Case Study

Pre-IND Meeting for an antibody-drug conjugate (ADC) for an advanced cancer indication

Challenge

Client in need of expertise for IND development and FDA interaction for First-in-Human study

- European SME beginning first discussions with the FDA regarding IND development and submission of an ADC product for an advanced cancer indication
- Intent to gain agreement on completed nonclinical program to support first in-human (FIH) study

Solution

PharmaLex experts provided hands-on support and lead for all FDA interaction

- PharmaLex conducted a gap analysis of nonclinical pharmacology and toxicity studies required for assessments of relevant species and safety margins according to the ICH S9 Q&A
- Assisted client with review and submission of pre-IND meeting materials
- Regulatory lead for FDA meeting discussions and management of all follow-up activities
- Preparation of the nonclinical, clinical and CMC sections of the IND

Outcome

Productive Pre-IND meeting with the FDA leading to a successful IND submission

- Client gained FDA written advice on completed and intended nonclinical program to support FIH study
- Received FDA feedback on CMC requirements for manufacturing process
- Collaborative discussions regarding clinical design relative to patient population and endpoints
- Outcome: FDA accepted the IND and the FIH study could be started