Basel, 26 April 2013

**CHMP recommends conditional EU approval of Roche’s Erivedge for advanced basal cell carcinoma, a rare but potentially devastating form of skin cancer**

Roche (SIX: RO, ROG; OTCQX: RHHBY) announced today that the European Union’s Committee for Medicinal Products for Human Use (CHMP) has recommended conditional approval of Erivedge (vismodegib) for the treatment of adult patients with symptomatic metastatic basal cell carcinoma, or locally advanced basal cell carcinoma inappropriate for surgery or radiotherapy. Conditional approval would make Erivedge the first licensed treatment for patients in Europe with these disfiguring, debilitating and even fatal forms of skin cancer, which are known collectively as advanced basal cell carcinoma.¹,²,³

“The CHMP’s recommendation of Erivedge is encouraging news for patients with these devastating forms of skin cancer,” said Hal Barron, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Erivedge was shown to substantially shrink tumours in a significant proportion of patients in clinical trials, and we hope this medicine will soon be available to patients in Europe.”

The CHMP stated, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for Erivedge and therefore recommended the granting of the marketing authorisation. This marketing authorisation is conditional, and will require the submission of additional data from ongoing studies. The CHMP grants conditional approval to medicinal products that fulfill an unmet medical need.

Basal cell carcinoma is the most common type of skin cancer in Europe, the United States and Australia.⁴,⁵,⁶ Whilst the majority of people diagnosed can be cured with surgery and/or radiotherapy,⁷ for the small proportion that are not (estimated at one percent)⁸ the disease may progress to an advanced form, either becoming locally advanced and growing deeper into the skin and underlying tissues, or metastasising and spreading to other parts of the body.⁹,¹⁰ Advanced basal cell carcinoma is extremely difficult to treat and there are currently no approved treatments in Europe.

**About basal cell carcinoma**

Basal cell carcinoma is a slow-growing skin cancer typically caused by long term and/or occasionally...
excessive exposure to the sun\textsuperscript{x} It is extremely common accounting for as many as 80 percent of all non-melanoma skin cancers.\textsuperscript{ix} Critically, only a small number of people (estimated at one percent) diagnosed with the disease will go on to develop a more advanced stage of the disease which is unsuitable for surgery.\textsuperscript{ii}

Advanced basal cell carcinoma can be categorised in two ways: basal cell carcinoma that grows deep into the skin (locally advanced) and basal cell carcinoma that spreads to other parts of the body (metastatic).\textsuperscript{iii, viii} Advanced forms of basal cell carcinoma are extremely difficult to treat and there are currently no approved treatments in Europe.\textsuperscript{ii}

**About Erivedge**

Erivedge, a type of medicine called a Hedgehog pathway inhibitor, is designed to selectively target abnormal signalling in a cell growth pathway, known as the Hedgehog signalling pathway. The Hedgehog signaling pathway is implicated in the development of certain types of cancer, including basal cell carcinoma.x

Roche is developing Erivedge under a collaboration agreement with Curis, Inc. Erivedge was discovered by Genentech and jointly validated by Genentech and Curis through a series of preclinical studies. Through this collaboration, Genentech (U.S.), Roche (ex-U.S. excluding Japan) and Chugai Pharmaceuticals (Japan) are responsible for the clinical development and commercialisation of Erivedge. Curis is eligible to receive cash payments upon the successful achievement of specified clinical development and regulatory approval milestones, as well as royalties upon commercialisation of Erivedge.

In January 2012 Erivedge became the first licensed medicine for patients with advanced basal cell carcinoma when the U.S. Food and Drug Administration (FDA) approved it under the priority review programme that provides for an expedited six-month review of drugs that offer major advances in treatment.\textsuperscript{x,xii} It has subsequently been approved in Mexico, Israel and South Korea.\textsuperscript{xii} In the first three months of 2013, the sales of Erivedge amounted to 13 million Swiss francs.

**ERIVANCE BCC**\textsuperscript{xii}

Today’s conditional recommendation was based on findings from the pivotal ERIVANCE BCC phase II study which enrolled 104 advanced basal cell carcinoma patients (71 had locally advanced and 33 had metastatic disease) from 31 study sites in the US, Australia and Europe. The study showed Erivedge substantially shrank tumours or repaired visible lesions, as defined by objective response rate, in 42.9 percent of patients with locally advanced and 30.3 percent of patients with metastatic basal cell carcinoma as assessed
by independent review.

The most common adverse events included muscle spasms, hair loss, altered taste sensation, fatigue and weight loss. Serious adverse events (SAEs) were observed in 26 patients (25 percent), however of these only four (4 percent) patients had SAEs that were considered to be related to treatment with Erivedge. Fatal events were reported in seven patients (7 percent) although none were considered by investigators to be related to treatment with Erivedge. In all cases, patients had other pre-existing diseases or symptoms that were related to their presumed cause of death.

**STEVIE**

The safety profile of Erivedge is being further assessed in STEVIE, a global, single-arm, open-label, multicentre study of patients with advanced forms of basal cell carcinoma. The study aims to enrol 1,200 patients. An interim analysis from STEVIE confirmed a similar safety profile to that observed in the ERIVANCE BCC study.

**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, infectious diseases, inflammation, metabolism and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner 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 2012 Roche had over 82,000 employees worldwide and invested over 8 billion Swiss francs in R&D. The Group posted sales of 45.5 billion Swiss francs. 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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1 Amin, SH, et al. laryngoscope 2010;120:2456-2459.
xii Prescribing Information; ErivedgeTM.
xiii FDA Press release; FDA approves new treatment for most common type of skin cancer. January 2012.
xiv COFEPRIS; La Secretaria de Salud Aprueba 29 Medicamentos Innovadores. October 2012.