

# AbbVie's Veliparib Combo Trial Fails to Improve Lung Cancer Patients' Survival

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AbbVie's oral PARP inhibitor veliparib was ineffective against squamous non-small cell lung cancer (NSCLC) when administered with chemotherapy, a Phase 3 trial indicated.

Despite the results, the company said it still believes there is a place for PARP inhibitors in cancers with faulty DNA repair mechanisms, such as those with BRCA mutations.

The trial (NCT02106546) assessed the effectiveness of a combination of veliparib, Paraplatin (carboplatin) and Taxol (paclitaxel) as a first-line therapy for patients with metastatic or advanced squamous NSCLC.

The trial was a randomized, multicenter, double-blind intent-to-treat study. An intent-to-treat study follows participants who start a trial, whether or not they stop complying with the treatment that researchers planned for them. Those who stop complying are called the intent-to-treat population.

The 970 patients in the trial were divided into three groups, according to their smoking history. One group consisted of those who had smoked more than 100 times in their lives and at least once in the previous 12 months. Another group consisted of people who had smoked more than 100 times in their lives but not in the previous 12 months. The third group had smoked fewer than 100 times.

The study's primary endpoint, or goal, was improving overall survival in the first group, those who had smoked in the past year and more than 100 times in their lifetimes. Secondary endpoints included overall survival in the intent-to-treat population, as well as progression-free survival and overall response to therapy in the first group and in the intent-to-treat population. Overall response is either a full or partial response to treatment.

In announcing that the trial failed to meet its primary endpoint, AbbVie said it will present the full results at a medical meeting.

The company tested the same combo therapy in patients with triple-negative breast cancer. That treatment also failed to improved the patients' outcomes.

"In these clinical trials, we wanted to explore whether a PARP inhibitor could augment chemotherapy in patients with squamous non-small cell lung cancer and triple negative breast cancer by disrupting the repair of cancer cells," Dr. Gary Gordon, an AbbVie vice president, AbbVie, said in a [press release](#). "Unfortunately, these data do not support the use of veliparib in combination with chemotherapy in these patients."

AbbVie is conducting a Phase 2 trial (NCT02412371) of a combo therapy in patients with stage 3 NSCLC. It will the effectiveness and tolerability of veliparib plus Taxol/Paraplatin-based chemoradiotherapy followed by veliparib plus Taxol/Paraplatin. The trial is currently recruiting patients.

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