CASE STUDY

Due Diligence to Support a Client's Decision-Making

Background and Problem

A client needed due diligence performed on the preclinical data, translational dose rationale and first-in-human (FIH) clinical protocol for a central nervous system (CNS) small molecule indicated for a chronic neurodegenerative orphan disease.

Our Solution

Preclinical absorption, distribution, metabolism, and excretion (ADME), pharmacokinetics (PK), and pharmacodynamics (PD) data for the asset were evaluated in context with the clinical plans to support drug development decision-making. The key aspects of the program revolved around the asset claims for human CNS penetration and PK, target engagement, and PD response with different immediate-release (IR) and modified-release (MR) dose formulations developed for once daily oral dosing to treat the disease. Modeling and simulations were used to predict clinical doses and efficacious exposure levels, which were evaluated for credibility. The dose projections were further considered relative to the nonclinical safety findings for the IR/MR dose forms to derive a preliminary therapeutic index. Additional safety risks for PK drug-drug interactions and cardiovascular and CNS safety were summarized along with mitigation strategies.

Outcome

The preclinical/clinical due diligence evaluation was favorable, and the client chose to move forward with in-licensing the asset.

Due Diligence Services

Allucent can assemble a team of experts to support a due diligence assessment of the nonclinical, clinical pharmacology, and regulatory aspects of a potential asset. Common issues will be evaluated for the asset in relation to therapeutic area, compound class, and industry guidance documents.

Contact us today to learn how Allucent's modeling and simulation services can help your organization gain insights that move your clinical development program forward.

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Helping bring new therapies to light

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