

## Press Release

Boulogne, July 3, 2023



# DELPHARM & CREAPHARM announced they have successfully joined forces to better serve HMNC Brain Health and met the FPI deadline in its BH-200-03 European phase 2 clinical trial.

DELPHARM and CREAPHARM announced today that they have combined their expertises to synergistically support HMNC Brain Health, a global clinical-stage biopharmaceutical company pioneering the development of personalized therapies in psychiatry.

On June 20, 2023, HMNC announced enrollement of the First Patient In (FPI) in Phase 2, PoC trial in more than 300 patients with Major Depressive Disorder (MDD) conducted in eight countries in Europe.

This trial is a crucial component of the Nelivabon program, one of HMNC Brain Health's flagship precision psychiatry programs, aimed at developing BH-200, a potent vasopressin V1b receptor antagonist, for improved treatment of patients with MDD who have underlying HPA-axis (Hypothalamus-pituitary-adrenal axis) dysfunction. Moreover, it will test the predictive capabilities of the V1b polygenic score, which the company aims to eventually develop into a companion diagnostic for BH-200.

## FROM DRUG PRODUCT MANUFACTURING TO CLINICAL TRIAL SUPPLY MANAGEMENT

DELPHARM and CREAPHARM have formed a collaboration to seamlessly meet the requirements of HMNC Brain Health, simplifying their tasks by managing end-to-end operations for both non-GMP technical batches and clinical batches. This includes the process handover, clinical batch manufacturing, matching placebo manufacturing, stability studies, analytical studies which were managed by DELPHARM's experts in the Development Department (completion in December 2022) just before CREAPHARM CLINICAL SUPPLIES's teams handled the Investigational Medicinal Product (IMP) and placebo blistering, walletting and clinical labelling, QP-release and clinical logistics to European sites.

This FPI is a new milestone within this **tripartite partnership** between DELPHARM, CREAPHARM and HMNC Brain Health. Also, it recognizes the scientific and technical expertise of DELPHARM in drug development & clinical batch manufacturing while reflecting CREAPHARM's expertise in global clinical trial supply management and its deadline commitment.

## PROVIDING SOLUTIONS TO EACH CHALLENGE WITH FLEXIBILITY

DELPHARM was able to provide solutions to the manufacturing challenge related to limited API availability. DELPHARM experts rescheduled manufacturing slots while meeting capsule quantity needs which evolved with the clinical project design.

CREAPHARM made HMNC Brain Health benefit from the right blinding strategy while the final QC check ensured the likelihood as a mandatory prerequisite.

Margot Loones, Development Project Manager at Delpharm said about this collaboration: **"Hand in hand collaboration and team spirit between each partner leads to a successful project: making clinical batches available in a record time for patients."**

**"Each specialist contributed to the success of this clinical trial set-up, sharing expertise & experience, with an innovative approach aimed at moving things forward."**, added Céline Tinguely, general Manager at CREAPHARM CLINICAL SUPPLIES.

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### DISTRIBUTING IMP ALL OVER EUROPE

250 shipments are planned for now, from CREAPHARM CLINICAL SUPPLIES Le Haillan to the clinical sites in 7 European countries.

The clinical labeling in 11 languages and the strong support of the CREAPHARM's depot partners contribute to meet the different local regulations.

**"Our strategic alliance with DELPHARM & CREAPHARM has enabled us to take forward our compound to a Phase II clinical study as per the planned timelines. We look forward to continuing our successful collaboration for our next projects as well."** concluded Daniel Gehrlach, Associate Director at HMNC Brain Health.

### ABOUT HMNC

HMNC Brain Health (HMNC Holding GmbH) is a global precision psychiatry biopharma company pioneering the development of personalized therapies powered by predictive companion diagnostics, leading to higher remission rates. The Company develops a unique pipeline for targeting both Major Depressive Disorder (MDD) and Treatment-Resistant Depression (TRD). The Company has presence in both the Germany and the US and is backed by a renowned global VC, several family offices, and a strategic healthcare investor.

HMNC's development pipeline includes 2 precision psychiatry programs in which it aspires to develop a V1bR antagonist with a companion diagnostic (V1bCDx), and a CRHR1 antagonist with its companion diagnostic (CRHR1CDx).

Additionally, in a joint venture with Develco Pharma, the company is developing an oral-prolonged release formulation, KETO1, a racemic ketamine with minimal dissociative side effects. The pharmacokinetic profile of KETO1 could significantly improve the risk profile and patient convenience in TRD population, by minimizing dissociative side effects compared to the currently applied intravenous and intranasal ketamine therapies.



### ABOUT DELPHARM

DELPHARM DEVELOPMENT is the business unit of DELPHARM offering full development services for a large range of dosage forms for new chemical entities or innovative fixed dose combinations thereof clinical batches supply for Phase 1-3 for OSD and injectable dosage forms. DELPHARM is a worldwide leader in contract development and manufacturing (CDMO) of medicines for pharmaceutical companies.

> [delpharm.com/en/development](https://delpharm.com/en/development)  
> [development@delpharm.com](mailto:development@delpharm.com)

### ABOUT CREAPHARM

CREAPHARM CLINICAL SUPPLIES is the pharmaceutical industry global partner for Clinical Trial Supply Management (CTSM), specialized in clinical packaging, labeling and clinical logistics.

With the aim to provide high value-added services that meet the specific needs of each client, CREAPHARM offers a tailor-made approach. The teams give and bring their best to achieve operational excellence and maximize the success of each clinical trial.

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