**Freezing Instead of Resection Of Small Breast Tumors (FROST Trial): A study of cryoablation in the management of early stage breast cancer**

Emily T Ho MD, MS; Dennis R Holmes MD, FACS

John Wayne Cancer Institute at Providence St. John’s Health Center, Santa Monica, CA

**Background**

ACOSOG Z1072 demonstrated complete target tumor ablation in 92% of stage I invasive breast cancers treated with cryoablation prior to resection. We hypothesize that cryoablation can achieve complete tumor ablation and adequate local control in a selected population of women with early stage invasive breast cancer managed with cryoablation alone, without planned surgical resection.

**FROST Trial Schema**

**Primary endpoint:** determine rate of complete tumor ablation defined as absence of residual carcinoma

**Secondary endpoints:**
- 5-year ipsilateral breast tumor recurrence rate
- Breast cosmesis (assessed by BCCT.core)
- Adverse events

**Methods**

FROST trial is a phase II, single-arm, multicenter study activated June 2016 with an accrual goal of 220 subjects.

**FROST Eligibility Criteria**

- Age ≥ 50
- Unifocal primary invasive ductal carcinoma diagnosed by core needle biopsy
- Maximum tumor size ≤ 1.5 cm based on mammography, ultrasound and MRI
- Clinically node negative

Subjects will register and follow study schema below:

Those who have no residual disease will go on to receive a 5-year (minimum) course of adjuvant endocrine therapy

**ClinicalTrials.gov Identifier:** NCT01992250

FROST Trial is sponsored by Sanarus Technologies, Inc. Study P.I. Dennis R. Holmes, MD, FACS

Please contact Pam Ellis, Clinical Coordinator if interested in participating

(925) 460-6080  pellis@sanarus.com