

Information Regarding Clinical Trial

Title	A Randomized, Open-Label, Phase 3 Study of Abemaciclib Combined with Standard Adjuvant Endocrine Therapy versus Standard Adjuvant Endocrine Therapy Alone in Patients with High Risk, Node Positive, Early Stage, Hormone Receptor Positive, Human Epidermal Receptor 2 Negative, Breast Cancer
Protocol Number	I3Y-MC-JPCF
Sponsor	Lilly
Investigator	J. Thaddeus Beck, MD 3232 N. North Hills Blvd. Fayetteville, AR 72703
Study Related Phone Numbers	479-587-1700 (24 hours)
Key Points for Study	<ul style="list-style-type: none"> - 2 years on-study tx period + endocrine tx to complete 5 yrs + 5 years f/u - Must randomize within 16 mos after definitive breast surgery - May have up to 12 weeks of endocrine tx following most recent non-endocrine therapy - May have received neoadjuvant or adjuvant chemo (21 day washout) or radiation (14 day washout) - Stage IB-IIIC - No adjuvant fulvestrant during study - No history of VTE - No previous endocrine tx for breast ca prevention - No previous tx with CDK4/6 inhibitor