A RAPID PATHWAY TO CLINIC
How Recipharm and CTC supported Swedish biotech Betagenon with its important phase I milestones.

INTRODUCTION
A Swedish biotechnology company called Betagenon was ready to take its new drug candidate, CLIMF to clinical trials. The molecule is an AMP-activated protein kinase (AMPK) activator for the treatment of chronic energy balance disorders in metabolically challenged elderly and/or obese individuals. Clinical First Exploratory (CTE) and Recipharm were elected to perform the work needed to reach the customer’s important phase I milestones. Although phase I laid the gritty foundation to succeed in phase II, providing a successful phase I was an important goal for the start.

DEVELOPING THE DRUG
The first step in the project was to establish a manufacturing process and a scalable production platform. For a phase I study, a master formulation formulation was prepared and scale-up experiments were conducted. In parallel, a study was performed to provide the necessary estimates of bioavailability in the intended patient population. The formulation properties of the molecule and the excipients were of importance, including colour, particle size and sedimentation properties.

MANUFACTURING PRODUCT FOR CLINIC
The manufacturing scale for the first study was later increased in size to ensure the desired amount of clinical material was generated to cover the phase II and phase III requirements. Betagenon selected the clinical supply service by providing a complete package, including labelling, randomisation and packaging of patient’s drug to supply the different centres.

THE CLINICAL TRIAL
Properties for the clinical trial were set and involved close collaboration between the sponsors, Recipharm and CTC. The first in house protocol had a combined adaptive design with three single cohort runs for the single ascending dose (SAD) part and multiple ascending dose (MAD) part (flexible interval). By performing the first protocol, CTC created study designs and approved documentation. The study was then initiated and carried forward, with an early interaction with the regulatory authorities and approval after 12 days.

BIOANALYSIS
Regarding the bioanalytical method development, an adaptive design was used to adapt the method to the specific plasma matrix of interest. The bioanalytical method had to be designed to ensure proper sensitivity of the analyte at all steps of the method. Biometric evaluation of the method was conducted to make sure that the study samples could have important decisions for all the studies carried out.

COORDINATION
In order to improve the progress and span of the stage, coordination between the project team and the clinical research team was established. Introducing computerised randomisation was also an integral part of the whole process. This project involved close partnership working between the two Recipharm sites and CTC. Due to the close contact between the two sites, the sponsor could handle only efficiently the on-time delivery of materials.

EXCIPIENTS
By coordinating and working together from the start of the project, each partner had the opportunity to influence, support, and benefit from challenges that may arise or be of concern at any stage.

CONCLUSIONS
In addition, the biostatistical and clinical facilities had direct and continuous communication, which included the overall project progress. The allowed for precise coordination of each sample step and sample, as well as a great transfer of the obtained computational data.

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SUMMARY
Working with CTC and Recipharm has allowed us to streamline our phase I project, speeding up our timelines and reducing risk. Close collaboration between the clinical research, development, manufacturing and bioanalytical experts helped us to overcome hurdles along the journey to clinic.

ABOUT RECIPHARM
Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Switzerland and the UK. Our mission is to facilitate clinical and translational research by providing our customers with a full service offering, taking products from early development through to commercial production. For the 30 years we have been in business, our path has been shaped by partnerships that unlock the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and costs. Despite our growing global footprint, we continue to be driven by our founders’ original goal and continue to deliver value for each customer’s unique journey to the best at all that we do. That’s the Recipharm way.

ABOUT CTC
CTC is a full-service-GCP with clinical research at its heart. Our mission is to facilitate and deliver clinical research to pharmaceutical customers with cost-effective and reliable services. Established in 1982, CTC has three dedicated clinical research facilities in Sweden, which offers a standardised, dedicated facility for drug development.

CHALLENGES
1. Challenge: Timing of the CME
2. Challenge: Bioanalysis
3. Challenge: Times and coordination

RESUMEN
Recipharm es una empresa líder en desarrollo y manufactura (CDMO) situada en Estocolmo, Suecia. Ofrece servicios de desarrollo y manufactura en Francia, Alemania, India, Suiza y Reino Unido. Nuestra misión es facilitar y llevar a cabo investigaciones clínicas y translacionales por medio de ofrecer servicios integrales a nuestros clientes, desde la fase de desarrollo hasta la producción comercial. Durante los 30 años que estamos en el mercado, nuestro camino ha sido definido por las asociaciones que han desbloqueado el ciclo completo del producto, proporcionando experiencia farmacéutica y administrando la complejidad, tiempo y costos. A pesar de nuestro crecimiento mundial, continuamos siendo guiados por el objetivo inaugural de nuestros fundadores y continuamos entregando valor para cada viaje único de cada cliente hasta el mejor de todos. Eso es la forma Recipharm.

CONTACTS
Email: Content.lead@recipharm.com
Phone: +46 8 471 52 02
Website: www.recipharm.com

SERVICES DELIVERED:
- GMP manufacture of active pharmaceutical ingredient (API)
- Drug product manufacturing
- Design and clinical conduct of a first in human study (SAD and MAD in healthy volunteers and patients)
- Bioanalytical

PROJECT HIGHLIGHTS:
- First study performed and report delivered approximately 8 months from project initiation
- Results study timelines by approximately six months using a combined adaptive design

ACKNOWLEDGMENTS
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