OBJECTIVES & ENDPOINTS

❖ PRIMARY OBJECTIVE
- To evaluate the biological activity of ONA by the rate of Complete Cell Cycle Arrest determined by Ki67 (±2.7%).

❖ KEY SECONDARY AND EXPLORATORY OBJECTIVES
- Secondary endpoints include safety and correlating biological activity with IHC of tumor expression (ER, PgR, Ser294-PgR, CD24, CD44, ALDH1, Ki67), estradiol, and progesterone blood levels, and gene expression profile (Nanostring nCounter® Breast 360TM panel).

HYPOTHESIS

Olapristone, a type 1 progesterone inhibitor, induces a significant proliferative arrest in ER+PR+/HER2-negative early breast cancer.