Brepco Biopharma announces that it has filed an application for a Paediatric Use Marketing Authorization with the European Medicines Agency for Neoatricon® (dopamine HCl).

Dublin, Ireland August 26, 2022 -- Brepco Biopharma announces that it has filed for marketing authorization with the European Medicines Agency for Neoatricon®, a proprietary, paediatric and neonate-appropriate formulation of dopamine. The product is eligible for approval under the EU's Paediatric Use Marketing Authorization legislation. As such, if approved, it will be eligible for 10 years market and data exclusivity.

About 200,000 paediatric patients, mostly newborn babies and infants, are treated for hypotension in the US and Europe each year. The conditions associated with hypotension are typically life-threatening and patients often require urgent treatment. Dopamine is the first-line drug intervention for the majority of these patients. However, it is not approved for use in paediatric patients, nor is it supplied in a dosage form suitable for children and babies. Because it is an age-appropriate formulation, Neoatricon will be safer to administer to babies and children than the current adult-only approved product.

As part of the product's development program Brepco, along with a consortium of EU and Canadian hospitals led by Cork University Hospital, conducted a clinical trial in babies born at less than 28 weeks gestational age to better understand how hypotension in this vulnerable population should be treated.

About Dopamine. Despite being approved only for adult use dopamine is commonly used in pediatric and neonatal medicine. Dopamine has been listed on the World Health Organization List of Essential Medicines for Children and was granted an Orphan Designation for the prevention of non-traumatic intraventricular hemorrhage by the US Food and Drug Administration.

About Neoatricon®. It is a ready-to-use sterile solution for injection of Dopamine Hydrochloride. It has been specifically developed as an age-appropriate formulation and does not require dilution prior to administration. It is intended for use in the treatment of vascular hypotensive disorders in neonates, newborns and children up to (and including) the age of 17 years.

Hypotension in premature babies: Survival of infants born prematurely has increased significantly over the last three decades, especially amongst the smallest and most immature babies. The improved survival rate has brought the increased challenge of treating conditions that are unique to very premature babies. Hypotension is one such condition that commonly impacts premature babies and can lead to an (non-traumatic) intraventricular hemorrhage (IVH) which may lead to death or neurodevelopmental disability.

About Brepco: Brepco develop products for the unique needs of pediatric patients.

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