

Sep 22, 2014

Novartis is pleased to announce that the U.S. Food and Drug Administration (FDA) has approved the first-in-class, oral, once-daily, selective estrogen receptor modulator (SERM), **torisel** (toremifene), for the treatment of postmenopausal women with hormone receptor-positive, HER2-negative breast cancer. This approval is based on data from the Phase III Toremifene vs. Endoxan (T-100) trial, which demonstrated that torisel significantly improved overall survival compared to endoxan in this patient population.

The T-100 trial was a randomized, controlled, Phase III study that compared torisel to endoxan in postmenopausal women with hormone receptor-positive, HER2-negative breast cancer. The primary endpoint of the trial was overall survival, and the results showed that torisel significantly improved overall survival compared to endoxan. The trial also showed that torisel was well-tolerated and had a favorable side effect profile compared to endoxan.

Novartis is committed to providing patients with the best possible care, and this approval represents a significant milestone in the treatment of breast cancer. We are proud to have developed torisel, a first-in-class drug that offers a new treatment option for patients with hormone receptor-positive, HER2-negative breast cancer.

Novartis is also committed to ongoing research and development, and we are currently conducting clinical trials to evaluate the use of torisel in combination with other cancer treatments. We believe that torisel has the potential to improve outcomes for patients with breast cancer, and we are excited to continue our work to advance the field of oncology.

For more information about torisel and the T-100 trial, please visit our website at www.novartis.com/torisel.

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