Central European Society for Anticancer Drug Research Announces Start of Enrollment in First Randomized Trial of Pharmacokinetic-Guided Dose Adjustment of Paclitaxel in Non-Sm...

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VIENNA and BETHLEHEM, Pa., April 26, 2011 /PRNewswire/ -- In collaboration with Saladax Biomedical, Inc., the Central European Society for Anticancer Drug Research (CESAR) announced today that enrollment has begun in the CEPAC-TDM trial of paclitaxel therapeutic drug management (TDM) with subsequent pharmacokinetic-guided dose adjustment in patients being treated for advanced non-small cell lung cancer (NSCLC). The study will determine if optimizing dosing of paclitaxel will reduce grade 4 neutropenia, without affecting progression-free survival and overall survival. Saladax is developing a nanoparticle-based automated immunoassay to provide rapid, simple and cost-effective measurement of paclitaxel levels to allow timely personalized dose adjustment.

This multicenter randomized trial is planned to enroll 280 patients. In the first phase of the study, eight study centers will participate in Germany and Switzerland, with the first three patients already enrolled in Lowenstein, Germany. The study is sponsored by CESAR and supported by Saladax Biomedical.

The CEPAC-TDM study is the first large scale, randomized trial to evaluate the clinical utility of paclitaxel drug dose management and is the largest randomized trial of its type. A dosing algorithm has been derived that uses 24-hour paclitaxel plasma concentration and clinical parameters, based on a large population model of paclitaxel. In addition to the clinical results, extensive data on health economic outcomes will be generated through the trial.

Markus Joerger, MD PhD, explains: "The CEPAC-TDM clinical trial has the potential to markedly improve patient quality of life through a reduction of febrile neutropenia and hospitalization, and debilitating neuropathy, as it tailors paclitaxel to the individual patient's drug metabolism."

Study details

The CEPAC-TDM study is a phase III open-label, randomized, parallel-group clinical trial compar
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SOURCE [1]

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Links:
[1] http://www.bio-medicine.org/medicine-technology-1/Central-European-Society-for-Anticancer-Drug-Research-Announces-Start-of-Enrollment-in-First-Randomized-Trial-of-Pharmacokinetic-Guided-Dose-Adjustmen-16653-1/