Stemline’s Orserdu approved for patients with ESR1 mutations

Jan. 31, 2023—The U.S. Food and Drug Administration has approved Stemline Therapeutics’ Orserdu (elacestrant) for the treatment of postmenopausal women or adult men with ER+, *HER2*-, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. The FDA also approved the Guardant360 CDx assay (Guardant Health) as a companion diagnostic device to identify patients with breast cancer for treatment with Orserdu.

Efficacy was evaluated in EMERALD (NCT03778931), a randomized, open-label, active-controlled, multicenter trial that enrolled 478 postmenopausal women and men with ER-positive, HER2-negative advanced or metastatic breast cancer of which 228 patients had *ESR1* mutations. Patients were required to have disease progression on one or two prior lines of endocrine therapy, including one line containing a CDK4/6 inhibitor.

Orserdu was granted priority review and fast track designation by the FDA.