Fixed price IND Package

Overview

Cadila Pharmaceuticals Sweden offers a complete pre-clinical development program at a fixed price to make your candidate drug ready for first-in-human clinical trial application in Europe, while keeping your development costs under control.

Development work is performed by Cadila Pharmaceutical´s experienced pre-clinical and formulation/CMC departments, following relevant GLP and GMP guidelines to ensure full regulatory compliance.

PRECLINICAL STUDIES

The pre-clinical studies of the program include the activities normally required by European authorities for a first-in-man (FIM) clinical study of an oral product.

ADME

Metabolic stability in vitro / CYP substrate, inhibition and induction profile / Plasma protein binding / Stability in plasma/blood / Cell permeability and transporter assays / PK in rodent / PK in non-rodent / Red blood cell partitioning

Genotoxicity studies

AMES (GLP) / Micronucleus in vivo / Chromosomal abberations.

Toxicology studies

DRF (7-14 day repeat-dose) in rodent / DRF (7-14 day repeat-dose) in non-rodent / 4 week repeat-dose in rodent (GLP) / 4 week repeat-dose toxicity study in non-rodent (GLP) / Phototoxicity

Safety pharmacology core battery

Irwin´s test (CNS activity) in rodent / Studies of cardiovascular effects (in vitro hERG and in vivo telemetry) / Study on respiratory effects

CMC ACTIVITIES

With API (scale-up synthesis, process development, and API manufacturing) quoted separately or provided by the collaborator, the package includes formulation development and supply of drug product for first clinical trial, including release for European markets.

Physico-chemical properties

Identity/purity/pKa/log P, log Kd/Solubility

Formulation development for preclinical studies

Manufacturing of pre-GLP formulations / Stability data and pH dependence of selected formulation for preclinical studies.

Analytical development

Stage 1: Development of methods for pharmaceutical analysis / Limited pharmaceutical/chemical characterization of scale-up batches

Stage 2: Validation of methods for pharmaceutical analysis of API (GMP) / Chemical characterization of API:/ Test and release of API and reference standard (GMP) / Stability studies on API and reference standard (GMP) / Validation of methods for pharmaceutical analysis of GLP formulations (GMP) / Stability studies on GLP formulations (GMP) / Validation of methods for pharmaceutical analysis of FIM formulations (GMP) / Stability studies on FIM clinical supplies (GMP)

Drug product

Selection of dosage form and development of formulation for FIM study / Manufacturing FIM clinical supplies (GMP) / Packaging, labelling,

Regulatory

Formatting of data obtained in package into IMPD suitable for submission to European authorities. IMPD drafting in general or for other data (e.g. pharmacology, clinical, prior studies) to be quoted separately or provided by collaborator.

Clinical trial material will be released for European clinical trial use.

Key facts

- Dedicated project manager assures seamless program execution
- All development work and manufacturing performed compliant to major markets.
- Possible to tailor program for your specific needs
- Complete package price: 900 000 USD

Deliverables

- IMPD writing for data from work performed as part of package, supplemented with individual reports.
- Drug product released for your FIM clinical study

Base price assumptions

- Oral product
- Primary pharmacology, panel screening, placebo and API synthesis quoted separately, or provided by collaborator
- Experimental scope subject to limitations.