FDA Approves WGc-043, EB Virus-Related mRNA Therapeutic Cancer Vaccine for Use in Clinical Trials

This is the first approval of an EB virus-related mRNA therapeutic cancer vaccine and is a landmark achievement in future research on cancer treatment.

The FDA has approved the cancer vaccine, WGc-043 (WestGene), an Epstein-Barr (EB) virus-related mRNA therapeutic cancer vaccine, for an investigational new drug (IND) application. The IND application allows the vaccine to be used in clinical trials with human subjects, which can be significant in the fight against cancers and serve as a positive advancement in cancer treatment.[1]

The IND approval offers a new hope to patients who have advanced EB virus-related cancers. EB virus is highly associated with more than 10 malignancies, including different types of cancer (nasopharyngeal carcinoma [NPC], natural killer T-cell lymphoma [NKTL], as well as gastric, lung, breast, liver, esophageal, and cervical cancers) and autoimmune diseases (eg, multiple sclerosis and systemic lupus erythematosus).[1]

According to experts, the WGc-043 vaccine has promising efficacy, a low toxicity, broad applicability, efficient scalability, and cost effectiveness. The vaccine has already completed investigator-initiated trials that treated NPC and NKTL, and demonstrated superior efficacy and safety compared with other available mRNA therapeutic vaccines.[1]

Currently, a phase 1 clinical trial (NCT05714748) is recruiting participants to determine a therapeutic candidate vaccine that targets EB virus-related malignant tumors in patients who were between 18 and 70 years of age that failed second-line standard therapy. The investigators used 20 μg as the starting point, and doses increased using an escalation scheme. Each participant received 1 corresponding dose, and an intramuscular injection was administered again every 7 days. After 4 doses, the fifth dose was given after a 1-month interval. The trial's primary end points were frequency and number of adverse events (AEs), objective response rate, progression-free survival, and overall survival (OS).[2]

Another mRNA-based vaccine, mRNA-4157, showed efficacy in prolonging recurrence-free survival (RFS) in patients with resected high-risk melanoma when used in combination with pembrolizumab (Keytruda; Merck & Co) and when used as an adjuvant therapy. The randomized, open-label, phase 2 trial (NCT03897881) that mRNA-4157 plus pembrolizumab was evaluated in had also demonstrated a reduced risk of death by approximately 44% compared to pembrolizumab alone.[3]

At a median follow-up point of 101 and 105 weeks, recurrence or death was reported in 24 of 107 patients (22.4%) in the vaccine plus pembrolizumab arm, and in the pembrolizumab alone arm, it was 20 of 50 patients (40%). Additionally, RFS rates (95% CI) at 18 months were 78.6% (69.0%, 85.6%) in those who received the combination regimen compared with 62.2% (46.9%, 74.3%) in the monotherapy arm. The combination had also demonstrated a reduction in the risk of recurrence or death by 44% (HR = 0.561; 95% CI: (0.309, 1.017). There were no clinically meaningful AEs, according to the investigators, with treatment-related AEs reported being grade 1 or 2 in severity. The most common grade 3 AE in this trial related to mRNA-4157 was fatigue.[3]

Additionally, a more recent vaccine demonstrated positive improvements in survival; however, this vaccine was not mRNA-based. Similar to the prior study, this second-generation vaccine was also administered in patients who had melanoma, and the findings demonstrated positive OS rates in both the second-generation vaccine and a first-generation vaccine, but OS was better in those who received the prior. Additionally, younger men with earlier-stage melanoma were shown to benefit from vaccination more than other participants. At 10 years, OS estimates were 0.84 ± 0.05 (SE) and 0.72 ± 0.11 for men and women, respectively.[4]

The WGc-043 vaccine was developed by WestGene, a biotech company that specializes in mRNA technology. Currently, the company has a pipeline of over 20 mRNA-based therapeutic products that target a variety of diseases. If successfully launched, WGc-043 will provide a treatment option for patients who either have advanced EB virus-positive solid tumors or hematologic malignancies.[1]

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