Media release

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Subcutaneous formulation of Roche’s Herceptin approved in Switzerland for the treatment of HER2-positive breast cancer

Subcutaneous formulation reduces administration time to two to five minutes.

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that a new, subcutaneous formulation of Herceptin (trastuzumab) has been approved by the Swiss Therapeutic Products Agency (Swissmedic) for the treatment of HER2-positive breast cancer. The approval is for early stages of treatment. The treatment costs will be assumed by the health insurers.

“More than 800 women in Switzerland are diagnosed with HER2-positive breast cancer every year,” said Dr. Olivia Pagani from the Oncology Institute of Southern Switzerland in Bellinzona. “We are pleased that we can offer subcutaneous Herceptin to patients as a new and efficient treatment option that enables them to spend less time in hospital.”

Research shows that maintaining a normal life and spending time with friends and family can improve the wellbeing of women with breast cancer.\(^1\)\(^2\) The new formulation can reduce the amount of time needed to administer Herceptin to just a few minutes – rather than 30 to 90 minutes with the standard intravenous form.

About the pivotal studies

Swissmedic’s approval was largely based on data from the HannaH, SafeHER and PrefHER studies, which showed that the efficacy and safety of the subcutaneous formulation of Herceptin were comparable to treatment with Herceptin administered intravenously in women with HER2-positive breast cancer. The PrefHER study additionally showed that doctors as well as patients have a clear preference for the subcutaneous administration of Herceptin.
**About Herceptin**

Herceptin (trastuzumab) is a humanised monoclonal antibody designed to target and block the function of HER2, a protein on the cell surface with cancer-causing potential when it is overexpressed. The mode of action of Herceptin activates the body’s immune system and suppresses HER2 signalling to target and destroy the tumour. Herceptin has demonstrated efficacy in treating both early and advanced (metastatic) HER2-positive breast cancer. Given on its own as monotherapy, as well as in combination with or following standard chemotherapy, Herceptin has been shown to improve overall survival, response rates and disease-free survival in women with HER2-positive breast cancer.

Herceptin is marketed in the United States by Genentech, in Japan by Chugai and internationally by Roche. Since 1998, Herceptin has been used to treat more than 1.2 million women with HER2-positive breast cancer worldwide. Eligibility for Herceptin treatment is determined by a diagnostic test, saving time from the outset by identifying those patients who can derive benefit from this treatment.

The subcutaneous form of Herceptin is a ready-to-use liquid formulation that is administered as a 600 mg/5 ml fixed dose with a three-weekly regimen. This simplifies healthcare procedures by removing the need for reconstitution or dose calculation according to the patient’s body weight. Moreover, a loading dose is not required when using subcutaneous administration.

The subcutaneous formulation of Herceptin uses technology developed by Halozyme Therapeutics, Inc. (NASDAQ: HALO) that temporarily and reversibly degrades hyaluronan, making the tissue more permeable. This enables the 5 ml volume of the subcutaneous formulation of Herceptin to be rapidly dispersed and absorbed over a greater area.

**About breast cancer**

Breast cancer is the most common cancer among women worldwide.3 Every year, more than 5,000 new cases4 of breast cancer are diagnosed in Switzerland. In HER2-positive breast cancer, increased quantities of the human epidermal growth factor receptor 2 (HER2) are present on the surface of the tumour cells. This is known as “HER2 positivity” and affects approximately 15-20 percent of women with breast cancer.5 HER2-positive breast cancer is a particularly aggressive form of breast cancer.6
About Roche

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

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. Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims for improving patient access to medical innovations by working with all relevant stakeholders. 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 eight years in a row by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2016 employed more than 94,000 people worldwide. In 2016, Roche invested CHF 9.9 billion in R&D and posted sales of CHF 50.6 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.

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References