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Phase III Trial of Tocosol Paclitaxel Does Not Meet Primary Endpoint

A Phase III trial of Tocosol Paclitaxel in women with metastatic breast cancer did not meet its primary endpoint of non-inferiority on objective response rate when compared with the Taxol control arm, Sonus Pharmaceuticals reported.

The objective response rate for Tocosol Paclitaxel was 37 percent versus 45 percent for Taxol. The outcome did not support the submission of a new drug application, Sonus added.

The rates of neutropenia and febrile neutropenia in the Tocosol Paclitaxel arm were significantly higher than the Taxol arm, which may be related to the higher dose of the drug compared with Taxol. The study results also did not demonstrate the expected benefit in peripheral neuropathy, which was not statistically different between the two arms, the company said.

Based on these results, Sonus and German drugmaker Bayer Schering Pharma said they will close all clinical trials of Tocosol Paclitaxel.