Drugs

PEER-REVIEWED FEATURE

Envafolimab: Adis Evaluation

Key Points

- A PD-L1 inhibitor invented by Alphamab Oncology is being co-developed by Alphamab Oncology and 3D Medicines for the treatment of solid tumours, by Alphamab and Ascletis Pharmaceuticals for chronic viral infections and by Alphamab Oncology, 3D Medicines and TRACON Pharmaceuticals for soft tissue sarcoma
- Received its first approval on 24 November 2021 in China
- Approved for use in adult patients with MSI-H or dMMR advanced solid tumours, including patients with advanced colorectal cancer, that have progressed after treatment with a fluoropyrimidine, oxaliplatin and irinotecan, as well as patients with other advanced solid tumours that have progressed after prior systemic treatment and who have no satisfactory alternative treatment options

Summary

Envafolimab (恩维达®) is a subcutaneously (SC) administered single domain anti-programmed death ligand 1 (PD-L1) antibody being developed for the treatment of various solid tumours and chronic hepatitis B in China, and for soft tissue sarcomas and biliary tract cancer in the USA. Single-domain antibodies are more soluble and more rapidly penetrate tissues than full monoclonal antibodies, enabling SC administration. Based on the results of a pivotal phase II trial, SC envafolimab was recently approved in China for the treatment of adult patients with previously-treated microsatellite instability-high (MSI-H) or deficient MisMatch Repair (dMMR) advanced solid tumours. This article summarizes the milestones in the development of envafolimab leading to this first approval.

Markham, A. Drugs. 2022. https://doi.org/10.1007/s40265-022-01671-w