Media Release

Basel, 29 April 2016

CHMP recommends EU approval for Roche's Avastin in combination with Tarceva for patients with a specific type of advanced lung cancer

Avastin plus Tarceva showed a substantial increase in the time patients live without their disease progressing compared to Tarceva alone

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Union's Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion for the use of Avastin® (bevacizumab) in combination with Tarceva® (erlotinib) for the first-line treatment of adult patients with unresectable advanced, metastatic or recurrent non-squamous non-small cell lung cancer (NSCLC) with Epidermal Growth Factor Receptor (EGFR) activating mutations. NSCLC is the most common type of lung cancer, the leading cause of cancer-related death in Europe and across the world.[1-3] Approximately 10-15 percent of Europeans with NSCLC will have tumours with EGFR-activating mutations, representing an estimated 33,000 cases in Europe per year or 90 every day.[1,3-5]

"Patients with EGFR mutated lung cancer who were treated with the combination of Avastin plus Tarceva lived significantly longer without their disease progressing compared to patients treated with Tarceva alone." said Sandra Horning, M.D., Chief Medical Officer and Global Head of Product Development. "We are delighted that this strategy of combining targeted medicines has improved patient outcomes. Today's CHMP opinion brings us one step closer to providing this combination therapy option to patients."

The EU filing was based primarily on data from the pivotal phase II JO25567 study.[6] In the study, patients who received Avastin plus Tarceva lived a median of 6.3 months longer without their disease progressing (progression-free survival, PFS) compared to those who received Tarceva alone.[6] This represents a statistically significant 46 percent relative reduction in the risk of disease progression or death (median PFS: 16.0 months versus 9.7 months; [HR]=0.54, p=0.0015), meaning the study met its primary endpoint.[6] Avastin and Tarceva each target pathways which are known to be key drivers in the growth and development of tumours, and the beneficial effect of Avastin plus Tarceva is supported by results of other clinical studies which showed the combination was effective and tolerable.[7,8]

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About the JO25567 study

JO25567 is a randomised phase II study conducted by Chugai that assessed the safety and efficacy of first-line Avastin in combination with Tarceva compared to Tarceva alone in Japanese patients with non-squamous NSCLC with EGFR-activating mutations. Study data from 154 patients showed:

- Patients who received Avastin plus Tarceva lived a median of 6.3 months longer without their disease progressing (progression-free survival, PFS) (primary endpoint) compared to those who received Tarceva alone, representing a statistically significant 46 percent reduction in the relative risk of disease progression or death (median PFS: 16.0 months versus 9.7 months; [HR]=0.54, p=0.0015).[6]
- No new and clinically significant adverse events were observed and the toxicity profile was shown to be managable.[6]

About Roche in lung cancer

Lung cancer is a major area of focus and investment for Roche, and we are committed to developing new approaches, medicines and tests that can help people with this deadly disease. At Roche we are aiming to provide effective treatment options for every person diagnosed with lung cancer. We currently have three approved medicines to treat certain kinds of lung cancer and more than ten medicines being developed to target the most common genetic drivers of lung cancer or to boost the immune system to combat the disease.

About NSCLC with EGFR-activating mutations

Lung cancer is the leading cause of cancer-related death in Europe and across the world.[1, 2] In Europe, it kills more people than breast and prostate cancers combined.[1] Each year, over a quarter of a million people die as a result of the disease, equating to more than 700 deaths every day in Europe.[1] NSCLC is the most common type of lung cancer and accounts for 85 percent of all lung cancer diagnoses.[3]

Epidermal Growth Factor Receptor (EGFR) is a protein that sits across the cell membrane and forms part of normal cell signalling. NSCLC with EGFR-activating mutations occurs when there is a mutation in a specific area of DNA in the EGFR gene (exon 19 and exon 21), which leads to a change in the structure and function of the EGFR proteins and results in EGFR signalling being constantly active. This can cause accelerated cell growth and division, development of metastases and angiogenesis. Approximately 10-15 percent of Europeans with NSCLC will have tumours with EGFR-activating mutations, representing an estimated 33,000 cases in Europe per year.[1,3-5]

About Avastin

With the initial approval in the United States 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 Europe for the treatment of advanced stages of breast cancer, colorectal cancer, non-small cell lung cancer, kidney cancer, ovarian cancer and cervical cancer, and is available in the United States for the treatment of colorectal cancer, non-small cell lung cancer, kidney cancer, cervical cancer and platinum-resistant, recurrent ovarian cancer. In addition, Avastin is approved in over 70 other countries worldwide for the treatment of patients with progressive glioblastoma following prior therapy. Avastin is approved in Japan for the treatment of the advanced stages of colorectal, non-small cell lung cancer, breast cancer, ovarian cancer and malignant glioma, including newly diagnosed glioblastoma.

Avastin has made anti-angiogenic therapy a fundamental pillar of cancer treatment today. Over two million patients have been treated with Avastin so far. A comprehensive clinical programme with more than 300 ongoing clinical trials is investigating the use of Avastin in over 50 tumour types.

About Tarceva

Tarceva is a once-daily, oral non-chemotherapy medicine for the treatment of advanced or metastatic NSCLC. It has been shown to inhibit EGFR, a protein involved in the growth and development of cancers. Tarceva is developed and commercialised by Astellas Pharma US in partnership with Genentech in the United States, Chugai in Japan and Roche in the rest of the world.

About Roche

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in *in vitro* diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. Twenty-nine medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Roche has been recognised as the Group Leader in sustainability within the Pharmaceuticals, Biotechnology & Life Sciences Industry seven years in a row by the Dow Jones Sustainability Indices.

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2015 employed more than 91,700 people worldwide. In 2015, Roche invested CHF 9.3 billion in R&D and posted sales of CHF 48.1 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

Additional information

- Roche in Oncology: www.roche.com/media/media_backgrounder/media_oncology.htm

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