IKS03: CA242-directed ADC for GI cancers

TARGET: CA242/ CanAg, a tumour-specific glycoform of MUC1 and relevant for GI tumours.

ANTIBODY: Anti-CanAg monoclonal, humanized IgG1

LINKER: Site-specific conjugation of β -glucuronide for tumour-selective enzymatic payload activation and release

DRUG/PAYLOAD: DNA cross-linker; a PBD prodrug (LCB20-0187)

DRUG DESCRIPTION: IKSO4 is a class-leading ADC that incorporates an anti-CanAg antibody conjugated to highly potent DNA cross-linking payload (talirine-like PBD) via site-specific conjugation, with tumour-selective payload activation and release: a 'PBD prodrug'. It is being developed as an 'ultra-low DAR' ADC which will be formulated alongside naked anti-CanAg antibody as a fixed dose formulation.

This is the only CanAg-directed ADC program in development and the first 'ultra-low DAR' fixed-dose ADC.

PRECLINICAL STUDIES: Preclinical studies have demonstrated best-in-class efficacy (MED in mouse xenografts) and safety (HNSTD NHPs),

In xenograft models for multiple GI cancers including CRC, GC and PDAC, and a wide range of expression levels, IKS04 induced complete regression with doses of 0.2-0.4~mg/kg.

In non-GLP toxicology studies in NHPs, HNSTD is between 2- to-3.5-fold MED. IKSO4 administration results in a TI that is substantially higher than any other PBD-based ADC program and offers a potentially effective and well-tolerated treatment option for notoriously difficult cancers.

DEVELOPMENT STATUS: Preclinical: IND enabling.IND planned for Q4 2024

CLINICAL INDICATION: GI Tumours:

- Colorectal cancers (CRC)
- Gastric cancer (GC)
- Pancreatic cancer (PDAC)
- Bladder cancer (BLCA)
- Uterine & endothelial cancers (EC, EAC)
- Lung cancer (NSCLC)

CLINICAL TRIALS: IND is planned for Q1 2025

PARTNERING STATUS

Available for license: WW or Regional territories

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