion en Cancer de Ovario)
- MRC/NCRI (Medical Research Council/National Cancer Research Institute)
- NCIC Clinical Trials Group (Canadian Cancer Society Research Institute)
- NSGO (Nordic Society of Gynecologic Oncology)

SOURCE [2]

Source URL (retrieved on *08/31/2014 - 12:49am*):
http://www.chem.info/news/2010/07/second-phase-iii-study-showed-avastin-containing-regimen-helped-women-ovarian-cancer-live-longer-without-their-disease-getting-worse?qt-recent_content=0

Links:
[1] http://www.mrc.ac.uk
[2] http://www.roche.com/media/media_releases/med-cor-2010-07-02.htm