



Medicine: ribociclib (brand name: Kisqali®) for advanced HR positive, HER2-negative breast cancer

Novartis Pharmaceuticals UK Ltd

What is ribociclib for?

Ribociclib is used to treat breast cancer that is hormone receptor (HR) positive and human epidermal growth-factor receptor 2 (HER2) negative. HR positive breast cancer has proteins that cause the cancer to grow in response to certain hormones. HER2 negative breast cancer does not have the HER2 protein, which can cause some breast cancers to grow. Ribociclib is used to treat breast cancer that is locally advanced (spread nearby from where it started) or metastatic (spread to other parts of the body).

Ribociclib was considered for use in combination with a hormonal breast cancer medicine called fulvestrant.

SMC has previously accepted ribociclib in combination with an aromatase inhibitor for advanced HR-positive, HER2-negative advanced breast cancer. For further information please refer to [SMC 1295/18](#).

How does ribociclib work?

Ribociclib blocks the activity of two proteins called CDK4 and CDK6 which play a role in the way cells grow and divide. In HR-positive breast cancer, there is an increase in the activity of these proteins, which makes the cancer cells multiply too fast. By blocking these proteins, ribociclib slows the growth of the cancer cells.

What has SMC said?

SMC has accepted ribociclib for the treatment of advanced HR-positive, HER2-negative breast cancer, in combination with fulvestrant, as described above. This acceptance is restricted to use in patients whose cancer has:

- got worse on or within 12 months of treatment with hormonal breast cancer medicines given before or after surgery ([neo]-adjuvant) to treat early breast cancer, or
- got worse on or after initial treatment with hormonal breast cancer medicines given to treat advanced breast cancer.



Why has SMC said this?

SMC looks at how well new medicines work compared with current treatments available in Scotland and in relation to how much they will cost to buy and administer (for example, if the medicine has to be given at a clinic or side effects have to be monitored).

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland. When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not just those who may be treated with the medicine under consideration.

To do this SMC consider the following:

- Clinical trial and economic evidence from the company that makes the medicine.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.
- Information from patient groups about the potential impact of the medicine on patients and carers.

After careful consideration, applying extra flexibility because ribociclib is a medicine for an end of life condition, and after the company applied a confidential discount to the cost of the medicine, SMC was able to accept ribociclib as a possible treatment within NHSScotland.

What does SMC's decision mean for me?

If your healthcare professional thinks that ribociclib for use as described above is the right medicine for you, you should be able to have your treatment on the NHS in Scotland. For further information see:

Medicines in Scotland: What's the right treatment for me?

www.healthcareimprovementscotland.org/medicinesbooklet.aspx



More information

The organisation below can provide more information and support for people with breast cancer and their families. SMC is not responsible for the content of any information provided by external organisations.

Breast Cancer Now



<https://breastcancer.org/>



0808 800 6000

You can find out more about ribociclib in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.



<http://www.ema.europa.eu>

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