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Abstract

A phase II, open-label, multicenter study of GW572016 in patients with trastuzumab-refractory metastatic breast cancer

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Background: GW572016 is an oral, reversible and specific receptor tyrosine kinase inhibitor of both ErbB1 and ErbB2 (HER-2/*neu*). Signaling through these receptors regulates tumor cell proliferation and survival. Phase I trials suggest activity of GW572016 in a number of tumor types including breast cancer. The objectives of this study are the assessment of safety and efficacy of monotherapy GW572016 at 1500 mg daily in women with trastuzumab-refractory metastatic breast cancer (MBC). Initially 1250 mg of GW572016 was used, but the study was amended after 13 patients to administer 1500 mg daily. **Methods:** Eligible patients had overexpressing (IHC) MBC with disease progression following either 1 or 2 prior trastuzumab-containing regimens. Safety (NCI CTC criteria) and efficacy (RECIST criteria) assessments were performed by the attending physician. All patients at 4- and 8-week intervals on treatment. **Results:** As of Dec. 2003, 44 patients were enrolled. Preliminary efficacy results regarding the initial 36 patients include 3 partial responses (PR) (8+ weeks, 12+ weeks, and 44 weeks) and 5 stable disease (SD) (range 12 - 36+ weeks). For 15 patients with preliminary safety data, adverse events (AEs) considered by investigators to be study drug related were all grades 1 - 2 except grade 3 rash. For these 15 patients, study drug related AEs that were observed in more than 1 patient included anorexia, nausea, rash, vomiting, diarrhea and weight loss. **Conclusions:** GW572016 1500 mg daily demonstrated preliminary evidence of efficacy in patients with ErbB2-overexpressing MBC refractory to trastuzumab-containing regimens. In the first 36 patients evaluated for efficacy, the clinical benefit rate (PR + SD) is 22%. GW572016 appears well tolerated in this population. Inhibition of both ErbB1 and ErbB2 with GW572016 represent a promising approach in the treatment of breast cancer.

Author Disclosure

Employment or Leadership	Consultant or Advisory	Stock Ownership	Honoraria	Research Funding	Expert Testimony	Other Relationships

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