RUSTIC

S1919

PHASE II, MULTI-ARM, **R**ANDOMIZED **U**MBRELLA **S**TUDY TO EVALUATE THE **T**HERAPEUTIC EFFICACY AND SAFETY OF **I**MMUNE-ONCOLOGY DRUG **C**OMBINATIONS IN METASTATIC BREAST CANCER

Study Chairs: Lajos Pusztai, MD, PhD
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Study Lead Statistician: William Barlow, PhD

SWOG CANCER RESEARCH NETWORK

SWOG CLINICAL TRIALS PARTNERSHIPS

Declaration

Trial funded by AstraZeneca through the Hope Foundation SWOG CTP

Statistical and Data Management Center receives support from this funding

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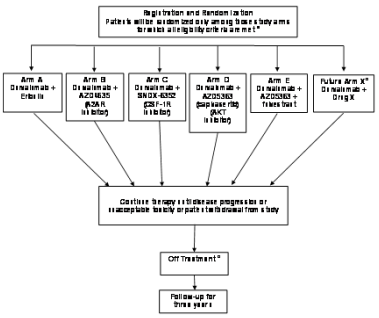
Overview

- Basic overview of the trial
- Subsequent speakers will describe additional details about RUSTIC
- S1919 (RUSTIC) Training Session
  Friday Oct 4 8:00-9:00 AM
  Wrigley (Concourse Level, West Tower)

Eligibility

- Metastatic breast cancer that is HER2-negative
- Can be either hormone-receptor positive or negative
- Either 0 or 1 lines of previous chemotherapy
- Additional eligibility for the overall trial
- Additional eligibility criteria for each treatment arm (assessed prior to randomization)



Treatment Arms

- Arms A, B, C
  - Hormone-receptor positive cohort
  - Hormone-receptor negative cohort
- Arms D, E
  - Hormone-receptor positive cohort only
- Each arm has two co-Chairs (Arms D & E share co-Chairs)

Arms

- Patients are randomized only among the arms for which they are eligible
  - HR-positive Arms A to E may be possible
  - HR-negative Arms A to C may be possible
- Each cohort operates independently
- One cohort in an arm could close but the other cohort in that arm would remain open
- Safety run-ins will be conducted for each arm where necessary

Design

- Outcome: Clinical benefit (Complete or partial response or stable disease)
- Design: Each cohort is a Simon two-stage design with up to 38 patients total
- → 8 parallel cohorts for a total of 304 patients in the overall trial
- Activation early 2020

Questions?