Roche’s Erivedge receives approval in Switzerland for the treatment of adults with advanced basal cell carcinoma
A novel agent shrinks disfiguring lesions caused by basal cell carcinoma. First-time approval of Erivedge in Europe

Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that Erivedge has been approved by the Swiss agency for the authorisation and supervision of therapeutic products (Swissmedic) for the treatment of basal cell carcinoma (BCC). Erivedge can be used in adult patients in whom BCC has spread to other parts of the body (metastasised), returned after surgery or is no longer treatable with surgery or radiation. Erivedge is the first effective medical treatment alternative.

Basal cell carcinoma occurs most frequently on the head, neck, arms, and other areas of skin exposed to the sun. While BCC tumours are generally characterised by slow growth and minimal soft tissue invasiveness, they may damage surrounding tissue, cartilage and bones as they advance, potentially causing considerable tissue destruction and disfiguration.

About basal cell carcinoma
Basal cell carcinoma (BCC) is the most common type of skin cancer in Europe, Australia and the United States. More than two million new cases worldwide are reported annually. An estimated 10,300 people a year are diagnosed with basal cell carcinoma in Switzerland.
In most cases, basal cell carcinoma is curable, particularly if the cancer is still restricted to a small area of the skin. In this stadium, surgical removal is the best treatment option. If the disease is left untreated or recurs after surgery, it may advance further and invade surrounding areas such as sensory organs (ears, nose and eyes), bone, or other tissues\textsuperscript{3,9,10}. Inoperable, locally advanced basal cell carcinoma is a serious problem. No effective treatment options existed for such patients up to now\textsuperscript{4}. The clinical symptoms of BCC patients often include open, bleeding, scab-forming sores that may be infected with bacteria and therefore emit an unpleasant odour. Such symptoms significantly impair patients’ quality of life and frequently result in their stigmatisation and social isolation.

In a small proportion of patients, untreated basal cell carcinoma may continue to advance over the years and spread throughout the body (0.0028% to 0.55% of diagnosed BCC cases progress to metastatic BCC)\textsuperscript{11,12}. Locally advanced basal cell carcinoma (laBCC) and metastatic basal cell carcinoma (mBCC) are referred to collectively as advanced basal cell carcinoma (aBCC). Advanced basal cell carcinoma is very rare; the annual number of such patients in Switzerland is estimated at 20 to 40.

**Risk factors for basal cell carcinoma**

The average lifetime risk for Caucasians of developing BCC is around 30\%\textsuperscript{13}. BCC is more common in men than in women, with a ratio of approximately 2:1\textsuperscript{14}. Exposure to ultraviolet radiation (UV), which results in cumulative DNA damage and genetic mutations, is a leading cause of BCC. The following risk factors also contribute to the development of BCC\textsuperscript{13,15}:

- Skin type 1 (i.e., always burns, never tans)
- Red or blond hair
- Blue or green eyes
- Freckles in childhood
- Sunburn in childhood
- A family history of skin cancer
- Immunosuppressive therapy
- Ingestion of arsenic

Moreover, patients who have already contracted BCC are at greater risk of developing further cases of BCC\textsuperscript{13}. 


**Pivotal study: ERIVANCE BCC/SHH4476g**

ERIVANCE BCC/SHH4476g is a global, single-arm, Phase II study investigating efficacy and safety. It is referred to as a single-arm study because Erivedge is a first-in-class drug for the treatment of a disease for which no effective therapy previously existed, and a cross-comparison of Erivedge with other treatment methods is therefore not possible. Treatment with Erivedge can achieve the following clinical benefits:

- In 94% of patients with mBCC and in 82% of patients with laBCC, Erivedge can shrink tumours or at least stabilise disease\(^\text{16}\).
- 54% of patients with laBCC have a histopathological response within 24 weeks, with no indication of residual basal cell carcinoma\(^\text{17}\).

**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](http://www.roche.com).

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**Roche Group Media Relations**

Tel.: +41 61.688 8888 88 / e-mail: [basel.mediaoffice@roche.com](mailto:basel.mediaoffice@roche.com)
- Alexander Klauser (Head)
- Silvia Dobry
- Daniel Grotzky
- Štěpán Kráčala
References
1 Drug prescribing information at www.swissmedicinfo.ch