KISQALI® ribociclib

Multidisciplinary team reference card

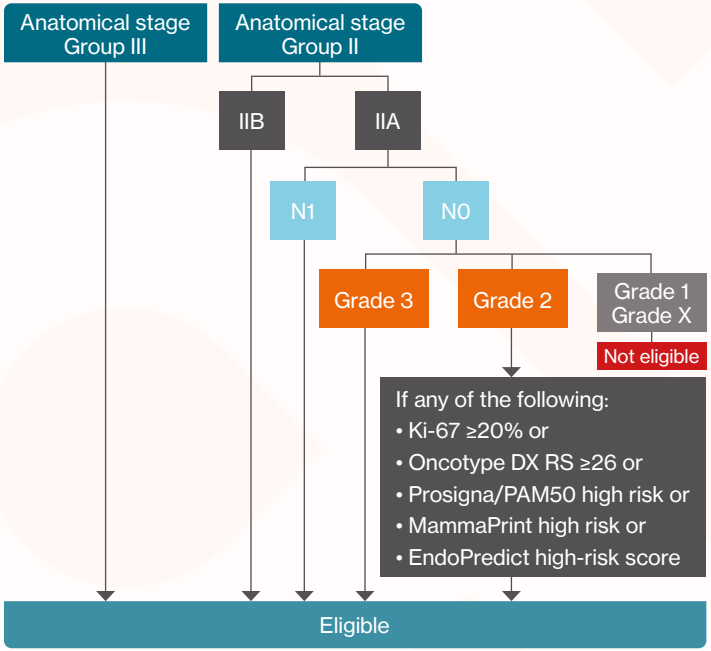
Eligibility criteria for ribociclib + NSAI in HR+/HER2– eBC patients

NATALEE enrolled patients with **Stage II or III HR+/HER2– eBC at high risk of recurrence, including N0 disease with high-risk features**

Diagnosis		NATALEE[1] Ribociclib + NSAI	monarchE (Cohort 1)*,[2] Abemaciclib + ET
Stage IIA	T0N1	✓	Only if Grade 3
	T1N1	✓	Only if Grade 3
	T2N0	Only if Grade 3 or Grade 2 with high genomic risk†	–
Stage IIB	T2N1	✓	Only if Grade 3
	T3N0	✓	–
Stage IIIA	T0N2	✓	✓
	T1N2	✓	✓
	T2N2	✓	✓
	T3N1	✓	✓
	T3N2	✓	✓
Stage IIIB	T4N0	✓	–
	T4N1	✓	Only if tumour size ≥5 cm or Grade 3
	T4N2	✓	✓
Stage IIIC	Any TN3	✓	✓

Adapted from Slamon DJ, et al. 2023 and Harbeck N, et al. 2021.

A broad range of your **Stage II or III patients with HR+/HER2– eBC may be eligible for ribociclib**



Adapted from Tarantino P, et al. 2024.

Cross-trial comparisons of outcomes should not be made in the absence of head-to-head trials.

Please refer to the SmPC for the co-administered treatments for dose modification guidelines and other relevant safety information in the event of toxicity.

Indication: ribociclib in combination with an aromatase inhibitor is indicated for the adjuvant treatment of patients with HR-positive, HER2-negative eBC at high risk of recurrence (see selection criteria in section 5.1 of the SmPC). In pre- or perimenopausal women, or in men, the aromatase inhibitor should be combined with an LHRH agonist. Ribociclib is not recommended to be used in combination with tamoxifen.[4]

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The NATALEE trial was a multicentre, randomised, open-label, Phase III clinical trial of ribociclib + NSAI vs NSAI in the adjuvant treatment of HR+/HER2– eBC. N=5,101. Patients received ribociclib 400 mg/day + NSAI for 3 years, while NSAI continued for ≥5 years. Any ET was permitted for up to 1 year prior to randomisation. Men and premenopausal women also received goserelin. Primary endpoint was iDFS. iDFS included invasive, ipsilateral breast tumour recurrence, local or regional invasive recurrence, distant recurrence, death (from breast cancer, non-breast cancer or unknown cause), invasive contralateral breast cancer or second primary invasive cancer (non-breast cancer).[5]

The most common adverse drug reactions (ADRs) (reported at a frequency ≥20%) in the dataset for which the frequency for ribociclib plus aromatase inhibitor (AI) exceeds the frequency for AI alone were neutropenia, infections, nausea, headache, fatigue, leukopenia and abnormal liver function tests.[4]

The most common Grade 3/4 ADRs (reported at a frequency of ≥2%) in the dataset for which the frequency for ribociclib plus AI exceeds the frequency for AI alone were neutropenia, abnormal liver function tests and leukopenia.[4]

Please see the SmPC for further information.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report or alternatively email medinfo.uk@novartis.com or call 01276 698370.

*Cohort 2 is not included in the abemaciclib indication.

†High genomic risk included patient with either Ki-67 ≥20% or high risk by gene signature testing.[1]

AE=adverse event; eBC=early breast cancer; ET=endocrine therapy; HR+=hormone-receptor positive; HER2–=human epidermal growth factor receptor 2 negative; HR+=hormone receptor positive; iDFS=invasive disease-free survival; LHRH=luteinising hormone-releasing hormone; NSAI=non-steroidal aromatase inhibitor; RS=recurrence score; SmPC=Summary of Product Characteristics.

1. Slamon DJ, et al. *Ther Adv Med Oncol.* 2023;15:1–16.
2. Harbeck N, et al. *Ann Oncol.* 2021;32(12):1571–1581.
3. Tarantino P, et al. Poster presented at the *San Antonio Breast Cancer Symposium* 2024; 10–13 December 2024; San Antonio, USA. Poster P2-12-02.
4. KISQALI (ribociclib) Summary of Product Characteristics.
5. Hortobagyi GN, et al. *Ann Oncol.* 2025;36(2):149–157.

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