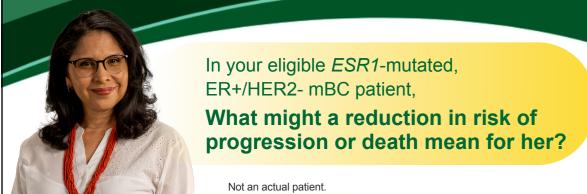
Preheader: [Variable preheader]



ORSERDU*

345 mg • 86 mg tablets

Dear Healthcare Professional.

Patients in the EMERALD trial with ESR1-mutated, ER+/HER2- mBC had a 45% reduction in the risk of progression or death with ORSERDU.

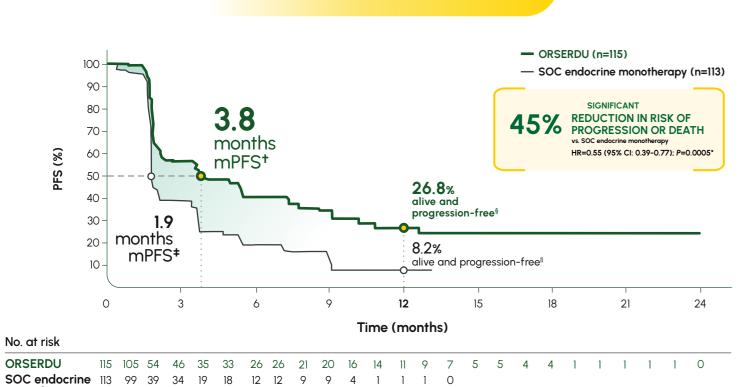
ORSERDU is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

In the EMERALD study, ORSERDU doubled the mPFS compared to SOC (fulvestrant or an Al [anastrozole, letrozole, or exemestane]) in patients with ESR1-mutated, ER+/HER2- mBC following progression on ET + CDK4/6i.1

Primary endpoint in EMERALD:

PFS in patients with ESR1-mutated mBC1-3

2X mPFS with ORSERDU vs. SOC12



ORSERDU reduced the risk of progression or death by 45% vs. SOC endocrine therapy.^{1,2}

Absolute difference in mPFS of 1.9 months between SOC and ORSERDU arms²

- Landmark analysis PFS rates at 3, 6, 12, and 18 months (95% CI): 55.9% (45.8-66.1) with ORSERDU vs. 39.6% (29.4-49.7) with SOC endocrine monotherapy; 40.8% (30.1-51.4) with ORSERDU vs. 19.1% (10.5-27.8) with SOC endocrine monotherapy; 26.8% (16.2-37.4) with ORSERDU vs. 8.2% (1.3-15.1) with SOC endocrine monotherapy; and 24.3% (13.7-35.0) with ORSERDU vs. not evaluable with SOC endocrine monotherapy, respectively. 1,3
- The landmark PFS analyses at 3, 6, 12, and 18 months in patients with *ESR1*-mutated mBC were prespecified endpoints of the EMERALD trial.3
- *HR and P value refer to the entire PFS curve.1 95% CI: 2.2-7.3.2 95% CI: 1.9-2.1.2 95% CI: 16.2-37.4.1 95% CI: 1.3-15.1.1

Learn more about 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.

Please see additional Important Safety Information below.

STUDY DESIGN: EMERALD was an open-label, global, phase 3 trial of postmenopausal women or men with confirmed ER+/HER2- advanced or metastatic breast cancer (N=478) who had progressed after 1-2 lines of ET, at least one in combination with a CDK4/6i, randomized (1:1) to receive ORSERDU or endocrine therapy (fulvestrant) or an aromatase inhibitor (anastrozole, letrozole or exemestane). A major efficacy endpoint was PFS by BIRC in patients with ESR1 mutations (n=228). A post-hoc, exploratory analysis evaluated efficacy and safety in patients with ESR1 mutations treated with prior ET + CDK4/6i ≥12 months (n=159). 1,2

Learn more about ORSERDU

Click here to request more information from a sales representative.

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).
- 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 here to see the full Prescribing Information.

For State pricing disclosures for ORSERDU[®], please click HERE

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BIRC, blinded independent review committee; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; CI, confidence interval; ER+, estrogen receptor-positive; ESR1, estrogen receptor 1; ET, endocrine therapy; HER2-, human epidermal growth factor receptor 2-negative; HR, hazard ratio; mBC, metastatic breast cancer; mPFS, median progression-free survival; PFS, progression-free survival SOC, standard of care.

References: 1. Bidard FC, Kaklamani VG, Neven P, et al. Elacestrant (oral selective estrogen receptor degrader) versus standard endocrine therapy for estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer: results from the randomized phase III EMERALD trial. J Clin Oncol. 2022;40(28):3246-3256. 2. ORSERDU [prescribing information]. New York, NY: Stemline Therapeutics, Inc., a Menarini Group Company; 2023. 3. Data on file. Stemline Therapeutics, Inc., a Menarini Group Company.



ORSERDU is a registered trademark of the Menarini Group.

© 2025 Stemline Therapeutics, Inc., a Menarini Group Company. All rights reserved. 03/25 MAT-US-ELA-00622-v2

Privacy and Terms of Use | CCPA Policy | Cookie Policy | Unsubscribe

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



Not an actual patient.

ORSERDU* 345 mg • 86 mg tablets

Dear Healthcare Professional.

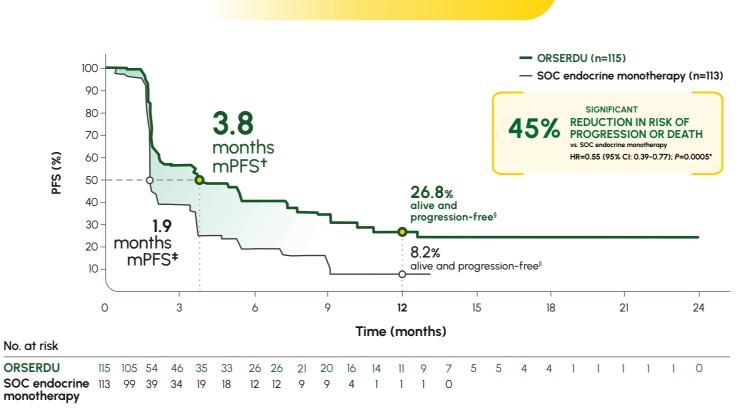
Patients in the EMERALD trial with ESR1-mutated, ER+/HER2- mBC had a 45% reduction in the risk of progression or death with ORSERDU.

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 the EMERALD study, ORSERDU doubled the mPFS compared to SOC (fulvestrant or an AI [anastrozole, letrozole, or exemestane]) in patients with ESR1-mutated, ER+/HER2- mBC following progression on ET + CDK4/6i.1

Primary endpoint in EMERALD: PFS in patients with ESR1-mutated mBC1-3

2X mPFS with ORSERDU vs. SOC12



ORSERDU reduced the risk of progression or death by 45% vs. SOC endocrine therapy.^{1,2}

Absolute difference in mPFS of 1.9 months between SOC and ORSERDU arms²

- Landmark analysis PFS rates at 3, 6, 12, and 18 months (95% CI): 55.9% (45.8-66.1) with ORSERDU vs. 39.6% (29.4-49.7) with SOC endocrine monotherapy; 40.8% (30.1-51.4) with ORSERDU vs. 19.1% (10.5-27.8) with SOC endocrine monotherapy; 26.8% (16.2-37.4) with ORSERDU vs. 8.2% (1.3-15.1) with SOC endocrine monotherapy; and 24.3% (13.7-35.0) with ORSERDU vs. not evaluable with SOC endocrine monotherapy, respectively. 1,3
- The landmark PFS analyses at 3, 6, 12, and 18 months in patients with ESR1-mutated mBC were prespecified endpoints of the EMERALD trial.3

*HR and P value refer to the entire PFS curve.1 95% CI: 2.2-7.3.2 95% CI: 1.9-2.1.2 95% CI: 16.2-37.4.1 95% CI: 1.3-15.1.1

Learn more about 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.

Please see additional Important Safety Information below.

STUDY DESIGN: EMERALD was an open-label, global, phase 3 trial of postmenopausal women or men with confirmed ER+/HER2- advanced or metastatic breast cancer (N=478) who had progressed after 1-2 lines of ET, at least one in combination with a CDK4/6i, randomized (1:1) to receive ORSERDU or endocrine therapy (fulvestrant) or an aromatase inhibitor (anastrozole, letrozole or exemestane). A major efficacy endpoint was PFS by BIRC in patients with ESR1 mutations (n=228). A post-hoc, exploratory analysis evaluated efficacy and safety in patients with ESR1 mutations treated with prior ET + CDK4/6i ≥12 months (n=159). 1,2

Learn more about ORSERDU

Click here to request more information from a sales representative.

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).
- 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

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 here to see the full Prescribing Information.

For State pricing disclosures for ORSERDU®, please click HERE.

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BIRC, blinded independent review committee; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; CI, confidence interval; ER+, estrogen receptor-positive; ESR1, estrogen receptor 1; ET, endocrine therapy; HER2-, human epidermal growth factor receptor 2-negative; HR, hazard ratio; mBC, metastatic breast cancer; mPFS, median progression-free survival; PFS, progression-free survival SOC, standard of care.

References: 1. Bidard FC, Kaklamani VG, Neven P, et al. Elacestrant (oral selective estrogen receptor degrader) versus standard endocrine therapy for estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer: results from the randomized phase III EMERALD trial. J Clin Oncol. 2022;40(28):3246-3256. 2. ORSERDU [prescribing information]. New York, NY: Stemline Therapeutics, Inc., a Menarini Group Company; 2023. 3. Data on file. Stemline Therapeutics, Inc., a Menarini Group Company.



A Menarini Group Company

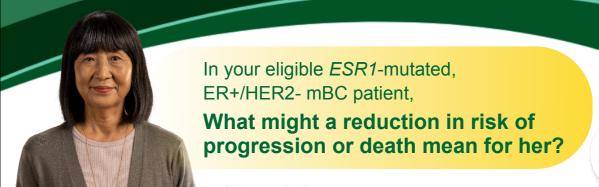
ORSERDU is a registered trademark of the Menarini Group. © 2025 Stemline Therapeutics, Inc., a Menarini Group Company.

All rights reserved. 03/25 MAT-US-ELA-00622-v2

Privacy and Terms of Use | CCPA Policy | Cookie Policy | Unsubscribe

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

Preheader: [Variable preheader]



345 mg • 86 mg tablets

Dear Healthcare Professional.

Patients in the EMERALD trial with ESR1-mutated, ER+/HER2- mBC had a 45% reduction in the risk of progression or death with ORSERDU.

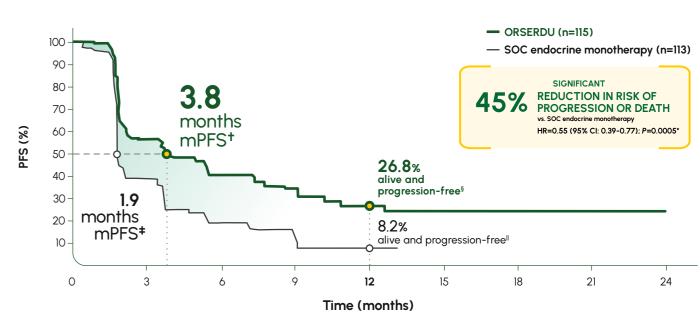
ORSERDU is indicated for the treatment of postmenopausal women or adult men with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy.

In the EMERALD study, ORSERDU doubled the mPFS compared to SOC (fulvestrant or an AI [anastrozole, letrozole, or exemestane]) in patients with ESR1-mutated, ER+/HER2- mBC following progression on ET + CDK4/6i.

Primary endpoint in EMERALD:

PFS in patients with ESR1-mutated mBC1-3





No. at risk 115 105 54 46 35 33 26 26 21 20 16 14 11 9 7 5 5 4 4 1 1 1 1 **SOC endocrine** 113 99 39 34 19 18 12 12 9 9 4 1 1 1 0

ORSERDU reduced the risk of progression or death by 45% vs. SOC endocrine therapy.^{1,2}

Absolute difference in mPFS of 1.9 months between SOC and ORSERDU arms²

- Landmark analysis PFS rates at 3, 6, 12, and 18 months (95% CI): 55.9% (45.8-66.1) with ORSERDU vs. 39.6% (29.4-49.7) with SOC endocrine monotherapy; 40.8% (30.1-51.4) with ORSERDU vs. 19.1% (10.5-27.8) with SOC endocrine monotherapy; 26.8% (16.2-37.4) with ORSERDU vs. 8.2% (1.3-15.1) with SOC endocrine monotherapy; and 24.3% (13.7-35.0) with ORSERDU vs. not evaluable with SOC endocrine monotherapy, respectively. 1,3
- The landmark PFS analyses at 3, 6, 12, and 18 months in patients with ESR1-mutated mBC were prespecified endpoints of the EMERALD trial.3

*HR and *P* value refer to the entire PFS curve.1 †95% CI: 2.2-7.3.2 ‡95% CI: 1.9-2.1.2 \$95% CI: 16.2-37.4.1 195% CI: 1.3-15.1.1

Learn more about 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.

Please see additional Important Safety Information below.

STUDY DESIGN: EMERALD was an open-label, global, phase 3 trial of postmenopausal women or men with confirmed ER+/HER2- advanced or metastatic breast cancer (N=478) who had progressed after 1-2 lines of ET, at least one in combination with a CDK4/6i, randomized (1:1) to receive ORSERDU or endocrine therapy (fulvestrant) or an aromatase inhibitor (anastrozole, letrozole or exemestane). A major efficacy endpoint was PFS by BIRC in patients with ESR1 mutations (n=228). A post-hoc, exploratory analysis evaluated efficacy and safety in patients with ESR1 mutations treated with prior ET + CDK4/6i ≥12 months (n=159). 1,2

Learn more about ORSERDU >

Click here to request more information from a sales representative.

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).

 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

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 here to see the full Prescribing Information.

For State pricing disclosures for ORSERDU®, please click HERE

Abbreviations: ALT, alanine aminotransferase; AST, aspartate aminotransferase; BIRC, blinded independent review committee; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; CI, confidence interval; ER+, estrogen receptor-positive; ESR1, estrogen receptor 1; ET, endocrine therapy; HER2-, human epidermal growth factor receptor 2-negative; HR, hazard ratio; mBC, metastatic breast cancer; mPFS, median progression-free survival; PFS, progression-free surviva SOC, standard of care.

References: 1. Bidard FC, Kaklamani VG, Neven P, et al. Elacestrant (oral selective estrogen receptor degrader) versus standard endocrine therapy for estrogen receptor-positive, human epidermal growth factor receptor 2-negative advanced breast cancer: results from the randomized phase III EMERALD trial. J Clin Oncol. 2022;40(28):3246-3256. 2. ORSERDU [prescribing information]. New York, NY: Stemline Therapeutics, Inc., a Menarini Group Company; 2023. 3. Data on file. Stemline Therapeutics, Inc., a Menarini Group Company.



ORSERDU is a registered trademark of the Menarini Group.

© 2025 Stemline Therapeutics, Inc., a Menarini Group Company. All rights reserved. 03/25 MAT-US-ELA-00622-v2

Privacy and Terms of Use | CCPA Policy | Cookie Policy | Unsubscribe