Gate2Brain Receives EMA Orphan Drug Designation for Its Groundbreaking Pediatric Cancer Treatment

Barcelona, November 2024 – Gate2Brain, a cutting-edge technology platform focused on enhancing drug delivery to the brain, has reached a major milestone in the fight against pediatric brain tumors by obtaining Orphan Drug Designation (ODD) from the European Medicines Agency (EMA) for its innovative product, G2B-002.

This designation recognizes G2B-002 as a potential treatment for a rare and severe disease, specifically granted to drugs aimed at conditions affecting fewer than 5 in 10,000 people in the European Union, and which offer significant advantages over limited or non-existent alternatives.

Key Highlights of Gate2Brain's Achievement:

1. EMA Orphan Drug Designation: G2B-002 has received EMA Orphan Drug Designation, a fundamental achievement that accelerates its progress toward clinical trials for pediatric brain tumor treatment, supported by a team of experts in biotechnology and pediatric neuro-oncology.

2. Innovation in Drug Delivery: Gate2Brain has developed a patented technology that allows drugs to cross the blood-brain barrier (BBB) more effectively, increasing precision and efficacy in treating brain tumors.

3. Social and Scientific Commitment to Pediatric Oncology: For its first indication, G2B-002 targets diffuse intrinsic pontine glioma (DIPG) and pediatric glioblastoma (pGBM), two aggressive brain tumors that are among the leading causes of childhood cancer mortality.

A Boost to Transform Pediatric Brain Cancer Treatment

The EMA's orphan designation for G2B-002 represents a decisive step in developing new therapies for complex pediatric cancers, especially those affecting the brain. Gate2Brain's proprietary technology facilitates high-precision drug delivery across the blood-brain barrier, enhancing both the effectiveness and safety of brain tumor treatment.

G2B-002, Gate2Brain's most advanced product and a proof of concept for its technology, is based on a peptide transport system that delivers an anti-cancer agent. This system has demonstrated efficacy against pediatric brain tumors with an intact BBB, such as pediatric glioblastoma (pGBM) and diffuse intrinsic pontine glioma (DIPG), the first conditions to benefit from this technology.

Furthermore, these results show potential applications for other therapeutic agents and biological barriers, with significant clinical implications.

Innovation and Commitment to Pediatric Patients

With a research program centered on pediatric brain tumors as its first indication, Gate2Brain aims to leverage EMA's recognition to advance G2B-002 to clinical trials and pave the way for a new era of treatment options in a high unmet need area. "*We are moving toward clinical trials that could transform the treatment of pediatric brain tumors*," said Meritxell Teixidó, CEO of Gate2Brain, underscoring the company's strong commitment to pediatric patients and their families.

About Gate2Brain

Gate2Brain is a technology platform spin off from **IRB Barcelona**, the **University of Barcelona**, and **the Sant Joan de Déu Hospital**, founded in 2020. Gate2Brain uses its proprietary peptide-based technology to cross biological barriers, such as the blood-brain barrier, to improve drug delivery to the brain and reduce side effects. The company has received support from institutions including **Fundación Botín** (Mind the Gap), **Banco Sabadell** (BStartup Health), **CDTI**, the **European Innovation Council** (EIC Accelerator), Startup Capital d'**ACCIÓ** and CaixaResearch Consolidate de la **Fundació "la Caixa"**.

Gate2Brain envisions improving patients' quality of life through technology that enhances drug delivery efficiency.

With the support of:

Con el apoyo de:

Gate2Brain, S.L.
info@gate2brain.com
www.gate2brain.com
Parc Cientific Barcelona
Baldiri Reixac, 4-8, Torre I
08028 Barcelona, Spain