Information Regarding Clinical Trial

Title	A Phase II, open-label, randomized study to compare the efficacy of Venetoclax in combination with Fulvestrant compared with Fulvestrant alone in women with ER+ HER2-, inoperable, locally advanced or metastatic breast cancer who experienced disease recurrence or progression during or after treatment with CDK4/6 therapy for at least 8 weeks.
Protocol Number	WO40181
Sponsor	Hoffman-La Roche
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	Measurable disease with at least 1 evaluable lesion. ECOG 0-1 Need fresh or archived tumor biopsy sample < 3 mo. old. (No FNAs) **Must have had at least 8 weeks on CDK4/6 inhibitor prior to progression.** No previous XRT to **target** lesions. No untreated or active CNS metastases No previous tx with Fulvestrant or other SERDs. No more than 2 prior lines of hormonal therapy in the locally advanced or metastatic setting.