CASE STUDY

How Syngene enabled an emerging pharma company to develop an innovative drug to treat erectile dysfunction

Syngene

Putting Science to Work

The Requirement

The client is a clinical-stage emerging pharma company developing innovative drugs that target key unmet medical needs within the central and peripheral nervous system.

The client had discovered a molecule to treat erectile dysfunction (ED). The drug is a monoamine reuptake inhibitor that preferentially inhibits the synaptic reuptake of dopamine followed by serotonin.

The client partnered with Syngene to transition the drug from late discovery to early-phase clinical studies. This would include end-to-end integrated chemistry manufacturing control (CMC) services.

After developing the formulation for first-in-human (FIH) clinical studies, Syngene would have to develop immediate-release (IR) and extended-release (ER) formulations suitable for onsite compounding for Phase 2 clinical studies.

Eventually, the formulation would have to be amenable to commercialization. The AUC, Cmax, and tmax for IR formulations would have to be similar to those of a drug in a bottle (DIB). The ER formulations would have to have lower Cmax, a longer tmax, and a similar AUC as those of IR pellets or DIB.

The Challenge

- Conversion of a solution (onsite compounding) formulation into an oral solid dosage form amenable to clinical studies (bridging studies) and later for commercialization, with similar in-vivo performance
- Selection of a suitable polymer and plasticizer combination (type and concentration) to achieve the desired extended dissolution profile
- Impact of a stabilizer on the dissolution profile in ER pellets

The Solution

In a short space of six months, Syngene developed a DIB solution formulation for use in FIH clinical studies.

Further, for the phase-2 studies, our drug product team developed a multi-particle system (pellets) using Wurster Coating technology in about nine months. This included a three-month stability study and preclinical PK data.

IR pellets were developed by coating the drug on an inert carrier (0.5 mm beads) along with a basifier. The IR pallets were further coated with extended-release polymers such as ethyl cellulose and HPMC solution/dispersion to achieve an extended-release dissolution profile lasting eight to ten hours.

To assess appropriate drug release, we developed a suitable dissolution method. We also evaluated in-vivo performance in preclinical species (mini-pigs). Based on the study findings, we optimized the prototype formulation. Later, we scaled up the formulation to manufacture clinical drug supplies. The drug product was then shipped to the UK for use in clinical studies.

The clinical studies proved highly positive. The client observed good in vitro and in-vivo correlation during clinical trials. The study data analysis demonstrated statistically significant and clinically relevant efficacy in ED-related endpoints, including no observations of critical adverse events.

Backed by positive results regarding efficacy and safety, the client is now proceeding with late-phase clinical trials, including launching the drug product among this patient group.

The treatment is expected to improve the quality of life for many patients who are not responding to existing drugs for erectile dysfunction in the market.

Conclusion

This case demonstrates Syngene extensive experience in formulation development, having worked with numerous global clients for over 30 years.

We have experience determining optimal dosage levels for therapeutic formulations in oral solid, liquid, and injectable forms. We have also designed and developed phase-appropriate formulations for multiple NCEs from preclinical to early-phase clinical studies, and late-phase drug product development.

Our integrated services extend across NCEs, late-phase product development, and over-the-counter products, focusing on quality, speed, and cost-efficiency.

To know more about our Formulation services, contact our experts

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About Syngene

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development, and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods, and specialty chemical sectors. Syngene's more than 6000 scientists offer both skills and the capacity to deliver great science, robust data security, and quality manufacturing, at speed, to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, and Bristol-Myers Squibb as well as 2.2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK, Zoetis and Merck KGaA.

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