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GOSERELIN DOSING OPTIONS INCLUDED IN THE NATIONAL COMPREHENSIVE CANCER NETWORK® (NCCN) BREAST CANCER GUIDELINES

Deerfield, IL – February 5, 2024 – TerSera Therapeutics LLC announced today that The National Comprehensive Cancer Network® (NCCN) Breast Cancer Panel included both goserelin 3.6 mg every 4 weeks and goserelin 10.8 mg every 12 weeks, as methods for ovarian function suppression in Version 1.2024 of the Breast Guidelines revised as of January 25, 2024.¹

"In addition to the 3.6 mg monthly dose, I am pleased to see that NCCN recognizes the role of goserelin 10.8 mg every 12 weeks as an option for premenopausal women with hormone receptor positive (HR+) breast cancer," said Virginia Kaklamani, MD, Professor of Medicine in the Division of Hematology and Medical Oncology at the University of Texas Health Sciences Center San Antonio and leader of the breast cancer program at the Mays Cancer Center, home to UT Health San Antonio MD Anderson.

The inclusion of goserelin 10.8 mg every 12 weeks in the breast cancer guidelines as a method for ovarian function suppression is a category 2A recommendation. Multiple international studies have evaluated the safety and efficacy of goserelin 10.8 mg every 12 weeks for ovarian function suppression in premenopausal patients with HR+ breast cancer.²⁻⁵

In the United States, ZOLADEX® (goserelin implant) 3.6 mg is the only dosage form approved for use in breast cancer. ZOLADEX 10.8 mg is not approved by FDA for breast cancer. Please see the full Prescribing Information for [ZOLADEX 3.6 mg](#) and [ZOLADEX 10.8 mg](#) and additional Important Safety Information below.

Worldwide, ZOLADEX 3.6mg is approved for use in breast cancer in 125 countries. Additionally, ZOLADEX 10.8mg is approved for use in breast cancer in over 60 countries, with multiple additional regulatory reviews underway.

This is the third update to NCCN guidelines regarding goserelin over the past few months related to head and neck cancers (V1.2024), ovarian cancer (V1.2024), and breast cancer (V1.2024).

About ZOLADEX® (goserelin implant)

ZOLADEX is an injectable luteinizing hormone-releasing hormone agonist (LHRHa) used to treat prostate cancer, breast cancer, and certain benign gynecological disorders. First approved in the U.S. in 1989, ZOLADEX is available as a 3.6 mg implant dosed every 28 days or as a 10.8 mg implant dosed every 12 weeks.^{6,7}

U.S. INDICATIONS

ZOLADEX 3.6 mg and ZOLADEX 10.8 mg are indicated for:

- Management of locally confined Stage T2b-T4 (Stage B2-C) carcinoma of the prostate in combination with flutamide. Treatment with ZOLADEX and flutamide should start 8 weeks prior to initiating radiation therapy and continue during radiation therapy.
- Palliative treatment of advanced carcinoma of the prostate.



ZOLADEX 3.6 mg is also indicated for:

- Management of endometriosis, including pain relief and reduction of endometriotic lesions for the duration of therapy. Experience with ZOLADEX for the management of endometriosis has been limited to women 18 years of age and older treated for 6 months.
- Use as an endometrial-thinning agent prior to endometrial ablation for dysfunctional uterine bleeding.
- Palliative treatment of advanced breast cancer in pre- and perimenopausal women.

IMPORTANT SAFETY INFORMATION

Anaphylactic reactions to ZOLADEX have been reported in the medical literature. ZOLADEX is contraindicated in patients with a known hypersensitivity to GnRH, GnRH agonist analogues, or any of the components in ZOLADEX.

ZOLADEX is contraindicated during pregnancy unless used for palliative treatment of advanced breast cancer. ZOLADEX can cause fetal harm when administered to a pregnant woman. If used during pregnancy, the patient should be apprised of the potential hazard to the fetus. There is an increased risk for pregnancy loss due to expected hormonal changes that occur with ZOLADEX treatment. ZOLADEX should not be given to women with undiagnosed abnormal vaginal bleeding.

Pregnancy must be excluded for use in benign gynecological conditions. Women should be advised against becoming pregnant while taking ZOLADEX. Effective nonhormonal contraception must be used by all premenopausal women during ZOLADEX therapy and for 12 weeks following discontinuation of therapy.

Transient worsening of tumor symptoms, or the occurrence of additional signs and symptoms of breast cancer, may occasionally develop during the first few weeks of treatment. Some patients may experience a temporary increase in bone pain. Monitor patients at risk for complications of tumor flare.

Hyperglycemia and an increased risk of developing diabetes or worsening of glycemic control in patients with diabetes have been reported in men receiving GnRH agonists like ZOLADEX. Monitor blood glucose levels and glycosylated hemoglobin (HbA1c) periodically and manage according to current clinical practice.

Increased risk of developing myocardial infarction, sudden cardiac death and stroke has been reported in association with use of GnRH agonists like ZOLADEX in men. Patients receiving a GnRH agonist should be monitored for symptoms and signs suggestive of development of cardiovascular disease and be managed according to current clinical practice.

Hypercalcemia has been reported in some breast cancer patients with bone metastases after starting treatment with ZOLADEX. If hypercalcemia does occur, appropriate treatment measures should be initiated.

Hypersensitivity, antibody formation and acute anaphylactic reactions have been reported with GnRH agonist analogues.

ZOLADEX may cause an increase in cervical resistance. Therefore, caution is recommended when dilating the cervix for endometrial ablation.

GnRH agonists may prolong the QT/QTc interval. Providers should consider whether the benefits of androgen deprivation therapy outweigh the potential risks in patients with congenital long QT syndrome, congestive heart failure, frequent electrolyte abnormalities, and in patients taking drugs known to prolong the QT interval. Electrolyte abnormalities should be corrected. Consider periodic monitoring of electrocardiograms and electrolytes.



Injection site injury and vascular injury including pain, hematoma, hemorrhage and hemorrhagic shock, requiring blood transfusions and surgical intervention, have been reported with ZOLADEX. Extra care should be taken when administering ZOLADEX to patients with low BMI and/or to patients receiving full dose anticoagulation.

Depression may occur or worsen in women receiving GnRH agonists.

Treatment with ZOLADEX may be associated with a reduction in bone mineral density over the course of treatment. Data suggest a possibility of partial reversibility. In women, current available data suggest that recovery of bone loss occurs on cessation of therapy in the majority of patients.

In women, the most frequently reported adverse reactions were related to hypoestrogenism. The adverse reaction profile was similar for women treated for breast cancer, dysfunctional uterine bleeding, and endometriosis.

The most commonly reported adverse reactions with ZOLADEX in clinical trials for endometriosis were: hot flashes (96%), vaginitis (75%), headache (75%), decreased libido (61%), emotional lability (60%), depression (54%), sweating (45%), acne (42%), breast atrophy (33%), seborrhea (26%), and peripheral edema (21%).

The most commonly reported adverse reactions with ZOLADEX in clinical trials for endometrial thinning were: vasodilation/hot flashes (57%), headache (32%), sweating (16%), and abdominal pain (11%).

The most commonly reported adverse reactions with ZOLADEX in breast cancer clinical trials were hot flashes (70%), decreased libido (47.7%), tumor flare (23%), nausea (11%), edema (5%), and malaise/fatigue/lethargy (5%). Injection site reactions were reported in less than 1% of patients.

For ZOLADEX 3.6 mg: Hot flashes (62%), sexual dysfunction (21%), decreased erections (18%), lower urinary tract symptoms (13%), lethargy (8%), pain (worsened in the first 30 days) (8%), edema (7%), upper respiratory infection (7%), rash (6%), and sweating (6%).

For ZOLADEX 10.8 mg: Hot flashes (64%), pain (general) (14%), gynecomastia (8%), pelvic pain (6%), and bone pain (6%).

In the locally advanced carcinoma of the prostate clinical trial, additional adverse event data were collected for the combination therapy with radiation group during both the hormonal treatment and hormonal treatment plus radiation phases of this study. Adverse experiences (incidence >5%) in both phases of this study were hot flashes (46%), diarrhea (40%), nausea (9%), and skin rash (8%). Treatment with ZOLADEX and flutamide did not add substantially to the toxicity of radiation treatment alone.

Please see Full Prescribing Information for [ZOLADEX 3.6 mg](#) and [ZOLADEX 10.8 mg](#).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit fda.gov/medwatch or call 1-800-FDA-1088. You can also contact TerSera Therapeutics at 1-844-334-4035 or medicalinformation@tersera.com.

About TerSera Therapeutics

TerSera Therapeutics is a biopharmaceutical company with a focus in oncology, acute care, and non-opioid pain management. Founded in 2016, TerSera is building new cornerstones of care through its portfolio of unique therapeutics, amplifying their ability to deliver meaningful outcomes for patients. For more information about TerSera Therapeutics, please visit tersera.com.



References

1. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Breast Cancer Version 1.2024. © National Comprehensive Cancer Network, Inc 2024. All rights reserved. [Accessed January 29, 2024]. To view the most recent and complete version of the guideline, go online to NCCN.org. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], NCCN GUIDELINES[®], and all other NCCN Content are trademarks owned by the National Comprehensive Cancer Network, Inc. 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.
2. Noguchi S, Kim HJ, Jesena A, et al. Phase 3, open-label, randomized study comparing 3-monthly with monthly goserelin in premenopausal women with estrogen receptor-positive advanced breast cancer. *Breast Cancer*. 2016; 23:771-779.
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5. Wu H, Bian L, Xie J, et al. 111P Goserelin 3 monthly depot is noninferior to goserelin monthly depot in the treatment of breast cancer: A real-world evidence study. *ESMO Open*. 2023;8(1):101335.
6. ZOLADEX (goserelin implant) 3.6 mg prescribing information. TerSera Therapeutics LLC.
7. ZOLADEX (goserelin implant) 10.8 mg prescribing information. TerSera Therapeutics LLC.

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