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ASIA EDITION

Singapore's EDDC receives US FDA Fast Track Designation for Antibody-Drug Conjugate

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EBC-129 is the first made-in-Singapore antibody-drug conjugate (ADC) to enter clinical development

The Experimental Drug Development Centre (EDDC), Singapore's national platform for drug discovery and development, has announced that the US Food and Drug Administration (FDA) has granted Fast Track Designation for EBC-129 for the treatment of pancreatic ductal adenocarcinoma (PDAC).

EBC-129 is a first-in-class antibody drug conjugate (ADC) targeting a novel, tumour-specific N256 glycosylated epitope on CEACAM5 and CEACAM6. It is currently undergoing Phase 1 clinical trials for the treatment of patients with solid tumours with high unmet medical need.

The Fast Track Designation facilitates the expedited development of EBC-129, enabling more frequent engagement with the FDA to discuss the clinical development plan. It also provides potential eligibility for Priority Review and Accelerated Approval, as well as rolling review of any future Biologic License Application (BLA).

The ongoing Phase 1 trial of EBC-129 is assessing the safety and tolerability of EBC-129 as a single agent and in combination with pembrolizumab in patients with advanced solid tumours. Enrolment for the PDAC cohort in the Phase 1 dose expansion study is now complete, while recruitment continues for the gastroesophageal adenocarcinoma (GEA) and d immunohistochemistry (IHC)-positive cohorts.