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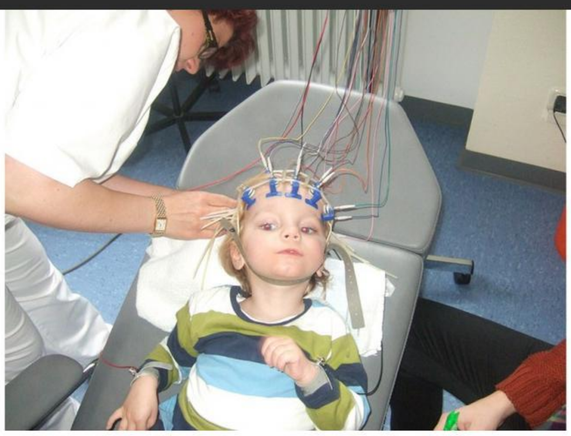
REGULATORY BREAKTHROUGH FOR BRAINREPAIR UG START-UP - STEM CELL TREATMENT FOR NEWBORNS

EMA Orphan Drug Designation is followed by agreement on Paediatric Investigation Plan



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Press Release

Bochum's medics have developed a unique method based on own (autologous) cord blood stem cells to treat white matter brain damage causing cerebral palsy (CP) in newborn babies for which the European Medicines Agency has granted the worldwide first 'Orphan Drug Designation' (ODD). This designation guarantees market exclusivity in all EU member states for 12 years upon market authorisation. "With this agreed Paediatric Investigation Plan (PIP), we enter the finishing straight towards approval because the planned randomized placebo-controlled study (RCT) to confirm safety and efficacy will be performed on a limited number of preterm newborns (born before 37 weeks gestation) and includes an interim analysis after 50% of participants have been included," says Prof. Dr. Arne Jensen, Co-Founder and CEO of BrainRepair UG, a spin-off of the Ruhr-University Bochum (RUB). "White matter brain damage affects approx. 15.000 newborns each year in the EU," he continues, "is frequently followed by stiff muscular paralysis (cerebral palsy), the most common disability in childhood, and comprises an enormous burden for the children, their families, and society with estimated healthcare costs of EUR 56B each year." Prof. Arne Jensen stresses, "All our personal, scientific, clinical, and philanthropic efforts serve the ultimate goal – to combat infantile Cerebral palsy and stop CP in children! Therefore, we must make this first curative stem cell treatment from own cord blood available for all children in need as soon as possible."

About BrainRepair UG

BrainRepair UG is a clinical stage start-up developing cutting-edge stem cell treatments based on human cord blood for a wide range of indications related to brain injury in children including those caused by oxygen lack and inflammation (PVL, HIE, NE), hemorrhage, stroke, cerebral palsy (CP), traumatic brain injury (TBI), and spinal cord injury (SCI). BrainRepair UG is the first Biotech company worldwide whose stem cell products have been awarded 'Orphan Medicinal Product Designations' for the treatment of brain injury in newborn infants (PVL, NE) by the European Commission and the European Medicines Agency, EMA. BrainRepair's Headquarter is in Bochum, Germany. You may visit the website at https://brainrepair.eu/ for more information.

Links:

Autologous Cord Blood Therapy for Infantile Cerebral Palsy: From Bench to Bedside, *Obstet Gynecol Int* vol.2014,12p; https://www.hindawi.com/journals/ogi/2014/976321/

EMA Orphan medicinal Product Designation Periventricular leukomalacia (PVL): https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3161744

EMA Orphan medicinal Product Designation Newborn encephalopathy (NE): https://www.ema.europa.eu/en/medicines/human/orphan-designations/eu3161743

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