

To: [HCP's email address]
From: [Variable friendly from] <[Variable from]>
Subject Line: [Variable subject line]
Preheader: [Variable preheader]

Guidelines
Recommended
Option

In ER+/HER2- mBC following
progression on ET + CDK4/6i,
**ORSERDU is the
standard of care for
ESR1m in 2nd Line**

ONCE-DAILY

ORSERDU[®]
elacestrant
345 mg-86 mg tablets

Dear **Healthcare Professional,**

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

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.^{3,4}

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).

1L treatment³

ET + CDK4/6i

TEST

If *ESR1* mutation
IS detected:
Elacestrant (ORSERDU)
is a recommended
treatment option³

If *ESR1* mutation
IS NOT detected:
Consider other
ET-based or targeted
treatment options³

TEST

At 1L progression:
Test for *ESR1* mutations
via liquid biopsy^{3,5}

At 2L progression:
Test for *ESR1* mutations via liquid biopsy if not detected
previously, as elacestrant (ORSERDU) may still be an option^{3,5}

At 3L + treatment³

Consider other ET-based
treatment options
Systemic therapies, including
chemotherapy/ADCs

National Comprehensive Cancer
Network[®] (NCCN[®]) supports the use
of systemic therapy if there is no
clinical benefit after up to 3 sequential
endocrine therapy regimens,
or if there is a visceral crisis³

mBC
diagnosis

For patients who are
non-endocrine
refractory and
without a visceral
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Systemic therapy

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Elacestrant (ORSERDU) is the **only NCCN Guidelines-recommended**
treatment option for *ESR1*-mutated, HR+/HER2- mBC in 2nd Line
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*NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. Refer to the NCCN Guidelines for all the recommendations.

Discover the efficacy and
safety of ORSERDU

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.

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Learn more about ORSERDU

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IMPORTANT SAFETY INFORMATION

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).
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Drug Interactions

- **Concomitant use with CYP3A4 inducers and/or inhibitors:** Avoid concomitant use of strong or moderate CYP3A4 inducers 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.
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The safety and effectiveness of ORSERDU in pediatric patients have not been established.

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