Regulatory Strategy

Scientific Input

Regulatory Operations

IND Support for Asian Biotech

NEED

- Asian biotechnology company with a Central Nervous System (CNS) compound originally developed to treat a neurological disorder
- Preclinical pharmacology studies revealed potential for additional neurological indication
- Assistance requested with the preparation and filing of a new Investigational New Drug (IND)

APPROACH

- Reviewed original IND filing and provided a detailed gap analysis and regulatory strategy for the new indication
- Prepared and filed the new IND within an aggressive target time line
- FDA placed the clinical program on a partial clinical hold due to nonclinical data
- Developed a regulatory strategy and assisted in the design of a pivotal nonclinical toxicology study to provide conclusive data to FDA for removing the partial clinical hold
- Interacted with an academic consortium of leading Neurology experts to design and implement a novel, Phase IIa clinical proof-of-concept study, which allowed initial patient cohorts to be treated while under a partial clinical hold
- FDA removed the hold 30 days after submission of the complete response and initial safety data on the Phase IIa study

BENEFITS

- Leveraged existing nonclinical and Phase I safety and PK data to allow an initial proof-of-concept study as the IND-opening clinical trial
- Obtained removal of the partial clinical hold and effective FDA input into proof of concept study design allowing the client to meet all critical milestones
- Completion of the multi-site, proof-of-concept trial on time , with the positive results supportive of the new target indication
- Quality ICH-consistent Clinical Study Report prepared on time

See Other Case Studies

Semen Clinical Studies

Difficult to Recruit Population

Bioanalytical Support of Oncology Studies