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## Roche Personalized Healthcare in Oncology

The ability to identify patient sub-groups and better understand disease mechanisms has ushered in an era of developing new diagnostic tools and targeted drugs for Roche. This is primarily due to the fact that there has been a dramatic increase in new biological targets resulting from insights of root causes of diseases at the molecular level made possible by new, sophisticated technologies offered over the past decade. In addition, new biomarker and diagnostic tests are becoming increasingly available to provide valuable information about potential positive recipients for these novel agents.

This pairing of targeted compounds to patients with a high likelihood to be receptive to that treatment offers an alternative to the traditional broad-spectrum approach when treating cancer. Translating excellence in science into effective treatments for patients is at the core of Roche's scientific vision for "Personalised Healthcare" (PHC), and is the highest priority now and into the future.

Fitting the treatment to the patients, the approach Roche associates with PHC, adds value to patients, society, physicians, and insurers in a way never before seen in the healthcare industry. With thriving Diagnostics and Pharmaceutical divisions, Roche is already delivering on its promise to make Personalised Healthcare a reality. And, the current pipeline is poised to continue delivering novel diagnostic tests and cancer treatments in 2011 and beyond.

### PHC today: Roche's current successes in oncology

**Breast cancer and stomach cancer:** Roche's drug Herceptin is a targeted cancer therapy known as a monoclonal antibody (or targeted biologic therapy). It targets HER2 positive tumours, which can be found in sub-groups of patients with breast and stomach cancers. From a Personalized Healthcare perspective, physicians can first determine if a patient's cancer cells are HER2 positive with Ventana's HER2 IHC and ISH tests before prescribing anti-cancer agents. Ventana Medical Systems is a member of the Roche Group.

## **Roche's PHC pipeline: leading edge tests & pharmaceuticals**

### **Non-Small Cell Lung Cancer (NSCLC)**

**Tarveca:** A phase III study showed progression-free survival benefit of first-line Tarveca in a Western population with advanced lung cancer with EGFR mutations. The Roche Group and OSI/ Astellas Inc. are collaborating on the development of a PCR-based companion diagnostic test (cobas 4800 EGFR mutation test) to identify people with NSCLC that harbours EGFR activating mutations.

**MetMAB:** Researchers discovered that aberrant activation of the HGF/MET pathway leads to a variety of cancers. Roche is developing both the immunohistochemical (IHC) tissue test (Ventana's cMET IHC test) to identify tumours that have high levels of cMET receptor expression and the companion treatment MetMAB (RG3638), a monovalent anti-MET monoclonal antibody.

**Metastatic melanoma (skin cancer):** Vemurafenib is a potential first-in-class medicine designed to selectively inhibit the mutated BRAF protein found in about half of all cases of metastatic melanoma. Roche is developing the cobas 4800 BRAF mutation test that identifies tumours with the BRAF V600 genetic mutation.

**HER2-positive breast cancer:** Roche is developing new compounds for its line of targeted treatments, Trastuzumab emtansine and Pertuzumab. Trastuzumab emtansine is an antibody-drug conjugate of Trastuzumab and the cytotoxin DM1, Pertuzumab is a "HER2 dimerisation inhibitor." IHC/ISH tests from the Roche Group will guide decision-making as learned from Herceptin based therapies.

Currently, Roche's Pharmaceuticals and Diagnostics divisions are collaborating on more than 160 research and development projects that are further advancing Personalised Healthcare.

### **PHC rationale for payers and business**

From a healthcare insurer's perspective, "fitting the treatment to the patients" is a business imperative to optimize resource usage. Additionally, patient compliance increases when the efficacy of the drug is clear to the person undergoing treatment, which is important to insurance payers. Personalized Healthcare also helps avoid unnecessary or disadvantageous treatment, reducing the risks of side effects and costs for their treatments.

The business impact of Personalised Healthcare is clear: It makes good economic sense to bring diagnostics and medicines to market that target disease subtleties and patient sub-groups. Roche leverages both its Diagnostics and Pharmaceutical divisions in a concerted effort to this end. Today, Roche is delivering powerful solutions to physicians, patients, and healthcare systems -- and more are progressing well in Roche's development pipeline.

### **Conclusion**

Tailoring treatments to specific patient sub-groups who share similar characteristics in their genetic makeup or in the molecular nature of the disease has proven to be highly successful. Because Roche embraced this goal several years ago, the company is making Personalised Healthcare a reality now. Roche is not only active in oncology, but covers virology, inflammation, and the central nervous system, as well. Roche will continue on this path throughout 2011 and beyond, providing new, targeted treatment options beneficial for physicians, payers, and most importantly, patients.