RUSTIC

S1919

PHASE II, MULTI-ARM, RANDOMIZED UMBRELLA STUDY TO EVALUATE THE THERAPEUTIC EFFICACY AND SAFETY OF IMMUNE-ONCOLOGY DRUG COMBINATIONS IN METASTATIC BREAST CANCER

Study Chairs: Lajos Pusztai, MD, PhD & Priyanka Sharma, MD

Study Lead Statistician: William Barlow, PhD
Declaration

Trial funded by AstraZeneca through the Hope Foundation SWOG CTP

Statistical and Data Management Center receives support from this funding
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)
Registration and Randomization
Patients will be randomized only among those study arms for which all eligibility criteria are met.

Arm A
Duvalumab + Eribulin

Arm B
Duvalumab + AZD4635 (A2AR inhibitor)

Arm C
Duvalumab + SNDX-6352 (CSF-1R inhibitor)

Arm D
Duvalumab + AZD5363 (capivasertib) (AKT inhibitor)

Arm E
Duvalumab + AZD5363 + fulvestrant

Future Arm X
Duvalumab + Drug X

Continue therapy until disease progression or unacceptable toxicity or patient withdrawal from study

Off Treatment

Follow-up for three years
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?
S1919
RUSTIC

Jacqueline Scurlock
SDMC
How is RUSTIC Different?

• Rave EDC (RUSTIC Rave) differences
• Registration Process
• Source Documentation
A whole new Rave

Rave Classic

New Rave EDC (RUSTIC Rave)
Site Level View

Rave Classic

Rave EDC (RUSTIC Rave)
Queries

Rave Classic

Rave EDC (RUSTIC Rave)
Subject Registration
Registration

Registration will happen in Rave EDC
Source Documentation

- There is no Source Documentation upload in the Rave EDC (Rustic Rave)
- Currently working on new location
- Stay tuned
Up Next is Katie Minichiello

Process Overview for RUSTIC
PROCESS OVERVIEW OF SWOG-CTP STUDIES (S1919)

Katie Minichiello
Statistics and Data Management Center
Seattle, WA
Overview

• CRA Access

• Site Access

• SAE Process
SWOG Way: CRA Access

• CRA Access
SWOG-CTP Way: CRA Access

• CRA Access
SWOG Way: Site Access

- Site Access
SWOG-CTP Way: Site Access

- Site Access
SWOG Way: SAE Process

• Reported to SWOG Operations Office using the Cancer Therapy Evaluation Program Adverse Event Reporting System (CTEP-AERS)

• Then SWOG Ops forwards reports and documentation to the appropriate regulatory agencies and drug companies as required
SWOG-CTP Way: SAE Process

- Will not use CTEP-AERS
- Report via Medidata Rave
- SWOG Ops will still forward reports and documentation to the appropriate regulatory agencies and drug companies as required
SWOG-CTP Way: SAE Process

- SAE Report
  - Reporter Information
  - Treating Physician
  - Patient Information
  - Cycle/Course Information
  - Description of Event
  - Protocol Agents
Want to learn more about S1919 (RUSTIC)?

Come to our Training Session + Kick-Off Meeting!

Friday @ 8AM in XXX

Open to all SWOG members

And light refreshments will be provided!