Phase 2 Trial of TG4010, Opdivo Combo for NSCLC Gets Underway

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A Phase 2 trial evaluating the cancer vaccine TG4010 in combination with Opdivo (nivolumab) in metastatic non-small cell lung cancer (NSCLC) patients who failed one prior line of platinum-based chemotherapy has dosed its first patient.

The trial will be led by Karen Kelly, MD, a lung cancer expert and associate director for Clinical Research at UC Davis Comprehensive Cancer Center, California. Transgene, TG4010's manufacturer, will support the study's costs.

"We are convinced that the complementary mechanisms of action of TG4010 and Opdivo can enhance response rates, increase the duration of response and extend overall survival in patients," Maud Brandely, chief medical officer of Transgene, said

in a press release. “Today, advanced lung cancer remains a severe disease with a poor prognosis. Major improvements are needed in the therapeutic options available to physicians.”

TG4010 is an active immunotherapy designed to induce an immune response to MUC1-positive tumors, such as non-squamous NSCLC. It is a modified vaccinia virus (MVA) that expresses the MUC1 and the IL2 proteins.

MUC1 usually suffers from modifications in cancer cells that transform this protein into a highly immunogenic tumor-associated antigen. This means the immune systems detects these abnormal modifications as foreign and attacks cells showing such MUC1 alterations.

By expressing the MUC1 protein, TG4010 activates the innate and adaptive immune system toward MUC1-positive cancer cells. IL2 is a cytokine, a naturally occurring protein that boosts the activity of the immune system.

Prior studies have revealed a promising safety profile for TG4010, suggesting it would be a suitable candidate for combination with other therapies, such as the PD-1 inhibitor Opdivo.

The new Phase 2 trial (NCT02823990) is a multi-center, open-label study designed to assess the safety and effectiveness of TG4010 plus Opdivo in patients with metastatic non-squamous NSCLC whose disease progressed following one line of platinum-based chemotherapy. The study is designed to enroll up to 33 patients.

The study’s primary endpoint is overall response rate, deemed as the proportion of patients who achieved a partial or a complete response. Secondary endpoints include progression-free survival, overall survival, duration of response, and safety.

The first results from the are expected by the end of 2017.

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