Proactive, agile clinical API strategies, development & manufacture

Client - UK based Biotech developing oncology drugs using a proprietary delivery platform. 10+ years of association with Laurus for clinical API development & supply across 3 clinical candidates in Phase III, IIb and I respectively

Program

- Built on an approved oncology drug (drug-1), this candidate was designed to enhance to improve cellular concentration of active metabolite at high doses & still minimize the side-effects & long-term drug resistance
- Two indications in clinical phase III

Challenge

- Post phase-I, similar moieties in the clinic indicated potential safety issues with racemic mixtures
- The solubility of the racemic API wasn't sufficient to support the high dose ambitions of the clinical program & would've made the whole program unviable

Solution

- Laurus proactively appraised client on this new regulatory risk w.r.t. racemates & also prepped out & provided a pure diastereoisomer for toxicological evaluation
- Taking into consideration the prohibitive costs of large-scale reverse-phase chromatography, Laurus developed a enantioselective chemical process using a niche technology platform Laurus has strengths on

Outcome

- The client could take a pivot & initiate another phase-I using enantiopure API which then showed highly improved safety & bioavailability
- The program could be seamlessly advanced to PII & PIII owing to early optimization of the pure diastereoisomer chemical process
- Client decided to place rest of his clinical programs with Laurus
- MULTIPLE KILOS OF CLINICAL QUANTITIES DELIVERED