Urothelial carcinoma drug receives breakthrough therapy approval in China.

by Cliff Dominy, PhD

Chinese biotechnology company Mabwell has received Breakthrough Therapy Approval for its Nectin-4 antibody-drug conjugate from the Chinese Centre for Drug Evaluation[1]. Preliminary clinical trials demonstrated that it significantly benefits patients with urothelial carcinoma over existing therapies.

The new drug, 9MW2821, is an antibody-drug conjugate (ADC) targeting Nectin-4, a protein expressed in urothelial carcinoma tumours. The Chinese move follows a Food and Drug Administration decision earlier this year to grant 9MW2821 “Fast Track Designation” status in the US. Thus, 9MW2821 will likely be the second drug after enfortumab (Padcev) to be approved for treating this aggressive form of bladder cancer.

Breakthrough Therapy Designations are typically granted to drugs early in clinical trial development that show benefit to patients with life-threatening diseases. Mabwell's new drug must complete phase 3 safety and efficacy trials before receiving full approval. The advantage is that they can now receive assistance from the Chinese authorities to complete their trials.

There are currently thirteen antibody-drug conjugates approved for treating solid tumours, with over 100 more in development[2]. The complex comprises three components: a monoclonal antibody, a linker molecule, and a cytotoxic drug. The antibody is responsible for binding specifically to the target cell—in this case, the Nectin-4 expressing tumour. The cytotoxic drug is taken up by the tumour cells, where it initiates cell death, usually via apoptosis. The cytotoxic drug can vary depending on the nature of the tumour being targeted.

Monoclonal antibody-based immunotherapy has been around for 24 years. As the drug pipeline swells with new candidates, like 9MW2821, the outlook for people suffering from cancer has never been better.

References

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