

Basel, 2 June 2011

## **Roche enters collaboration with Bristol-Myers Squibb to study combination therapy with vemurafenib and ipilimumab in advanced skin cancer**

### **Roche provides further update on the vemurafenib development programme**

Roche (SIX:RO; OTCQX:RHHBY) today announced that it has entered into a clinical collaboration agreement with Bristol-Myers Squibb Company (NYSE:BMJ) to investigate the combination of vemurafenib with Bristol-Myers Squibb's ipilimumab in patients with BRAF-mutated metastatic melanoma.

"We have made significant progress in treating metastatic melanoma and hope to further improve outcomes by combining two agents that target this deadly disease in different ways," said Hal Barron M.D., Chief Medical Officer and Head, Global Product Development. "We look forward to working with BMS in this ground-breaking collaboration to explore new options for patients."

Under the agreement, the two companies will conduct a Phase I/II study to determine the safety and efficacy of the combination. If appropriate, the companies may conduct further development of the combination. The agreement represents an important cross-company collaboration to explore the combined potential of two new agents in metastatic melanoma, the deadliest and most aggressive form of skin cancer.

### **Update on the vemurafenib development programme**

Roche is pursuing a broad development programme with vemurafenib, a BRAF inhibitor, which includes additional combinations as well as studies in other tumour types.

"We are entering a new era for melanoma, and are committed to studying exciting combinations with investigational medicines in our own pipeline." added Barron.

For example, Roche is also conducting a trial studying the combination of vemurafenib with another of its investigational compounds, GDC-0973, a MEK inhibitor, in patients who previously received vemurafenib alone. MEK is a protein involved in cell growth and survival. It is thought that combining a BRAF inhibitor with a MEK inhibitor could lead to improved outcomes in people with BRAF V600 mutations, which are

found in about half of all metastatic melanoma cases.

People are enrolled into vemurafenib studies based on BRAF mutation status as determined by the cobas 4800 BRAF V600 Mutation Test, an investigational diagnostic from Roche.

BRAF V600 mutations are also associated with other types of tumours, including 8% of solid tumours.<sup>1</sup> Roche has recently begun a Phase II trial of vemurafenib to assess its efficacy and safety in people with metastatic or unresectable papillary thyroid cancer whose tumours test positive for BRAF V600 mutations and are resistant to radioactive iodine therapy. Papillary thyroid cancer is the most common type of thyroid cancer; it can spread to the lymph nodes in the neck, as well as to other parts of the body. BRAF gene mutations have been implicated in 30–70 percent of thyroid tumours.<sup>1</sup>

#### **About vemurafenib**

Vemurafenib is an investigational, oral, small molecule that is designed to selectively inhibit a cancer-driving mutated form of the BRAF protein. Vemurafenib is being co-developed under a 2006 license and collaboration agreement between Roche and Plexxikon, a member of the Daiichi Sankyo Group.

Roche recently announced the submission of new drug applications for vemurafenib in the U.S. and E.U. While Roche seeks approval of the drug, vemurafenib is available to eligible patients with BRAF V600 mutation-positive metastatic melanoma through a global Expanded Access Programme (EAP). More information about this programme or other vemurafenib studies is available at <http://www.clinicaltrials.gov> (in the U.S.) or on the Roche Clinical Trials Registry at [www.rocche-trials.com](http://www.rocche-trials.com) (in the E.U.).

#### **About GDC-0973**

GDC-0973 is a potent and highly selective inhibitor of MEK, a central component of the RAS-RAF pathway which may play a role in the growth and proliferation of certain tumours, including melanoma.

#### **About cobas 4800 BRAF V600 Mutation Test**

The cobas 4800 BRAF V600 Mutation Test is an investigational, polymerase chain reaction-based companion diagnostic being developed by Roche to identify people whose tumours carry BRAF V600 mutations. Roche submitted a Premarket Approval Application (PMA) for the cobas 4800 BRAF V600 Mutation Test in the U.S. The test will also be registered in Europe.

## **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 personalised healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2010, Roche had over 80'000 employees worldwide and invested over 9 billion Swiss francs in R&D. The Group posted sales of 47.5 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](http://www.roche.com).

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## Reference

<sup>1</sup> Dienstmann, R. & Tabernero, J. BRAF as a Target for Cancer Therapy. *Anticancer Agents Med Chem* **11**, 285-295 (2011).