THE BENEFITS OF NON-CLINICAL SCIENTIFIC AND REGULATORY SUPPORT FOR LATE PHASE STUDIES

OVERVIEW

The sponsor requested assistance with two issues; one in the United States and one in Europe. The first involved obtaining US FDA approval to start a long term Phase III clinical study for a biological drug administered intravenously (IV). In response to the initial Clinical Trial Application, the FDA requested that the sponsor conduct a chronic toxicological study in advance of the trial. The client also required assistance designing non-clinical toxicological studies necessary to conduct clinical trials by the inhalation route in Phase I-III in Europe. For this product, the inhalation route offered several potential benefits; including high exposure to the target organ (lung) and lower systemic uptake, thereby minimizing for side effects.

CHALLENGE

The primary challenge was to present valid and compelling scientific and regulatory data that supported waiving the costly and time-consuming conduct of chronic non-clinical studies by the intravenous route.

The second challenge was to design, conduct and evaluate inhalation toxicological studies and get regulatory approval for the planned trials by inhalation.

SOLUTION

In order to address the first challenge, inVentiv Health Clinical reviewed all available clinical and non-clinical safety information that had an impact on FDA's decision to request to conduct a chronic toxicological study by the IV route. Based on extensive long term clinical safety data generated globally by the IV route in humans and by providing evidence that a long term toxicological study would add no or very limited value for a number of scientific reasons, we presented a case to the FDA in support of waiving the chronic toxicological study.

inVentiv Health Clinical also designed toxicological studies by the inhalation route (studies performed at a preclinical CRO) and evaluated scientific/regulatory aspects of submissions and questions from different national regulatory agencies. This included a scientific advice meeting with one national European agency.

RESULTS

In collaboration with the Sponsor, inVentiv Health Clinical was able to obtain a waiver for the long term toxicology studies by the IV route. The clinical IV studies are now completed and the company has recently received FDA approval for marketing the product.

For the inhalation product, the client obtained regulatory approval and is currently conducting the Phase III trials in several European countries (including countries with regulatory agencies ranked as "top five").

CASE STUDY

This case study illustrates how robust non-clinical advice and consultancy can expedite and accelerate drug development and increase the likelihood of regulatory acceptance for development programs.

ABOUT INVENTIV HEALTH CLINICAL

inVentiv Health Clinical, formerly PharmaNet/i3, is a leading provider of global drug development services to pharmaceutical, biotechnology, generic drug, and medical device companies. With 7,000 employees in more than 36 countries, inVentiv Health Clinical offers therapeutically specialized capabilities for all phases of clinical development, bioanalytical services, and strategic resourcing from a single clinical professional to an entire functional team.