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TerSera® Presents Real-World Evidence on Treatment Patterns of Goserelin (ZOLADEX®) in Women with Breast Cancer at the 2024 American Society of Clinical Oncology (ASCO) Quality Care Symposium

Deerfield, IL – October 2, 2024 – TerSera Therapeutics LLC announced today the presentation of new real-world analyses on the treatment patterns of goserelin in women with breast cancer. The data were presented in a poster session at the 2024 American Society of Clinical Oncology (ASCO) Quality Care Symposium, held September 27th and 28th in San Francisco, CA.[1] A copy of the poster is available here.

The goal of this study was to demonstrate the characteristics of US patients with a diagnosis of breast cancer treated with either goserelin 3.6 mg or 10.8 mg and analyze goserelin treatment patterns using real-world evidence (RWE). This retrospective study used US electronic health record data through TriNetX, a global healthcare research network. The study included adult women with a history of breast cancer and with ≥2 prescriptions of goserelin between January 2017 – December 2022. Follow-up occurred until March 15, 2024.

Overall, 3,620 patients were identified: 2,870 treated with goserelin 3.6 mg, 410 with goserelin 10.8 mg, and 340 who switched from goserelin 3.6 mg to 10.8 mg. Patient demographics, treatment adherence, and healthcare resource utilization (HCRU) were examined and summarized using descriptive analytics.

“For young women with hormone-sensitive breast cancer at high-risk of relapse, suppression of ovarian function is an essential component of their long-term treatment plan," said Lonnie Brent, Pharm.D., Senior Vice President, Medical and Scientific Affairs for TerSera. “This real-world evidence presented at the ASCO Quality Care Symposium increases our understanding of the current treatment patterns for young women with breast cancer receiving goserelin."

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.[2] 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.[3] 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.[4,5] Recent studies have shown that breast cancer before age 40 differs biologically from the cancer faced by older women.[6]

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 Healthcare Top Workplace. For additional information, please visit tersera.com and follow us on LinkedIn.

References

1. Treatment patterns of goserelin 3.6 mg once monthly and 10.8 mg every three months in women with breast cancer: a real-world analysis. McCann KE, Kaklamani V, Osman N, et al. Poster presented at the American Society of Clinical Oncology (ASCO) Quality Care Symposium, September 27-28, 2021. Abstract #391; Poster Session B Poster F19.
2. Bray F, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. CA Cancer J Clin. 2024 Apr 4. doi: 10.3322/caac.21834.
3. National Cancer Institute. Surveillance, Epidemiology and End Results Program. Accessed September 2024.
4. Carey K. Anders et al., "Breast Carcinomas Arising at a Young Age: Unique Biology or a Surrogate for Aggressive Intrinsic Subtypes?" Journal of Clinical Oncology 29, no. 1 (2011): e18-e20.
5. Carey K. Anders et al., "Young Age at Diagnosis Correlates with Worse Prognosis and Defines a Subset of Breast Cancers with Shared Patterns of Gene Expression," Journal of Clinical Oncology 26, no. 10 (2008): 3324-3330.
6. Ann H. Partridge et al., “Breast Cancer in Younger Women,” Diseases of the Breast (4th ed.,), In J. Harris (Ed.) (2010): 1073-1083.