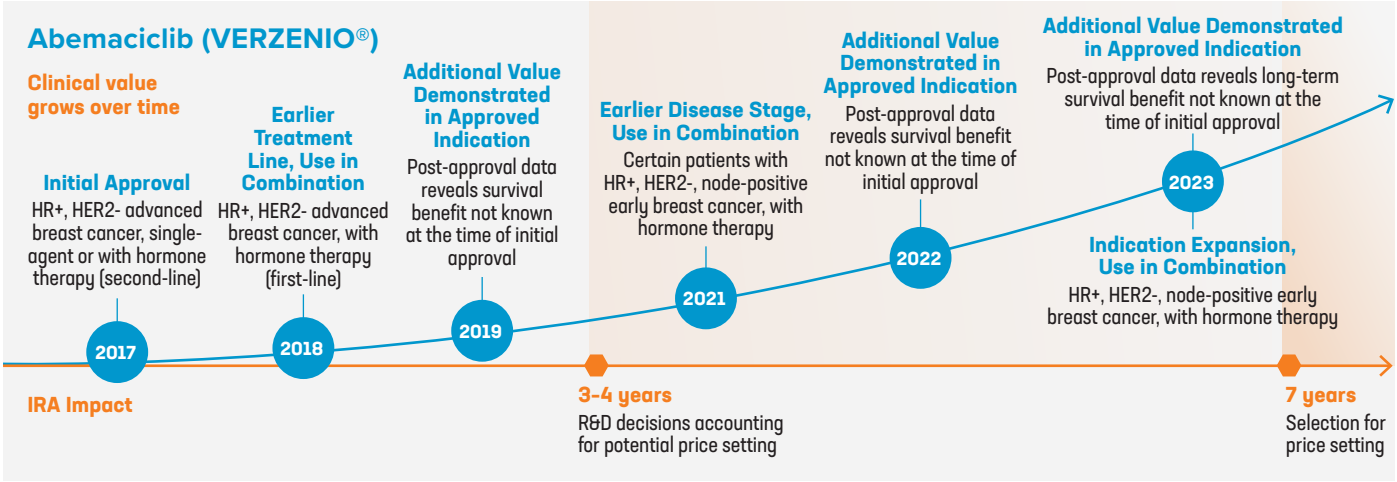
Abemaciclib | VERZENIO®

In 2017, the FDA granted approval to abemaciclib, in combination with the hormone therapy fulvestrant, to treat women with hormone receptor positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) advanced or metastatic breast cancer whose disease has progressed following hormone therapy.[1] HR+ means that tumor cells have receptors for hormones that can promote the growth of tumors.[2] Abemaciclib was simultaneously approved as a single agent to treat adult patients with this subtype of breast cancer whose cancer spread after treatment with prior hormone therapy and chemotherapy.[3] Abemaciclib is a CDK4/6 inhibitor, a type of oral therapy that inhibits proteins (cyclin-dependent kinase 4 and 6) involved in cell replication and interrupts the process through which breast cancer cells multiply.[4] This treatment class has rapidly transformed the landscape for HR+/HER2- advanced breast cancer, which makes up more than two out of three breast cancer cases and is rarely curable.[4,5] Since the initial approval, clinical studies have shown that abemaciclib can be used as adjuvant treatment after surgery to treat earlier stages of breast cancer, specifically when taken in combination with certain hormone therapies. The goal of adjuvant treatment after surgery is to prevent cancer from coming back and adjuvant therapy with abemaciclib has the potential to be curative for some patients with early breast cancer.[6,7]



Earlier Treatment Line (February 2018): Approved, for the treatment of postmenopausal women with HR+, HER2- advanced or metastatic breast cancer, in combination with a type of hormone therapy called an aromatase inhibitor. Clinical data showed that patients treated with this combination were 46% more likely to live without their cancer getting worse than patients treated with only hormone therapy.[8]

Additional Value Demonstrated in Approved Indication (September 2019): Follow-up data shows abemaciclib, in combination with the hormone therapy fulvestrant, significantly extends life by a median of 9.4 months compared to the hormone therapy alone.[9] New treatment options are important given the challenge of survival among women with more advanced breast cancer, with 5-year survival dropping from 99 percent for localized disease to 30 percent for cancer that has spread.[10]

New Indication, Earlier Disease Stage (October 2021): Approved, in combination with hormone therapy, for patients with HR+, HER2- early breast cancer that is present in the lymph nodes (node-positive). After breast cancer is removed through surgery, the presence of cancer cells in the lymph nodes indicates a higher chance of the cancer returning and spreading. Specifically, abemaciclib was approved as an adjuvant treatment (after surgery) for patients whose tumors express a biomarker (Ki-67), indicating rapid cancer growth with a high risk of tumors returning.[6] The goal of adjuvant therapy is to prevent the cancer from coming back.[7] Clinical data showed that patients treated with this combination were 37% more likely to be alive and free of any signs of breast cancer compared to hormone therapy alone. With this approval, abemaciclib became the first addition to adjuvant hormone therapy in nearly two decades for this indication.[6,11]

Additional Value Demonstrated in Approved Indication (December 2022): Follow-up data at four years was favorable for HR+, HER2-, node-positive, high-risk early breast cancer patients who took adjuvant abemaciclib, in combination with hormone therapy, compared to patients taking only hormone therapy. The clinical data showed that more patients treated with the combination were alive and free of any signs of breast cancer than those treated with only hormone therapy.[12]

Additional Value Demonstrated in Approved Indication (March 2023): Long-term follow-up data confirms a significant survival benefit for patients with HR+, HER2- advanced breast cancer who were treated with abemaciclib in combination with the hormone therapy fulvestrant after their disease progressed on hormone therapy, with 41% of patients alive after five years compared to only 29% of patients who received hormone therapy alone.[13]

Expansion of Label, Use in Combination (March 2023): Granted label expansion to remove the need for a Ki-67 biomarker test to treat patients with HR+, HER2-, node-positive early breast cancer at a high risk of returning. The label expansion is supported by four-year data showing that the combination reduces the risk of the cancer returning by 35% compared to hormone therapy alone.[14]

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