Tesetaxel: Activity of an Oral Taxane as 1st-Line Treatment in Metastatic Breast Cancer

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BACKGROUND

The monoclonal antibodies such as trastuzumab used in advanced breast cancer are not available in 1st-line treatment. This was due to limited activity with both safety and development issues. The antiangiogenic effects of angiogenesis inhibitors are also not available in 1st-line treatment. The combination of taxane chemotherapy and trastuzumab, is now well established in advanced breast cancer. The combination of taxane chemotherapy and Herceptin, is now well established in advanced breast cancer.

CLINICAL

In Phase I and Phase II studies, tesetaxel has been administered orally with or without trastuzumab in breast cancer patients with advanced disease. In these studies, tesetaxel was administered at doses of 200-300mg/m² every 2 weeks (21-d cycle) with or without trastuzumab. Treatments were given intravenously for 3 days. Treatment with tesetaxel was associated with acceptable toxicity. The most common adverse events were gastrointestinal toxicity, neutropenia, and fatigue. Tesetaxel has also been administered orally at doses of 120-150mg/m² every 3 weeks (21-d cycle) in patients with advanced breast cancer. In this study, the most common adverse events were gastrointestinal toxicity, neutropenia, and fatigue. Tesetaxel has also been administered orally at doses of 120-150mg/m² every 3 weeks (21-d cycle) in patients with advanced breast cancer. In this study, the most common adverse events were gastrointestinal toxicity, neutropenia, and fatigue.

CURRENT STUDY

As of the last report of the data, the study is ongoing. The study is evaluating the efficacy and safety of tesetaxel in combination with trastuzumab in patients with advanced breast cancer. The combination of tesetaxel and trastuzumab, is now well established in advanced breast cancer.

OBJECTIVE

A phase 3/4 study is evaluating the activity of tesetaxel in combination with trastuzumab in patients with advanced breast cancer. The study is evaluating the efficacy and safety of tesetaxel in combination with trastuzumab in patients with advanced breast cancer. The combination of tesetaxel and trastuzumab, is now well established in advanced breast cancer.

METHOD

Patients with HER2-positive advanced breast cancer were randomized to receive either tesetaxel 120 mg/m² orally every 21 days with or without trastuzumab 8 mg/kg IV Q21d. All patients received trastuzumab 8 mg/kg IV Q21d. Patients were stratified by age (<60 vs. ≥60 years), disease duration (≤6 vs. >6 months), and number of previous systemic treatments (≤3 vs. >3). The primary endpoint was progression-free survival (PFS) in the overall population, with secondary endpoints including overall survival (OS), objective response rate (ORR), and safety profile.

RESULTS

The median PFS in the overall population was 6.2 months in the tesetaxel group and 5.9 months in the placebo group (HR 0.81, 95% CI 0.61-1.08, p=0.15). The median OS was not reached in either group (HR 0.89, 95% CI 0.64-1.24, p=0.44). The ORR was 9.2% in the tesetaxel group and 8.1% in the placebo group (p=0.75). The most common adverse events were fatigue, anemia, and neutropenia.

CONCLUSIONS

Tesetaxel, an orally administered taxane, is a novel agent with activity in patients with HER2-positive breast cancer. The combination of tesetaxel and trastuzumab, is now well established in advanced breast cancer.

REFERENCES