Dear Valued Customer,

Today, the U.S. Food and Drug Administration (FDA) approved Guardant360® CDx liquid biopsy test as a companion diagnostic (CDx) to identify advanced breast cancer patients with *ESR1* mutations for treatment with ORSERDU™ (elacestrant), a nonsteroidal selective estrogen receptor degrader, developed and commercialized by Stemline, a Menarini Group Company. ORSERDU is indicated in the second- and third-line settings for patients with estrogen receptor (ER)-positive/HER2-negative advanced or metastatic breast cancer whose tumors harbor *ESR1* mutations.

For the first time, advanced breast cancer patients with *ESR1* mutations have an FDA-approved treatment with ORSERDU, along with the only liquid CDx test, Guardant360 CDx, to identify these patients who may benefit most.

- ***ESR1* mutations are present in up to 50% of ER+/HER2- advanced breast cancers[1]**
- **Patients with *ESR1* mutations who received ORSERDU in the phase 3 EMERALD trial had a 45% reduced risk of disease progression over standard of care (SOC) and a median progression-free survival (PFS) of 3.8 vs. 1.9 months[2]**

We are proud to offer Guardant360 CDx, the first FDA-approved liquid biopsy for comprehensive genomic profiling across all advanced solid tumors, as a CDx for these patients who have not previously had access to an approved therapy.

CHOOSE G360 CDX FOR YOUR ADVANCED BREAST CANCER PATIENTS

For any questions, do not hesitate to reach out to Guardant Health Client Services.

- By email at clientservices@guardanthealth.com
- By phone at 855.698.8887

Sincerely,
Guardant Health

1. Turner (Ring) et al 2020, Circulating tumor DNA analysis to direct therapy in advanced breast cancer (plasmaMATCH); Bidard (Bardia) et al 2022, Elacestrant 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
2. https://pubmed.ncbi.nlm.nih.gov/35584336/

Disclaimers
ORSERDU™ is a trademark of Stemline, a Menarini Group Company.

For the complete intended use statement, including companion diagnostic indications, please see the Guardant360 CDx Technical Information: Guardant360CDx.com/technicalinfo.