

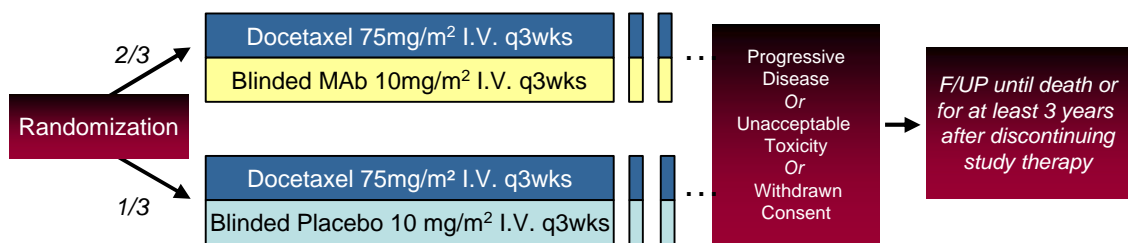
Launching a new phase III trial in HER2-negative patients to determine the activity of a MAb targeting the VEGFR-2

Study chairs: J. Mackey, MD; M. Martin, MD; K. Gelmon, MD; T. Pinter, MD.

STUDY RATIONALE

- The role of agents blocking the angiogenic pathway is still to be established in MBC.
- Docetaxel 75 mg/m² appears as a reasonable control arm based on its efficacy/safety ratio.
- We intend to test a MAb binding specifically to VEGFR-2. Its mechanism of action is different from bevacizumab which binds to the VEGF ligand.

STUDY DESIGN



STUDY OBJECTIVES

- Primary:
 - Compare PFS of the 2 combinations
- Secondary:
 - Compare OS, TTP, ORR, response duration and QoL
 - Compare the safety profile
 - Assess the immunogenicity of MAb
- Exploratory:
 - Calculate the change in circulating tumor cells
 - Analyze VEGFR polymorphisms
 - Assess tumor tissue samples for potential markers of therapeutic efficacy and/or safety
 - Explore the effect of genetic variation on therapeutic efficacy and/or safety

METHODOLOGIES

- Blinded placebo-controlled
- Central Randomization
- Independent Radiology Committee
- Independent Data Monitoring Committee

STUDY POPULATION

- **1,113 women** with HER2-negative, unresectable, locally-recurrent or MBC
- Measurable and/or non-measurable lesion(s)
- No previous chemotherapy for metastatic or locally-recurrent, inoperable breast cancer

ENROLLMENT

- Starting: Q3 2008
- Expected duration: 36 months
- 200 sites in North & South America, Europe, Asia, Middle-East, Africa, Australia and New-Zealand

For any questions please contact

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