CONTESSA 2: A Multinational, Multicenter, Phase 2 Study of Tesetaxel plus a Reduced Dose of Capecitabine in Patients with HER2-Positive, MBC who Have Not Previously Been Treated with a Taxane

Background
- Tesetaxel is a novel taxane that is taken orally Q3W with a low pill burden, no history of hypersensitivity reactions and improved activity against chemotherapy-resistant tumors.
- Clinical Studies:
  - Phase 2 study of tesetaxel in HER2 positive, HR positive MBC patients who have not previously received a taxane (NCT03858972)
  - CONTESSA 2: A Multinational, Multicenter, Phase 2 Study of Tesetaxel in HER2-negative, HR-positive MBC patients receiving tesetaxel as a single agent (NCT04787278)

Key Eligibility Criteria

Study Design
- 1. Have HER2 negative and ER or PR positive (≥ 10%) MBC
- 2. Have received any number of approved targeted therapies
- 3. Previously received prior treatment with a taxane
- 4. Received an approved combination of endocrine therapies (e.g., palbociclib, everolimus)
- 5. Have CMS metastases (allowed but not required)

Study Highlights
- Chemotherapy regimens for patients with MBC that offer robust efficacy while preserving quality of life are needed.
- Tesetaxel is a novel taxane that is taken orally Q3W with a low pill burden, no history of hypersensitivity reactions and improved activity against chemotherapy-resistant tumors.
- In a multinational, Phase 2 study, HER2 negative, HR positive MBC patients receiving tesetaxel as a single agent achieved a confirmed response rate of 45% with a low incidence of Grade ≥3 neuropathy and Grade 2 alopecia.
- The primary efficacy endpoint is ORR assessed by IRC and overall survival (OS) assessed by Independent Radiologic Review.
- Patients are NOT required to exhaust all prior medical options before entering the study.
- In February 2019, the study was initiated with planned enrollment of approximately 125 patients across 7 countries.

References