# Verzenio gets additional FDA approval, 4/18

**April 2018—**Eli Lilly announced the FDA has approved Verzenio (abemaciclib) in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer.

The safety and efficacy of Verzenio in combination with an AI as initial endocrine-based therapy were based on the results of the MONARCH 3 study, a randomized trial of 493 postmenopausal women with HR-positive, HER2-negative advanced breast cancer who had no prior systemic treatment for advanced disease. In patients who received neoadjuvant/adjuvant endocrine therapy, a disease-free interval of more than 12 months since completion of endocrine therapy was required. The median progression-free survival for patients taking Verzenio with fulvestrant was 28 months as compared with 14.8 months for patients taking a placebo with fulvestrant.

This Verzenio new drug application was given priority review as part of the FDA's expedited programs for serious conditions, a program used for therapies that address an unmet medical need in the treatment of serious or life-threatening conditions.

***Eli Lilly**, 317-276-2000*