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New England Journal of Medicine publication confirms Herceptin can improve survival in women with severe breast cancer

The use of breast cancer treatment Herceptin may allow severely affected women the best chance to live better and longer say study results in the New England Journal of Medicine (NEJM). Noting Herceptin's remarkable effect in severe breast cancer, study authors said: "Few studies in metastatic breast cancer have demonstrated a survival advantage of this magnitude associated with the addition of a single agent."

Key to receiving treatment with Herceptin is to be tested for HER2 status - if found positive, women are then eligible for this treatment. It works by targeting HER2, a gene associated with aggressive cancer cell growth. Approximately 1 in 5 women with severe breast cancer will be HER2 positive.

In the international trial involving 469 women with advanced breast cancer, international investigators found that Herceptin was shown to extend survival by 24% in HER2-positive patients compared to traditional chemotherapy alone. In fact, by analysing subgroups of strongly HER2-positive patients this study also found that Herceptin can extend survival by as much as 45%.

According to Dennis J. Slamon, M.D., Ph.D., the study's lead author and chief of the Division of Hematology and Oncology at UCLA's Jonsson Comprehensive Cancer Center "The advantages seen with Herceptin in this study, especially in terms of survival, are considered significant in these patients and call for additional studies involving Herceptin in an attempt to set a new standard of care for this type of breast cancer."

About Herceptin

Herceptin is the first cancer gene targeted treatment with proven survival benefit, resulting in improved outcomes when used alone or in combination with chemotherapy. Because of the proven clinical benefits Herceptin can offer HER2-positive patients, Herceptin is now recommended within the EU for the treatment of women with high levels of HER2. As clinical trials have shown, careful selection of HER2-positive patients results in superior efficacy of Herceptin and significant improvement in survival. As a result, Herceptin is now approved in more than 40 countries throughout the world for the treatment of metastatic breast cancer, and because of the compelling clinical efficacy for Herceptin in this setting, it is currently being investigated in the treatment of earlier stage breast cancer. Herceptin was developed by Genentech, a leading US biotechnology company in which Roche holds a major stake. In July 1998, Genentech granted Roche exclusive marketing rights for Herceptin outside the USA.

About Roche

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address needs for the prevention, diagnosis and treatment of disease, thus enhancing people's well-being and quality of life. Roche has approximately 64,000 employees and sells its products in over 170 countries.

Editor's notes:

1. **EJM results summary:** A total of 469 patients were enrolled between June 1995 and March 1997. Patients were evenly distributed between the Herceptin (trastuzumab) plus chemotherapy and chemotherapy alone groups. Addition of Herceptin (trastuzumab) to chemotherapy significantly prolonged median time to disease progression when compared to chemotherapy alone (7.4 versus 4.6 months), increased median duration of response (9.1 versus 6.1 months) and increased overall survival compared to chemotherapy alone (25.1 vs. 20.3 months). In general, Herceptin was well tolerated and adverse events were usually of mild to moderate.
2. **Study Authors:** Dennis J. Slamon, M.D., Ph.D., Brian Leyland-Jones, M.D., Steven Shak, M.D., Hank Fuchs, M.D., Virginia Paton, Pharm.D., Alex Bajamonde, Ph.D., Thomas Fleming, Ph.D., Wolfgang Eiermann, M.D., Janet Wolter, M.D., Mark Pegram, M.D., Jose Baselga, M.D. Larry Norton, M.D for the Herceptin Multinational Investigator Study Group

3. **From (initials indicate author):** the Division of Hematology/Oncology, UCLA School of Medicine, Los Angeles (D.J.S., M.P.); Department of Oncology, McGill University, Montreal, Canada (B.L-J.); Medical Affairs, Genentech, Inc. S. San Francisco, CA (SS., A.B., V.P.); Department of Biostatistics, University of Washington, Seattle (T.F.); Department of Obstetrics and Gynecology, Frauenklinik vom Roten Kreuz, Munich, Germany (W.E.); Department of Medical Oncology, Memorial Sloan-Kettering Cancer Center, N.Y.,N.Y. (L.A.N.); Department of Oncology, Rush-Presbyterian-St.Luke's Medical Center, Chicago, IL (J.W.); Department of Oncology, Hospital General Universitari Vall d'Hebron, Barcelona, Spain (J.B.).

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