

In ER+/HER2- mBC following progression on ET + CDK4/6i,

ORSERDU is the standard of care for ESR1m in 2nd Line



#### Dear Healthcare Professional,

The 2nd Line treatment landscape in ER+/HER2- mBC is complex, testing for *ESR1* mutations is key to identify treatment options.<sup>1,2</sup>

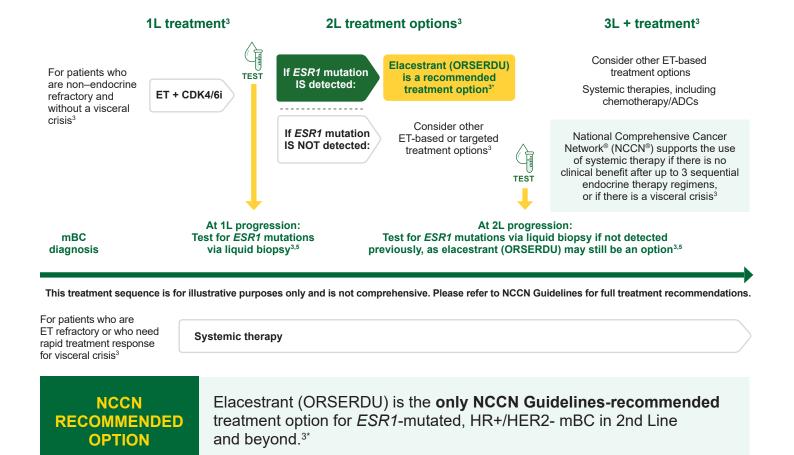
NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommend evaluating *ESR1* mutation status using next generation sequencing or PCR, preferably with blood samples. NCCN Guidelines® do not recommend testing with primary archived tissue given the acquired nature of *ESR1* mutations.<sup>3,4</sup>

The NCCN Guidelines-recommended sequential endocrine therapy for HR+/HER2-mBC patients and the choice of elacestrant as a 2nd Line option for those detected with *ESR1* mutations upon 1st Line progression is illustrated in the flowchart below.

ORSERDU is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, *ESR1*-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

#### In ER+/HER2- mBC

#### After progression on 1L ET + CDK4/6i, Test for *ESR1* mutations. Treat with elacestrant (ORSERDU).



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#### **SELECT IMPORTANT SAFETY INFORMATION**

- The labeling for ORSERDU contains warnings and precautions for dyslipidemia, and embryo-fetal toxicity.
- The most common serious adverse reactions in ≥1% of patients who received ORSERDU were musculoskeletal pain and nausea.
- The most common adverse reactions, including laboratory abnormalities, in ≥10% of patients who received ORSERDU were musculoskeletal pain, nausea, increased cholesterol, increased AST, increased triglycerides, fatigue, decreased hemoglobin, vomiting, increased ALT, decreased sodium, increased creatinine, decreased appetite, diarrhea, headache, constipation, abdominal pain, hot flush, and dyspepsia.

Please see additional Important Safety Information below.

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## Warnings and Precautions

- Dyslipidemia: Hypercholesterolemia and hypertriglyceridemia occurred in patients taking ORSERDU at an incidence of 30% and 27%, respectively. The incidence of Grade 3 and 4 hypercholesterolemia and hypertriglyceridemia were 0.9% and 2.2%, respectively. Monitor lipid profile prior to starting and periodically while taking ORSERDU.
- Embryo-Fetal Toxicity: Based on findings in animals and its mechanism of action, ORSERDU can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with ORSERDU and for 1 week after the last dose.

#### Adverse Reactions

- **Serious adverse reactions** occurred in 12% of patients who received ORSERDU. Serious adverse reactions in >1% of patients who received ORSERDU were musculoskeletal pain (1.7%) and nausea (1.3%). Fatal adverse reactions occurred in 1.7% of patients who received ORSERDU, including cardiac arrest, septic shock, diverticulitis, and unknown cause (one patient each).
- The most common adverse reactions (≥10%), including laboratory abnormalities, of ORSERDU were musculoskeletal pain (41%), nausea (35%), increased cholesterol (30%), increased AST (29%), increased triglycerides (27%), fatigue (26%), decreased hemoglobin (26%), vomiting (19%), increased ALT (17%), decreased sodium (16%), increased creatinine (16%), decreased appetite (15%), diarrhea (13%), headache (12%), constipation (12%), abdominal pain (11%), hot flush (11%), and dyspepsia (10%).

## Drug Interactions

 Concomitant use with CYP3A4 inducers and/or inhibitors: Avoid concomitant use of strong or moderate CYP3A4 inhibitors with ORSERDU. Avoid concomitant use of strong or moderate CYP3A4 inducers with ORSERDU.

# Use in Specific Populations

- Lactation: Advise lactating women to not breastfeed during treatment with ORSERDU and for 1 week after the last dose.
- **Hepatic Impairment:** Avoid use of ORSERDU in patients with severe hepatic impairment (Child-Pugh C). Reduce the dose of ORSERDU in patients with moderate hepatic impairment (Child-Pugh B).

The safety and effectiveness of ORSERDU in pediatric patients have not been established.

ORSERDU is available as 345 mg tablets and 86 mg tablets.

To report SUSPECTED ADVERSE REACTIONS, contact Stemline Therapeutics, Inc. at 1-877-332-7961 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

## Please click $\underline{\text{here}}$ to see the full Prescribing Information.

For State pricing disclosures for ORSERDU®, please click <u>HERE</u>.

**Abbreviations:** 1L, first line; 2L, second line; 3L, third line; ALT, alanine aminotransferase; AST, aspartate aminotransferase; ADCs, adjuvant drug compounds; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; ER+, estrogen receptor-positive; *ESR1*, estrogen receptor 1; *ESR1*m, estrogen receptor 1 mutation; ET, endocrine therapy; HER2-, human epidermal growth factor receptor 2-negative; HR+, hormone receptor-positive; mBC, metastatic breast cancer; NCCN, National Comprehensive Cancer Network; PCR, polymerase chain reaction.

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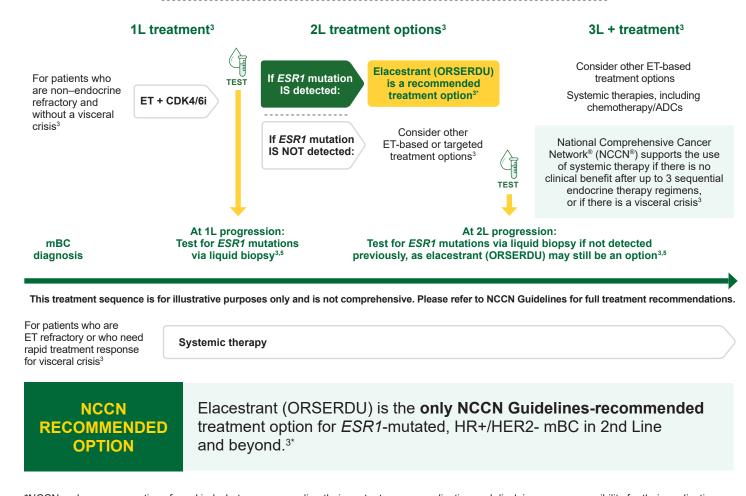
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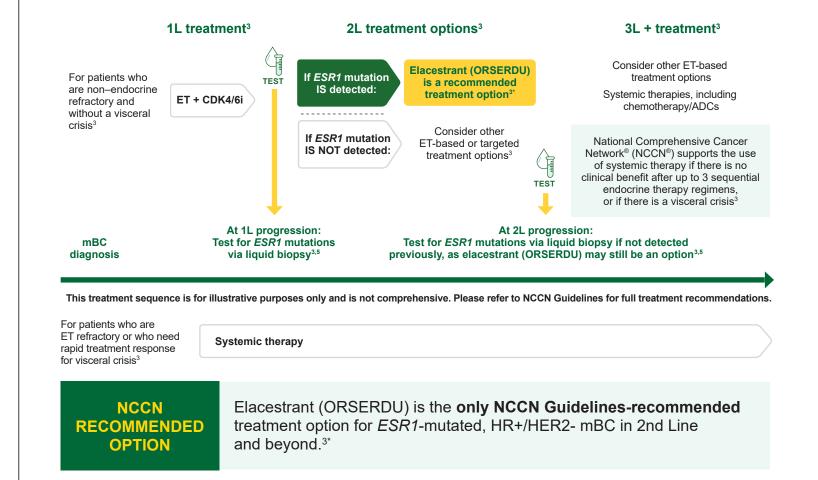
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