

# TRIO ENROLS FIRST PATIENT IN GLOBAL PHASE 3 GIREDESTRANT EARLY BREAST CANCER TRIAL

**Edmonton, AB, August 31, 2021** – Translational Research in Oncology (TRIO), a global academic clinical research organization, announced today enrolment of first patient in the LidERA Breast Cancer (TRIO045) trial, a Phase 3 randomized, multi-center, open-label global clinical trial of adjuvant endocrine therapy, giredestrant (GDC-9545) sponsored by F. Hoffmann-LaRoche.

Giredestrant is an oral selective estrogen receptor degrader (SERD) that was shown to be well tolerated with encouraging anti-tumour activity both alone and in combination with palbociclib in estrogen-receptor positive (ER+) metastatic breast cancer patients.

The two-arm trial is evaluating the efficacy and safety of adjuvant giredestrant compared with physician’s choice of adjuvant endocrine monotherapy in patients with estrogen receptor-positive, HER2-negative early breast cancer. Enrolment is expected to exceed 4000 patients globally. As one of three organizations involved in enrolment and trial management, TRIO will engage its global investigator network to initiate sites across 20 countries.

After recently announcing the completion of enrolment in the randomized neoadjuvant study with giresdestrant, TRIO038/coopERA, TRIO is well positioned to continue working with Roche on this adjuvant study.

“The initiation of the pivotal LidERA trial represents a landmark step in bringing forward a novel endocrine therapy option for patients with early stage breast cancer,” stated Dr. Bardia, LidERA study Co-Chair, member of TRIO’s Scientific Committee and Director, Breast Cancer Research Program at Massachusetts General Hospital, Harvard Medical School. “Being a potent oral agent with excellent safety profile, giredestrant may enable better disease control as well as lower toxicity, thus maximizing the therapeutic benefit and compliance for patients with breast cancer.”

More information on the LidERA Breast Cancer trial