

FOR IMMEDIATE RELEASE

TerSera® Presents New Real-World Evidence on Treatment Outcomes of Goserelin (ZOLADEX®) in Women with Breast Cancer at the 2024 San Antonio Breast Cancer Symposium

Deerfield, IL – December 12, 2024 – TerSera Therapeutics LLC announced the presentation of new real-world analyses on the use of goserelin 3.6 mg and goserelin 10.8 mg in premenopausal women with breast cancer. These data were presented in a poster session at the 2024 San Antonio Breast Cancer Symposium, held December 10-13 in San Antonio, TX.¹ A copy of the poster is available [here](#).

This was a retrospective, observational, non-inferiority study using structured, de-identified, patient-level data and curated progress notes from U.S. electronic medical record (EMR) data from the ConcertAI Patient360™ Breast Cancer Dataset. The objective of this study was to compare real-world treatment outcomes among breast cancer patients treated with goserelin 3.6 mg and 10.8 mg.

The primary outcome was the real-world event-free survival (rwEFS) rate at 12 months to assess the non-inferiority of the goserelin 10.8 mg dose given every 12 weeks vs. the 3.6 mg dose given every 4 weeks. The 12-month rwEFS rates for goserelin 3.6 mg and goserelin 10.8 mg, respectively, were 76.6% vs. 79.2% (treatment difference: 2.7% [95% CI: -1.8%, 7.0%]) which supports the non-inferiority of goserelin 10.8 mg to goserelin 3.6 mg at the prespecified -15% margin based on previously published oncology trials. In evaluating time to discontinuation, this study also found that more patients remained on goserelin 10.8 mg than 3.6 mg at years 1 and 2 post treatment initiation (51.2% vs. 39.6% and 32.4% vs. 23.1%, respectively), supporting previously published data in a separate real-world evidence analysis of breast cancer patients receiving goserelin 10.8 mg.²

“Ovarian function suppression (OFS) with gonadotropin-releasing hormone agonists (GnRHAs) is an essential component of therapy for a large proportion of pre- or perimenopausal women with hormone-sensitive breast cancer,” said Kelly E. McCann, M.D., Ph.D., assistant clinical professor of medicine at the UCLA Health David Geffen School of Medicine. “ZOLADEX 3.6 mg given every 4 weeks is the only FDA-approved GnRHa for women with breast cancer. Our data suggests that the 10.8 mg dose given every 12 weeks may also be an effective option.”

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/safety/medwatch or call 1-800-FDA-1088. You can also contact TerSera Therapeutics at 1-844-334-4035 or medicalinformation@tersera.com.

About HR-positive breast cancer

Breast cancer is the second most commonly diagnosed cancer and one of the leading causes of cancer-related deaths worldwide.³ In the United States, over 310,000 women will be diagnosed with breast cancer this year; 40,000 will be under the age of 50.⁴ Approximately 75% of diagnosed cases in women under age 50 are considered to be hormone positive (HR+) breast cancer. Compared to older women, young women generally face more aggressive cancers and lower survival rates.⁵⁻⁷ Recent studies have shown that breast cancer before age 40 differs biologically from the cancer faced by older women.^{6,7}



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. Worldwide, ZOLADEX 3.6 mg is approved for use in breast cancer in 125 countries. ZOLADEX 10.8 mg is approved for use in breast cancer in over 60 countries.

About TerSera Therapeutics

TerSera Therapeutics is a biopharmaceutical company with a focus in oncology 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. TerSera has been recognized as a 2024 Top Workplace. For additional information, please visit [TerSera.com](https://www.tersera.com) and follow us on [LinkedIn](#).

References

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