DCIS: RECAST Trial Ductal Carcinoma In Situ: Re-Evaluating Conditions for Active Surveillance Suitability as Treatment

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

A. Female, at least 18 years old B. Previous diagnosis of HR+ DCIS (at least 50% ER or PR; biopsy will have been performed previously at diagnosis) with or without microinvasion * Patients with a diagnosis of hormone positive DCIS who have undergone surgery with positive margins that have not been re-excised are candidates to enroll in the trial. C. Patients who have previously received endocrine therapy should have a washout period of at minimum 4-6 weeks prior to the screening MRI on the RECAST-DCIS trial D. Bilateral mammogram performed within up to 6 months (180 days) of the start of trial treatment may be used for screening evaluation. If a bilateral mammogram has been performed within 1 year (12 months) of the start of trial treatment, then a diagnostic unilateral mammogram within 6 months (180 days) of the start of trial treatment will be acceptable for screening evaluation. E. MRI performed on an I SPY (RECAST) approved scanner within 2 months (60 days) of the start of trial treatment for lesion evaluation may be used for screening evaluation. F. CBC w/ diff, CMP, and Lipid Panel within normal limits within a year of the start of trial treatment. Abnormal labs to be repeated within 60 days prior to the start of trial treatment. Patients will be considered eligible for screening labs that are abnormal or out-of-range if the investigator has deemed the lab results not-clinically significant G. Negative urine or serum pregnancy test within 1 month of the start of trial treatment H. Controlled HIV positive patients are allowed as long as their current medication does not contraindicate the study's investigational agent I. Willingness and ability to provide tumor samples for research

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Exclusion Criteria:

A. Pregnant or actively breastfeeding women B. History of allergic reactions attributed to compounds of similar chemical or biologic composition to study agent based on review of the medical record and patient history C. Invasive carcinoma or identification of a mass on MRI that is subsequently biopsied and found to be invasive cancer D. Co-enrollment in clinical trials of pharmacologic agents requiring an IND E. Ongoing treatment for DCIS other than what is specified in this protocol F. Uncontrolled intercurrent illness, including psychiatric conditions, that would limit compliance with study requirements G. Medical history or ongoing gastrointestinal disorders potentially affecting the absorption of investigational agent and/or tamoxifen. Active inflammatory bowel disease or chronic diarrhea, known active hepatitis A/B/C*, hepatic cirrhosis, short bowel syndrome, or any upper gastrointestinal surgery including gastric resection or banding procedures *Active hepatitis, defined as: A (positive HA antigen or positive IgM); B (either positive HBs antigen or positive hepatitis B viral DNA test above the lower limit of detection of the assay); C (positive hepatitis C antibody result, and quantitative hepatitis C (HCV) ribonucleic acid (RNA) results greater than the lower limits of detection of the assay) H. Participants who are unable to swallow normally or unable to take tablets and capsules. Predictable poor compliance with oral treatment

Conditions & Interventions

Interventions:
DRUG: Tamoxifen, DRUG: Exemestane, DRUG: Letrozole, DRUG: Anastrazole, DRUG: Testosterone + Anastrazole, DRUG: Elacestrant, DRUG: Z-endoxifen
Conditions:
Ductal Carcinoma in Situ
Keywords:
active surveillance, hormone therapy, endocrine therapy

More Information

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