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Clinical Trial Highlights from the 21st Annual San Antonio Breast Cancer Symposium

Trastuzumab (Herceptin®, Genentech) can be used as a single-agent, first-line treatment for certain women with metastatic breast cancer, according to a study presented by Charles L. Vogel, M.D., of the Columbia Cancer Research Network in Aventura, Fla., at the 21st Annual San Antonio Breast Cancer Symposium held December 12-15, 1998. The symposium was sponsored by the San Antonio Cancer Institute at the University of Texas Health Science Center at San Antonio.

In 1998 Herceptin was approved by the FDA as a first-line agent in combination with paclitaxel and as a single agent in second and third-line therapy for patients with metastatic breast cancer that overexpresses HER2.

In the new randomized, single-blind, multicenter study, 113 women with progressive metastatic breast cancer and tumors that overexpress HER2 and no prior stage IV chemotherapy regimens received either a high-or low-dose weekly regimen of Herceptin.

Thirty-one percent of patients treated with Herceptin were found to benefit clinically: 5.3 percent of patients had a complete response, 17.7 percent had a partial response, and 8 percent had had stable disease for more than six months. There were no significant differences in outcome between the high and low doses of Herceptin. Complete and partial remissions occurred in 25 percent of patients with liver metastases, 25 percent of patients with prior adjunctive doxorubicin, and 38 percent of the thirteen patients who had undergone prior stem cell transplantation.

In general, Herceptin was well tolerated. There were no discontinuations due to adverse events. More than 20 percent of patients experienced pain, asthenia, fever, nausea, chills, headache, diarrhea, and/or rash. Most adverse events were mild and easily managed.

No other treatment within the last twenty years has improved the outcome of patients with metastatic breast cancer to this extent, according to Debu Tripathy, M.D., associate professor of medicine at the University of California at San Francisco.

However, there is still room for improvement. "There are still a lot of people who get Herceptin and don't respond, so there is obviously more we need to do to improve on this treatment or to understand some of the biological pathways that we can target in addition to the HER2/neu pathway," Tripathy stated.

➪ *Part 1 of a two-part series. Look for Part 2 in the May/June* Oncology Issues.

Larry Husten is a medical writer in New York City.