Background

Chemotherapy regimens for patients with MBC that offer cure are not presently available. Quality of life is a major concern for patients with MBC. Tesetaxel is a novel taxane with several properties that make it unique – such as a longer half-life exposure with a low incidence of Grade ≥3 neuropathy and Grade 2 alopecia. In preclinical studies, Tesetaxel-resistant tumors showed higher drug accumulation than parental tumors. The paclitaxel P-glycoprotein (P-gp) efflux pump mediates gastric absorption as well as chemotherapy resistance. Atezolizumab is an antibody that targets programmed cell death ligation 1 (PDL-1) and is approved for the treatment of metastatic HER2-negative, HR-positive breast cancer.

Study Design (Cohort 1) and Table 1: Tesetaxel’s Unique Pharmacologic Properties

- Tissue selectivity
- Nanocapsule and proteinbound (PBP) 1 milubutaxel and tesetaxel is a single agent approved for the treatment at multiple tumor types.
- Use of liposomal nanoparticles targets patients at high risk for recurrence.
- Significant activity against chemotherapy-resistant tumors.
- More than 600 patients have been treated with tesetaxel in clinical studies.

- In a 2-multicenter Phase II trial, 28 HER2 negative, HR positive MBC patients receiving tesetaxel as a single agent showed a confirmed response rate of 79% (11 patients). The 90-day pain response rate was 81% in patients with prior breast exposure. 96% of patients reported 0-1 grade nausea and grade 0 alopecia (Figure 2).

- The CONTESSA-TRIO Table 1 shows that Tesetaxel is effective in a variety of tumor types: breast, ovarian, pancreatic, colorectal, liver, and lung. Tesetaxel is administered as a continuous infusion over 2 hours and has a long half-life exposure (Figure 3).

- Table 2 shows the ongoing Tesetaxel Clinical Studies for patients with MBC. In the CONTESSA study, 20 patients with MBC were treated with Tesetaxel, and 35 patients with breast cancer were treated with Tesetaxel alone. No significant adverse events were reported.

- Table 3: Key Eligibility Criteria. Patients are eligible if they:
  1. Have undergone previous chemotherapy for MBC and are not chemotherapy-naive.
  2. Have a disease-free interval of at least 12 months.
  3. Have metastatic tumor biopsy containing TMB by PDL-1 L1 status. Metastatic tumor biopsy is recommended for central determination.

- Table 4: Comparison of 3 Approved PD-L1 Diagnostic Assays. The Nivolumab 200 mg once every 3 weeks and Pembrolizumab 200 mg once every 3 weeks were both approved for the treatment of MBC. Nivolumab is administered as a continuous infusion over 2 hours and has a long half-life exposure (Figure 4).

- Table 5: Key Eligibility Criteria. Patients are eligible if they:
  1. Have undergone previous chemotherapy for MBC and are not chemotherapy-naive.
  2. Have a disease-free interval of at least 12 months.
  3. Have metastatic tumor biopsy containing TMB by PDL-1 L1 status. Metastatic tumor biopsy is recommended for central determination.

- Validated and commercialized in multiple settings and clinical trials. Tesetaxel is a novel taxane with several properties that make it unique – such as a longer half-life exposure with a low incidence of Grade ≥3 neuropathy and Grade 2 alopecia.

- Conflicts of Interest

**References**