FDA Grants Fast Track Designation for LYT-200 to Treat Head and Neck Cancers

Treatment with LYT-200 is currently being assessed in a phase 1/2 adaptive design trial in advanced/metastatic solid tumors and in a phase 1b clinical trial.

The FDA has granted fast track designation for the investigative treatment LYT-200, from PureTech Health, with an anti-PD1 therapy to treat recurrent/metastatic head and neck cancer, also known as head and neck squamous cell carcinomas.[1]

"In the US, there are approximately 66,000 people diagnosed with head and neck cancers each year, and the prognosis for metastatic disease is unfavorable, with a median survival rate of about 10 months," said Eric Sherman, MD, at Memorial Sloan Kettering Cancer Center and an investigator in PureTech's phase 1/2 clinical trial, in a press release. "There is an important need to explore promising new mechanisms and targets such as galectin-9 to bring therapeutic innovation to this patient population."[1]

Head and neck cancers can appear as a lump in the neck or a sore in the mouth or throat that persists, according to study authors. The lumps or sores could cause pain, difficulty swallowing, or a change/hoarseness in the voice. These cancers account for approximately 4% of all cancers in the US and researchers noted that most individuals diagnosed are 50 years and older. Current treatment options for head and neck cancers include surgery, radiation therapy, chemotherapy, targeted therapy, and immunotherapy.[2]

LYT-200 could offer a new potential treatment for individuals diagnosed with head and neck cancers as a human IgG4 monoclonal antibody that aims to target galectin-9, an aggressive cause of cancer. The study authors hope that it could improve poor survival rates. Galactin-9 is a driver and immunosuppressor that can work in combination with cytotoxic CD8 T cells and natural killer cells. Furthermore, LYT-200 was reported to be the most advanced clinical program in contradiction of galectin-9.[1]

Treatment with LYT-200 is currently being assessed in a phase 1/2 adaptive design trial in advanced/metastatic solid tumors and in a phase 1b clinical trial.[1] The phase 1/2 trial is evaluating LYT-200 as a monotherapy with tislelizumab (Tevimbra, BeiGene). This treatment has shown positive safety profile outcomes along with disease control and proposals of initial anti-tumor activity.

Additionally, the phase 1b trial analyzed LYT-200 as a monotherapy in combination with venetoclax (Venclexta, AbbVie Inc.) and hypomethylating agents in hematological malignancies. Positive safety outcomes, tolerability, and early signals of potential clinical activity were reported, according to study authors.[1]

Previously, LYT-200 displayed direct cytotoxic, anti-leukemic effects along with standard of care chemotherapy and venetoclax in preclinical models, according to study authors.[1]

“By granting Fast Track designation to LYT-200 for head and neck cancers, the FDA continues to highlight areas of critical need within oncology as well as the potential for LYT-200,” said Aleksandra Filipovic, MD, PhD, Head of Oncology at PureTech, in a press release. “As galectin-9’s role in suppressing immune-mediated activity has been well-validated, it represents an important area of clinical research, especially in aggressive cancers with increased mortality.”[1]

References

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