WILSERDLY™
giredestrant | 30 mg capsules

# lidERA Breast Cancer Trial Fact Sheet

WILSERDLY™ (giredestrant) is a prescription medicine used alone to treat adults with estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer that is in early stages (stage I, II, III) at intermediate to high risk of cancer coming back.

## What is HR+, HER2- breast cancer?

Hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer **is the most common form of breast cancer**, accounting for roughly **70% of all cases.**[1]



Approximately **225,000 U.S. women** will be diagnosed with HR+, HER2- breast cancer this year.[1,2]

**Estrogen receptor-positive (ER+) breast cancer** is the most common subtype of HR+ breast cancer.[2] ER+ means the cancer uses estrogen to fuel its growth.[2] HER2- means the tumor cells have little to no HER2 protein—a protein that, when present in high levels, accelerates cancer growth.[3,4]

## What is the lidERA breast cancer study?

lidERA is a Phase III clinical trial involving 4,170 people across multiple medical centers around the world.[5,6] The trial compared the efficacy and safety of WILSERDLY, a once-daily oral medication, with doctor's choice of hormone therapy (tamoxifen or aromatase inhibitor) to understand whether WILSERDLY could reduce the risk of breast cancer returning after surgery.[5]

## Who participated in the trial?

The study enrolled certain patients with stage I–III ER+, HER2- breast cancer who had a medium to high risk of their cancer returning after surgery.[5]

## What is the most important information I should know about WILSERDLY?

WILSERDLY can cause serious side effects like a slow heart rate. In women who are pregnant or planning to be, WILSERDLY can harm an unborn baby.

## How was the trial designed?

Participants were randomly assigned to receive either WILSERDLY or their doctor's choice of hormone therapy (tamoxifen or aromatase inhibitor).[5]

The trial measured invasive disease-free survival, which means the primary goal was to measure whether patients taking WILSERDLY lived longer without their cancer returning after surgery or certain other invasive cancer events occurring compared to patients taking tamoxifen or aromatase inhibitors.[5]

## What did the trial results show?

The lidERA study met its main goal, showing that WILSERDLY outperformed hormone therapies tested (tamoxifen and aromatase inhibitors) across key measures.[7] WILSERDLY significantly reduced the risk of invasive cancer returning or death by **30%** compared to tamoxifen or aromatase inhibitors.[7] Among patients treated with WILSERDLY, the most common side effects were muscle and joint pain, hot flush, and fatigue.[7] Compared with standard endocrine therapy, **13%** of patients temporarily interrupted treatment due to side effects, **5%** discontinued treatment because of side effects, and **11%** experienced a serious side effect.[7]

**This infographic is intended for U.S. consumer media only as background context for news reporting. The information provided is intended for reference purposes only and is not comprehensive of all aspects of breast cancer or available treatment options.**

## Important Safety Information

**What is WILSERDLY™?**
WILSERDLY is a prescription medicine used alone to treat adults with estrogen receptor-positive (ER+), human epidermal growth factor receptor 2-negative (HER2-) breast cancer that is in early stages (stage I, II, III) at intermediate to high risk of cancer coming back.

It is not known if WILSERDLY is safe and effective in children.

**What are the possible side effects of WILSERDLY?**
**WILSERDLY can cause serious side effects, including:**

- **Slow heart rate (bradycardia)**. WILSERDLY can cause your heart rate to slow down. Your healthcare provider will monitor your heart rate more frequently if you have a history of a slow heart rate or take certain heart medicines. Tell your healthcare provider if you develop any signs and symptoms of a slow heart rate, including:
  - dizziness
  - lightheadedness
  - fainting
  - shortness of breath
  - chest pain
  - tiredness

**The most common side effects and abnormal blood test results of WILSERDLY include:**

- muscle and joint pain
- decreased white blood cell counts
- increased liver enzymes (aspartate aminotransferase [AST], alanine aminotransferase [ALT], and alkaline phosphatase [ALP])
- sudden feelings of heat and sweating (hot flash)
- increased triglycerides and cholesterol blood levels
- tiredness
- decreased red blood cell counts
- increased calcium blood levels
- headache
- decreased calcium blood levels
- increased potassium blood levels
- increased creatinine blood levels (kidney function test)
- nausea
- decreased sodium blood levels
- slow heart rate
- decreased potassium blood levels
- COVID-19

WILSERDLY may affect fertility in males and in females who are able to become pregnant. Talk to your healthcare provider if this is a concern for you.

These are not all the possible side effects of WILSERDLY.

**Before taking WILSERDLY, tell your healthcare provider about all of your medical conditions, including if you:**

- have a slow heart rate (bradycardia)
- are pregnant or plan to become pregnant. WILSERDLY can harm your unborn baby
- **Females who are able to become pregnant:**
  - Your healthcare provider will do a pregnancy test before you start treatment with WILSERDLY.
  - Use effective non-hormonal birth control (contraception) during treatment with WILSERDLY, and for 2 weeks after the last dose of WILSERDLY. Talk to your healthcare provider about birth control methods that may be right for you.
  - Tell your healthcare provider right away if you become pregnant during treatment with WILSERDLY or think you may be pregnant.
- **Males with female partners who are able to become pregnant:**
  - Use effective birth control (contraception) during treatment with WILSERDLY, and for 2 weeks after the last dose of WILSERDLY.
- are breastfeeding or plan to breastfeed. It is not known if WILSERDLY passes into your breast milk. **Do not** breastfeed during treatment with WILSERDLY, and for 2 weeks after the last dose of WILSERDLY. Talk to your healthcare provider about the best way to feed your baby during this time.
- have an intolerance to some sugars found in milk and milk products. WILSERDLY capsules contain lactose monohydrate.

**Tell your healthcare provider about all the medicines you take**, including prescription medicines, and over-the-counter medicines, vitamins, and herbal supplements. Taking WILSERDLY with certain other medicines may affect how WILSERDLY works and may cause side effects. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**What should I avoid while taking WILSERDLY?**
Avoid eating grapefruit and drinking grapefruit juice during treatment with WILSERDLY.
Grapefruit may increase the amount of WILSERDLY in your blood.

Talk to your healthcare provider for more information about the benefits and risks of WILSERDLY.

**You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555**

Please see Important Safety Information as well as the WILSERDLY full Prescribing Information and Patient Information.

References:


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1 DNA Way, South San Francisco, CA 94080-4990


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M-US-00034253(v1.0) 11/26