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Roche obtains license for EGFR lung cancer assays and will develop Tarceva companion diagnostic test

Molecular assay aims to enhance personalized treatment with Tarceva by detecting EGFR activating mutations

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that it has obtained a worldwide sublicense from Genzyme Corporation to develop a diagnostic assay for the detection of Epidermal Growth-Factor Receptor (EGFR) mutations. At the same time, Roche and OSI Pharmaceuticals, Inc. (OSI) have agreed to collaborate on the development of a PCR- based companion diagnostic test to identify people with non-small cell lung cancer (NSCLC) that harbors EGFR activating mutations.

“The companion diagnostic test will use Roche’s proprietary molecular diagnostics technology,” said Daniel O’Day, Head of Roche’s Diagnostic Division. “The aim is to provide a simple tool that will quickly identify EGFR activating mutations and so enhance physicians’ ability to customize the use of Tarceva for people with advanced NSCLC.”

Tarceva has clinically demonstrated a survival benefit in a broad range of patients with advanced NSCLC. However, tumours with EGFR activating mutations have been shown to be particularly sensitive to Tarceva. The identification of patients’ EGFR mutation status would allow physicians to personalize treatment.

Roche has applied to the European Medicines Agency to extend the current label for Tarceva to include the first-line treatment of patients with advanced NSCLC harboring EGFR activating mutations.

Tarceva is the only EGFR inhibitor approved by both the U.S. Food and Drug Administration and European Medicines Agency for use in maintenance and second-line treatment settings for the treatment of patients with advanced or metastatic NSCLC with and without EGFR activating mutations.

The EGFR mutation assay will run on Roche’s cobas 4800 System, currently approved for use in detecting infectious microorganisms such as human papillomavirus (HPV), chlamydia and gonorrhea. In addition to
testing for the EGFR mutation, Roche is exploring other oncology applications for the cobas 4800 platform.

Jon L. Hart, Senior Vice President and General Manager, Genzyme Genetics added: “We are very pleased to execute this license with Roche. By expanding our own reach globally for EGFR testing, we reinforce our commitment to furthering the role of diagnostics in the area of personalized medicine.”

“Roche and OSI’s extensive development and clinical experience with Tarceva, combined with Roche’s unparalleled experience in molecular assay development, provide an excellent platform to create a robust and valuable companion diagnostic program for NSCLC patients,” said Gabe Leung, President, Pharmaceutical Business of OSI Pharmaceuticals.

**About the cobas 4800 System (not available in the US)**

The cobas 4800 System is designed to deliver new standards in laboratory testing efficiency and medically relevant diagnostic information with increased testing throughput. The system combines state-of-the-art sample preparation with Roche’s proprietary real-time PCR technology for the amplification and detection of genetic material (deoxyribonucleic acid or DNA). The intuitive, easy-to-use software integrates sample preparation, amplification and detection, and results management.

**About Tarceva**

Tarceva is a once-a-day pill that targets the EGFR pathway. Tarceva is designed to inhibit the tyrosine kinase activity of the EGFR signaling pathway inside the cancer cell, one of the critical growth factors in NSCLC and pancreatic cancer. The way Tarceva works to treat cancer is not fully known.

Tarceva is prescribed for patients with advanced-stage NSCLC whose cancer has not grown or spread after initial treatment with certain types of chemotherapy. Tarceva is also prescribed for people with advanced-stage NSCLC whose cancer has grown or spread after receiving at least one chemotherapy regimen. Tarceva is not meant to be used at the same time as certain types of chemotherapy for NSCLC. In pancreatic cancer, Tarceva in combination with gemcitabine is prescribed for patients with advanced-stage pancreatic cancer whose cancer has spread, grown, or cannot be surgically removed, and who have not received previous chemotherapy.

The most common side effects in patients who took Tarceva for non-small cell lung cancer (NSCLC) were mild to moderate rash and diarrhea. The most common side effects in patients who took Tarceva plus
gemcitabine for pancreatic cancer were feeling tired, rash, nausea, loss of appetite and diarrhea.

For full prescribing information, please visit http://www.tarceva.com.

About Genzyme
One of the world's leading biotechnology companies, Genzyme is dedicated to making a major positive impact on the lives of people with serious diseases. Since 1981, the company has grown from a small start-up to a diversified enterprise with approximately 10,000 employees in locations spanning the globe and 2009 revenues of $4.5 billion. In 2010, Genzyme was named to the Fortune 500.

With many established products and services helping patients in 100 countries, Genzyme is a leader in the effort to develop and apply the most advanced technologies in the life sciences. The company's products and services are focused on rare inherited disorders, kidney disease, orthopaedics, cancer, transplant and immune disease. Genzyme's commitment to innovation continues today with a substantial development program focused on these fields, as well as cardiovascular disease, neurodegenerative diseases, and other areas of unmet medical need.

Genzyme's press releases and other company information are available at www.genzyme.com and by calling Genzyme's investor information line at 1-800-905-4369 within the United States or 1-678-999-4572 outside the United States.

About OSI Pharmaceuticals, Inc.
OSI Pharmaceuticals is committed to "shaping medicine and changing lives" by discovering, developing and commercializing high-quality, novel and differentiated targeted medicines designed to extend life and improve the quality of life for patients with cancer and diabetes/obesity.

In June, 2010, OSI Pharmaceuticals, Inc. became a wholly owned subsidiary of Astellas US Holding, Inc. which is part of the Astellas US group of companies (Astellas). For additional information about OSI, please visit http://www.osip.com.

About Roche
Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world’s largest biotech company with truly
differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche’s personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2009, Roche had over 80,000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com

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**References**

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