

KISQALI - aBC treatment guidelines - HCP

[KISQALI® \(ribociclib\) Prescribing information](#)

[PIQRAY®▼ \(alpelisib\) Prescribing information](#)

Image



Image



## **Advanced breast cancer guideline recommendations for KISQALI® (ribociclib)**

### **Indications:<sup>1</sup>**

- KISQALI is indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as

initial endocrine-based therapy, or in women who have received prior endocrine therapy

- In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone agonist

KISQALI is not recommended to be used in combination with tamoxifen.

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## **Advanced breast cancer (aBC) is a virtually incurable disease associated with poor prognosis:<sup>2,3</sup>**

- **A median overall survival (OS) of 3 years**
- **5-year survival rate of 25%**

### **HR+/HER2- aBC is the most common subtype of metastatic breast cancer (mBC).<sup>3</sup>**

Treatment is aimed at improving OS, in addition to maintaining or improving quality of life.<sup>3</sup> Although the disease remains incurable, the availability of systemic therapies such as endocrine therapy (ET) has led to improvements in the management of this hormone-sensitive disease.<sup>4</sup>

Cyclin-dependent kinases 4 and 6 (CDK4/6) play a key role in cell cycle progression and have become an effective target in the treatment of aBC.<sup>5</sup>

### **For more information, please visit the page on the mechanism of action of CDK4/6 inhibitors**

[Learn more](#)

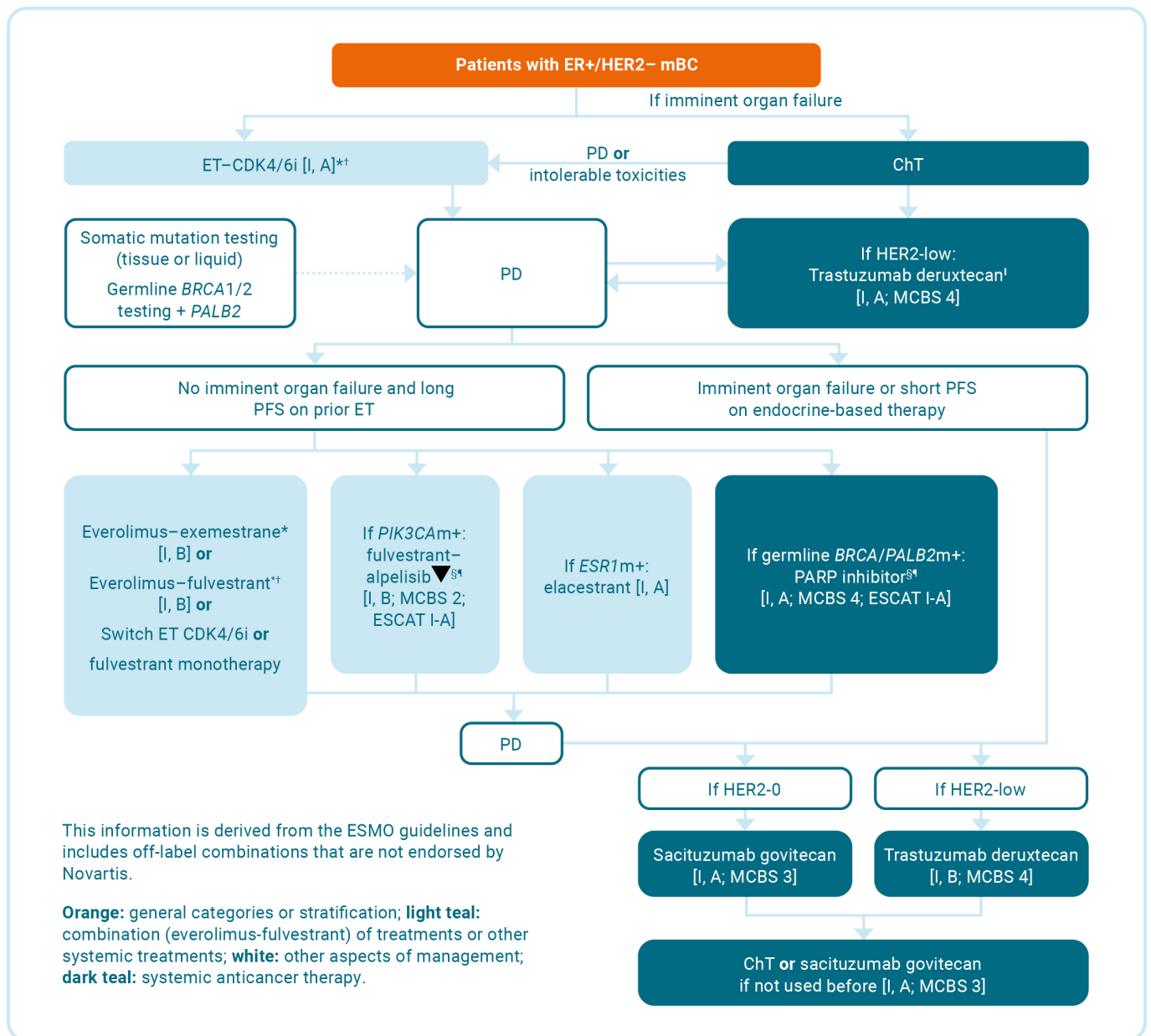
KISQALI is not recommended to be used in combination with tamoxifen.<sup>1</sup>

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## **ESMO clinical practice guidelines for the treatment of ER+/HER2-mBC<sup>6</sup>**

Image





Adapted from European Society for Medical Oncology. 2023.<sup>6</sup>

**Everolimus is not licensed in combination with fulvestrant or for use in premenopausal women. Novartis does not condone the off-label use of therapies. Please refer to individual Summary of Product Characteristics before prescribing. Alpelisib is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with HR+/HER2-, locally advanced or mBC with a PIK3CA mutation after disease progression following endocrine-based therapy.<sup>7</sup> Please consult the Summary of Product Characteristics before prescribing.**

**KISQALI received an ESMO-MCBS score of 5/5 when used in combination with LHRH and with ET<sup>8</sup>**

ET is defined as NSAI or tamoxifen and LHRH.

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The ESMO-MCBS is a standardised tool that quantifies the likely magnitude of clinical benefit. The scale considers OS, PFS, disease-free survival, hazard ratio, response rate, quality of life, prognosis of the condition and toxicity of patients in the non-curative setting, ranging from grades 1 to 5, with 4 and 5 denoting substantial clinical benefit.<sup>9</sup>

For further information, please refer to the ESMO-MCBS scorecard methodology.<sup>9</sup>

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\*OFS if the patient is premenopausal.<sup>6</sup>

†If relapse <12 months after end of adjuvant AI: fulvestrant-CDK4/6i;\* if relapse >12 months after end of adjuvant AI: AI-CDK4/6i.\*<sup>6</sup>

‡Preferred if the patient is *ESR1*m+ [ESCAT score: II-A].<sup>§6</sup>

§ESMO-MCBS v1.1 was used to calculate scores for therapies/indications approved in the EU

and US. The scores have been calculated by the ESMO-MCBS Working Group and validated by the ESMO Guidelines Committee.<sup>10</sup>

<sup>†</sup>ESCAT scores apply to genomic alterations only. These scores have been defined by the guideline authors and validated by the ESMO Translational Research and Precision Medicine Working Group.<sup>11</sup>

<sup>‡</sup>Trastuzumab deruxtecan can also be given following adjuvant ChT in the setting of fast progression (DESTINY-Breast04).<sup>6</sup>

aBC, advanced breast cancer; AI, aromatase inhibitor; *BRCA*, breast cancer gene; CDK4/6i, cyclin-dependent kinase 4/6-inhibitor; ChT, chemotherapy; ER, oestrogen receptor; ESCAT, ESMO scale for clinical actionability of molecular targets; ESMO, European Society for Medical Oncology; ESMO-MCBS, European Society for Medical Oncology magnitude of clinical benefit scale; ESR1, oestrogen receptor 1; ET, endocrine therapy; HER2-, human epidermal growth receptor 2-negative; HR+, hormone receptor-positive; m, mutated; mBC, metastatic breast cancer; OFS, ovarian function suppression; *PALB2*, partner and localiser of *BRCA2*; PARP, poly ADP-ribose polymerase; PD, progressive disease; PFS, progression-free survival; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha.

## References:

1. KISQALI® (ribociclib) Summary of Product Characteristics.
2. Cardoso F, et al. *Ann Oncol* 2020;31(12):1623–1649.
3. Hortobagyi GN, et al. *N Engl J Med* 2022;386:942–950.
4. McAndrew NP, et al. *JCO Oncol Pract* 2021;18(5):319–327.
5. Slamon DJ, et al. *Annals Oncol* 2021;32(8):1015–1024.
6. European Society for Medical Oncology. ER-positive HER2-negative Breast Cancer, v1.1 May 2023. Available at: <https://www.esmo.org/living-guidelines/esmo-metastatic-breast-cancer-living-guideline/er-positive-her2-negative-breast-cancer> [Accessed March 2025].
7. PIQRAY® (alpelisib) Summary of Product Characteristics.
8. European Society for Medical Oncology. Breast cancer. Available at: [https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards?cbs\\_score\\_cards\\_form%5BsearchText%5D=&mcbs\\_score\\_cards\\_form%5Btumourtype%5D=0&mcbs\\_score\\_cards\\_form%5Btumour-sub-type%5D=Breast+Cancer](https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards?cbs_score_cards_form%5BsearchText%5D=&mcbs_score_cards_form%5Btumourtype%5D=0&mcbs_score_cards_form%5Btumour-sub-type%5D=Breast+Cancer) [Accessed March 2025].

9. European Society for Medical Oncology. ESMO-magnitude of clinical benefit scale. Available at: <https://www.esmo.org/content/download/288502/5736211/1/esmo-mcbs-booklet.pdf> [Accessed March 2025].
10. Cherny NI, et al. *Ann Oncol* 2017;28(10):2340–2366.
11. Mateo J, et al. *Ann Oncol* 2018;29(9):1895–1902.

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