Phase 3 Trial Shows Promising Results for Durvalumab in Subset of NSCLC Patients

MAY 18, 2017

Patients with locally advanced, unresectable non-small cell lung cancer (NSCLC) who have not progressed following standard platinum-based chemotherapy and radiation therapy, may greatly benefit from treatment with the PD-L1 inhibitor Imfinzi (durvalumab).

An interim analysis from the PACIFIC Phase 3 trial (NCT02125461) has shown that the trial met its primary endpoint, with the time to disease progression or death in Imfinzi-treated patients being significantly longer than in placebo-treated subjects.

“These are highly encouraging results for patients with locally-advanced lung cancer for whom surgery is not an option,” Sean Bohen, executive vice president of Global Medicines Development and chief medical officer at AstraZeneca, said in a press release.

“We look forward to working with regulatory authorities around the world to bring Imfinzi to lung cancer patients as soon as possible. Alongside this, we continue to explore Imfinzi’s full potential as monotherapy as well as in combination with tremelimumab and other medicines in areas of continued unmet need across multiple types of cancer.”

PACIFIC is a randomized, double-blinded, placebo-controlled, multi-center trial designed to assess the safety and efficacy of Imfinzi vs. placebo in “all-comer” patients with locally-advanced, unresectable stage 3 NSCLC whose disease did not progress after receiving standard chemotherapy and radiation therapy.

The trial, designed to enroll up to 983 patients, is being conducted in more than 200 centers in 26 countries. It’s primary endpoints are progression-free survival and overall survival; secondary endpoints include one-year overall survival and one-year progression-free survival, duration of response, and objective response rate.

A planned interim analysis, conducted by an Independent Data Monitoring Committee, showed the trial had already met the PFS primary endpoint, with patients on the Imfinzi arm having a statistically significant and clinically meaningful increase in PFS, compared to those on placebo. The results also revealed a favorable benefit/risk profile.

While the companies did not disclose specific data, AstraZeneca and MedImmune have plans to present the study’s initial results at an upcoming medical meeting. They are also in conversations with regulatory agencies to submit Imfinzi for the treatment of this subset of NSCLC patients.

Imfinzi was recently granted accelerated approval by the U.S. Food and Drug Administration for the treatment of advanced bladder cancer patients.

In NSCLC, it is also being tested as a first-line monotherapy in the MYSTIC (NCT02453282) and PEARL Phase 3 trials (NCT03003962). It is also being developed in combination with the anti-CTLA-4 tremelimumab.