

ADOPTING THE EVOLVING MANAGEMENT OF HR+/HER2-MBC INTO PRACTICE



References

American Cancer Society. *Breast Cancer Facts & Figures 2022-2024*. Published 2022. Accessed March 25, 2025. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/breast-cancer-facts-and-figures/2022-2024-breast-cancer-fact-figures-acs.pdf>

André F, Ciruelos E, Rubovszky G, et al. Alpelisib for PIK3CA-mutated, hormone receptor-positive advanced breast cancer. *N Engl J Med*. 2019;380(20):1929-1940. doi:10.1056/NEJMoa1813904

André F, Ciruelos E, Juric D, et al. Alpelisib plus fulvestrant for PIK3CA-mutated, hormone receptor-positive, human epidermal growth factor receptor-2-negative advanced breast cancer: final overall survival results from SOLAR-1. *Ann Oncol*. 2021;32(2):208-217. doi:10.1016/j.annonc.2020.11.011

Andújar JMC, de la Peña FA, Zotano AG, et al. Optimizing therapeutic approaches for HR+/HER2-advanced breast cancer: clinical perspectives on biomarkers and treatment strategies post-CDK4/6 inhibitor progression. *Cancer Drug Resist*. 2025;8:5. doi:10.20517/cdr.2024.169

AstraZeneca. Camizestrant demonstrated highly statistically significant and clinically meaningful improvement in progression-free survival in 1st-line advanced HR-positive breast cancer with an emergent ESR1 tumour mutation in SERENA-6 phase III trial. Published February 26, 2025. Accessed March 25, 2025. <https://www.astrazeneca.com/media-centre/press-releases/2025/camizestrant-improved-pfs-in-1l-hr-breast-cancer.html>

Bhave MA, Quintanilha JCF, Tukachinsky H, et al. Comprehensive genomic profiling of ESR1, PIK3CA, AKT1, and PTEN in HR(+)/HER2(-) metastatic breast cancer: prevalence along treatment course and predictive value for endocrine therapy resistance in real-world practice. *Breast Cancer Res Treat*. 2024;207(3):599-609. doi:10.1007/s10549-024-07376-w

Bidard FC, Kaklamani VG, Neven P, et al. Elacestrant (oral selective estrogen receptor degrader) versus standard endocrine therapy for estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer: results from the randomized phase III EMERALD trial. *J Clin Oncol*. 2022;40(28):3246-3256. doi:10.1200/JCO.22.00338

Bidard FC, Hardy-Bessard AC, Dalenc F, et al. Switch to fulvestrant and palbociclib versus no switch in advanced breast cancer with rising ESR1 mutation during aromatase inhibitor and palbociclib therapy (PADA-1): a randomised, open-label, multicentre, phase 3 trial. *Lancet Oncol*. 2022;23(11):1367-1377. doi:10.1016/S1470-2045(22)00555-1

Brett JO, Spring LM, Bardia A, Wander SA. ESR1 mutation as an emerging clinical biomarker in metastatic hormone receptor-positive breast cancer. *Breast Cancer Res*. 2021;23(1):85. doi:10.1186/s13058-021-01462-3

ADOPTING THE EVOLVING MANAGEMENT OF HR+/HER2-MBC INTO PRACTICE



Burstein HJ, DeMichele A, Fallowfield L, et al. Endocrine and targeted therapy for hormone receptor-positive, human epidermal growth factor receptor 2-negative metastatic breast cancer-capivasertib-fulvestrant: ASCO rapid recommendation update. *J Clin Oncol.* 2024;42(12):1450-1453. doi:10.1200/JCO.24.00248

Chaudhary N, Chibly AM, Collier A, et al. CDK4/6i-treated HR+/HER2- breast cancer tumors show higher ESR1 mutation prevalence and more altered genomic landscape. *NPJ Breast Cancer.* 2024;10(1):15. doi:10.1038/s41523-024-00617-7

Cristofanilli M, Rugo HS, Im SA, et al. Overall survival with palbociclib and fulvestrant in women with HR+/HER2- ABC: Updated exploratory analyses of PALOMA-3, a double-blind, phase III randomized study. *Clin Cancer Res.* 2022;258(16):3433-3442. doi:10.1158/1078-0432.CCR-22-0305

Goetz MP, Toi M, Campone M, et al. MONARCH 3: Abemaciclib as initial therapy for advanced breast cancer. *J Clin Oncol.* 2017;35(32):3638-3646. doi:10.1200/JCO.2017.75.6155

Hortobagyi GN, Stemmer SM, Burris HA, et al. Ribociclib as first-line therapy for HR-positive, advanced breast cancer. *N Engl J Med.* 2016;375:1738-1748. doi:10.1056/NEJMoa1609709

Huppert LA, Gumusay O, Idossa D, and Rugo HS. Systemic therapy for hormone receptor-positive/human epidermal growth factor receptor 2-negative early stage and metastatic breast cancer. *CA Cancer J Clin.* 2023;73(5):480-515. doi:10.3322/caac.21777

Itovebi. Prescribing information. Genentech, Inc.; October 2024. Accessed March 25, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/219249s000lbl.pdf

Lu YS, Im SA, Colleoni M, et al. Updated overall survival of ribociclib plus endocrine therapy versus endocrine therapy alone in pre- and perimenopausal patients with HR+/HER2- advanced breast cancer in MONALEESA-7: A phase III randomized clinical trial. *Clin Cancer Res.* 2022;28(5):851-859. doi:10.1158/1078-0432.CCR-21-3032

Mitri Z, Constantine T, O'Regan R. The HER2 receptor in breast cancer: pathophysiology, clinical use, and new advances in therapy. *Chemother Res Pract.* 2012;743193. doi:10.1155/2012/743193

National Comprehensive Cancer Network. NCCN Guidelines for Breast Cancer V.3.2024. Accessed July 1, 2024. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

National Comprehensive Cancer Network. NCCN Guidelines for Genetic/Familial High-Risk Assessment: Breast, Ovarian, Pancreatic, and Prostate V.3.2025. Accessed March 26, 2025. https://www.nccn.org/professionals/physician_gls/pdf/genetics_bopp.pdf

Oliveira M, Pominchuck D, Nowecki Z, et al. Abstract GS3-02: GS3-02 Camizestrant, a next generation oral SERD vs. fulvestrant in post-menopausal women with advanced ER-positive HER2-negative breast cancer: results of the randomized, multi-dose Phase 2 SERENA-2 trial. *Cancer Res.* 2023;83(5 Suppl):GS3-02. doi:10.1158/1538-7445.SABCS22-GS3-02

ADOPTING THE EVOLVING MANAGEMENT OF HR+/HER2-MBC INTO PRACTICE



Piqray . Prescribing information. Novartis Pharmaceuticals Corporation; January 2024. Accessed March 25, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/212526s009lbl.pdf

Rugo HS, Rinn RS, Diéras V, et al. Palbociclib plus letrozole as first-line therapy in estrogen receptor-positive/human epidermal growth factor receptor 2-negative advanced breast cancer with extended follow-up. *Breast Cancer Res Treat*. 2019;174(3):719-729. doi:10.1007/s10549-018-05125-4

Shah, R, Rosso K, Nathanson DS. Pathogenesis, prevention, diagnosis and treatment of breast cancer. *World J Clin Oncol*. 2014;5(3):283-298. doi:10.5306/wjco.v5.i3.283

Siegel RL, Miller KD, Wagle NS, Jemal A. Cancer statistics, 2024. *CA Cancer J. Clin*. 2024;74(1):12-49. doi:10.3322/caac.21820

Slamon DJ, Neven P, Chia S, et al. Overall survival with ribociclib plus fulvestrant in advanced breast cancer. *N Eng J Med*. 2020;382(6):514-524. doi:10.1056/NEJMoa1911149

Sledge GW, Toi M, Neven P, et al. MONARCH 2: Abemaciclib in combination with fulvestrant in women with HR+/HER2- advanced breast cancer who had progressed while receiving endocrine therapy. *J Clin Oncol*. 2017;35(25):2875-2884. doi:10.1200/JCO.2017.73.7585

Sledge GW, Toi M, Neven P et al. The effect of abemaciclib plus fulvestrant on overall survival in hormone receptor-positive, ERBB2-negative breast cancer that progressed on endocrine therapy—MONARCH 2. *JAMA Oncol*. 2020;6(1):116-124. doi:10.1001/jamaoncol.2019.4782

Tripathy D, Im SA, Colleoni M, et al. Ribociclib plus endocrine therapy for premenopausal women with hormone-receptor-positive, advanced breast cancer (MONALEESA-7): a randomised phase 3 trial. *Lancet Oncol*. 2018;19(7):904-915. doi:10.1016/S1470-2045(18)30292-4

Truqap. Prescribing information. AstraZeneca Pharmaceuticals LP; February 2025. Accessed March 25, 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/218197s002lbl.pdf

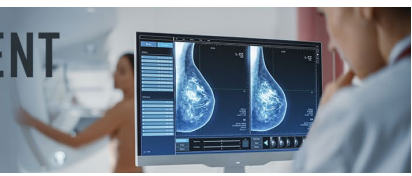
Turner NC, Swift C, Kilburn L, et al. *ESR1* mutations and overall survival on fulvestrant versus exemestane in advanced hormone receptor-positive breast cancer: a combined analysis of the phase III SoFEA and EFECT Trials. *Clin Cancer Res*. 2020;26(19):5172-5177. doi:10.1158/1078-0432.CCR-20-0224

Turner NC, Oliveira M, Howell SJ, et al. Capivasertib in hormone receptor-positive advanced breast cancer. *N Engl J Med*. 2023;388(22):2058-2070. doi:10.1056/NEJMoa2214131

Turner N, Huang-Bartlett C, Kalinsky K, et al. Design of SERENA-6, a phase III switching trial of camizestrant in *ESR1*-mutant breast cancer during first-line treatment. *Future Oncol*. 2023;19(8):559-573. doi:10.2217/fon-2022-1196

Turner NC, Im SA, Saura C, et al. Inavolisib-based therapy in *PIK3CA*-mutated advanced breast cancer. *N Engl J Med*. 2024;391(17):1584-1596. doi:10.1056/NEJMoa2404625

ADOPTING THE EVOLVING MANAGEMENT OF HR+/HER2-MBC INTO PRACTICE



Wolff AC, Somerfield MR, Dowsett M, et al. Human epidermal growth factor receptor 2 testing in breast cancer: ASCO-College of American Pathologists guideline update. *J Clin Oncol.* 2023;41(22):3867-3872. doi:10.1200/JCO.22.02864