

Powerful clinical efficacy

Real-world experience and evidence

Patient-reported outcomes

Established safety profile

One scheduled monitoring provision

One pill, once daily

A wealth of data from 2 large pivotal Phase III RCTs across lines and all patient types studied, including those with visceral disease, bone-only disease and elderly patients¹⁻⁹

>6 years' real-world experience^{10,11} and a wealth of fast-growing real-world evidence¹²⁻¹⁷ complementing strong clinical data

Health-related quality of life was maintained in both treatment arms across 2 large pivotal Phase III RCTs*18,19

Data from up to 5 years across RCTs^{1-3,5-7,9,20,21}

In the current SmPC, CBC is the only scheduled monitoring provision - it does not include provisions for ECG, electrolyte, or LFT monitoring^{†1}

Convenient dosing with one pill once a day, regardless of dose strength¹¹

Indications:

IBRANCE is indicated for the treatment of HR+/HER2- locally advanced or mBC:1

- In combination with an Al
- In combination with fulvestrant in women who have received prior ET
- In pre- or peri-menopausal women, the ET should be combined with an LHRH agonist



References: 1. IBRANCE Summary of Product Characteristics. 2. Rugo H, et al. Breast Cancer Res Treat. 2019;174(3):719-729. 3. Finn RS, et al. N Engl J Med. 2016;375(20):1925-1936. 4. IBRANCE EPAR Public assessment report. 25 Nov 2016. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/003853/ WC500217198.pdf. Accessed June 2021. 5. Cristofanilli M, et al. Lancet Oncol. 2016;17(4):425-439. 6. Rugo H, et al. Eur J Cancer. 2018;101:123-133. 7. Loibl S, et al. Oncologist. 2017;22(9):1028-1038. 8. Turner NC, et al. N Engl J Med. 2018;379(20):1926-1936. 9. Turner NC, et al. Ann Oncol. 2018;29(3):669-680. 10. FDA Approved drugs. IBRANCE. https://www.fda.gov/drugs/resources-information-approved-drugs/palbociclib-ibrance. Accessed June 2021. 11. McCain J. P T. 2015;40(8):511-520. 12. DeMichele A, et al. Breast Cancer Res. 2021;23(1):37. 13. Taylor-Stokes G, et al. Breast. 2019:43:22-27. 14. Mycock K, et al. Curr Oncol. 2021;28:678-688. 15. Waller J, et al. J Glob Oncol. 2019;5:JGO1800239. 16. Taylor-Stokes G, et al. ESMO 2020; poster 269P. 17. Mycock K, et al. EBCC 2020; poster 510. 18. Harbeck N, et al. Ann Oncol. 2016;27(6):1047-1054. 19. Rugo HS, et al. Ann Oncol. 2018;29(4):888-894. 20. Finn R, et al. Oncologist. 2021:26(5):e749-e755. 21. Verma S, et al. Oncologist. 2016;21:1165-1175.

*HRQoL as measured by the Functional Assessment of Cancer Therapy - Breast (FACT-B) total scores (PALOMA-2) and the European Organisation for Research and Treatment of Cancer Quality-of- Life (EORTC QLQ-C30) global QoL scores (PALOMA-3). †CBC should be monitored prior to the start of IBRANCE therapy and at the beginning of each cycle, as well as on Day 15 of the first 2 cycles, and as clinically indicated. For patients who experience a maximum of Grade 1 or 2 neutropenia in the first 6 cycles, CBC for subsequent cycles should be monitored every 3 months, prior to the beginning of a cycle and as clinically indicated. Patients should be monitored for signs and symptoms of infection and ILD/pneumonitis and treated as medically appropriate. Additional monitoring may be necessary based on the individual patient. There are no mandatory liver tests and no clinically relevant QTc prolongation. †As part of combination therapy with an Al or fulvestrant. Dosing for these combination partners should follow the dosing indications in the respective SmPCs.

AI = aromatase inhibitor; CBC = complete blood count; ECG = electrocardiogram; ET = endocrine therapy; HR+/HER2- = hormone receptor-positive, human epidermal growth factor receptor 2-negative; HRQoL = health-related quality of life; ILD = interstitial lung disease; LFT = liver function test; LHRH = luteinising hormone-releasing hormone; mBC = metastatic breast cancer; QoL = quality of life; RCT = randomised controlled trial; SmPC = Summary of Product Characteristics.

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English SmPC available here

German SmPC available here

Before prescribing, please refer to local recommendations applicable in your country and SmPC available at this virtual booth or on the EMA website.

