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ASIA EDITION

IASO Bio receives FDA IND clearance for CD20-targeted in vivo CAR-T therapy

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IASO208 becomes the first China-originated lentiviral vector-based in vivo CAR-T programme to receive US IND clearance and is set to advance directly into Phase Ib development.

IASO Biotechnology has received US Food and Drug Administration clearance for the Investigational New Drug application of IASO208, its CD20-targeted in vivo CAR-T therapy.

IASO208 is the first China-originated lentiviral vector-based in vivo CAR-T therapy to receive FDA IND clearance.

The candidate was developed using IASO Bio's proprietary InTelliCAR platform and is intended for patients with relapsed or refractory B-cell non-Hodgkin lymphoma.

Following discussions with the FDA and supported by early clinical data generated in China, IASO208 is expected to move directly into a Phase Ib study in the United States.

Unlike conventional ex vivo CAR-T manufacturing, in vivo CAR-T approaches aim to generate engineered immune cells directly inside the patient.

This could potentially reduce manufacturing complexity associated with collecting, modifying and expanding a patient's T cells outside the body.

IASO208 is currently being evaluated in an investigator-initiated, single-arm, open-label and dose-exploration study in China.

Patients in the study receive a single intravenous dose of IASO208 without leukapheresis or lymphodepleting conditioning.

IASO Bio said 11 patients had been dosed in the study to date.

Early clinical observations indicated initial tolerability and anti-tumour activity, supporting further clinical development.

The FDA clearance marks a significant international regulatory milestone for IASO Bio's in vivo CAR-T platform.

The company is developing cell therapies and biologics across haematological malignancies and autoimmune diseases.

The programme also reflects increasing industry interest in next-generation CAR-T technologies designed to simplify delivery and broaden patient access beyond highly specialised manufacturing centres.

The upcoming US Phase Ib study will provide additional evidence on the safety, tolerability and preliminary efficacy of IASO208 in patients with relapsed or refractory B-cell non-Hodgkin lymphoma.