康龙化成 PHARMARON

CELL THERAPY

CAR-T Cell Therapy Services

Pharmaron is able to support the preclinical demands for a CAR-T candidate to be IND-ready or IMPD-ready for First-in-Human (FIH) clinical trials. Pharmaron's global team of cell and gene therapy drug developers are experienced in the case-by-case testing strategy based on the diversity and specific inherent biological properties of a CAR-T cell therapy.

Non-clinical Capabilities

- Evaluation of safety and efficacy for the introduced vector's antigen recognition domain
- Characterization of cell product for potential graft versus host response or rejection
- Demonstration of mechanism of action *in vitro* and *in vivo* for CAR-T cell profiling, trafficking, persistence and immunogenicity
- Product-based *in vivo* testing strategy for efficacy and toxicology, engraftment, organ toxicity, tumorgenicity
- Bioanalytical assays to support *in vivo* preclinical and human clinical pharmacology & LTFU

Services

Pharmacology/Toxicity

- **Preclinical study design, bio-imaging, data acquisition, interpretation** from proof of concept to GLP Toxicology (GLP, Non-GLP)
- Broad range of **tumor bearing and immuno-compromised models** with expertise across all routes of administration
- **Bioanalytical method development, validation, sample analysis** for **persistence**, **PD Endpoints**, humoral and cellular **immunogenicity**

Analytical CMC Expertise

- **Analytical characterization with potency assay method development, validation** to support lot release of drug product for FIH through market approval
- **Stability testing,** compatibility studies, and cold-chain evaluation
- **QC release testing of drug substance and drug product** for clinical studies

Experience

- Extensive track record of lot release testing for FDA approved gene and cell therapy products
- >30 GLP, IND-enabling studies annually
- >10 years of experience developing, validating bioanalytical assays supporting efficacy and safety/toxicity studies
- >40 CGT programs in different stages of development
- >30 potency assays currently in development or GMP testing
- Four state-of-the-art GLP and/or GMP compliant facilities in the US and UK dedicated to CGT product development from preclinical to post-approval

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Laboratory Services

Chemistry, Manufacturing and Control

Clinical Development

Biologics & CGT

Pharmaron is a global life science service provider that offers a broad spectrum of research, development and manufacturing service capabilities throughout the entire drug discovery, preclinical and clinical development process across multiple therapeutic modalities, including small molecules, biologics and CGT products