BrePco Biopharma and Piramal Critical Care announce MHRA approval for Neoatricon® in the UK

A new paediatric formulation for the treatment of hypotension in neonates, infants and children

Dublin, Ireland, March 19, 2025: BrePco Biopharma Limited (BPCO) that develops products for the unique needs of paediatric patients and **Piramal Critical Care (PCC),** a global leader in critical care medicines, today announced that the UK Medicines and Healthcare products Regulatory Agency (MHRA) issued a grant of a Marketing Authorisation for the use of Neoatricon® - the first paediatric strength solution for infusion of Dopamine Hydrochloride. PCC has secured the commercialization rights for the EU, UK, and Norway and will be responsible for distributing Neoatricon® in these regions.

Developed by BPCO, Neoatricon® is an age-appropriate, ready-to-use, sterile solution for infusion of Dopamine Hydrochloride. It is available in a concentration of **1.5mg/mL** in a 30 mL vial and a higher strength containing **4.5mg/mL** in a 50 mL vial.

Currently, there are no approved Dopamine Hydrochloride formulations specifically indicated for use in neonates, infants, or children, with off-label use remaining a common practice. The approval of Neoatricon® addresses this critical gap by ensuring precise dosing, reducing the risk of under- or overdosing, and minimizing preparation time in neonatal and paediatric intensive care units (NICU & PICU), facilitating faster intervention in emergency settings.

Paul Breen, Director of BPCO remarked that "*The approval of this new paediatric formulation represents a much-needed opportunity to improve the outcomes for these vulnerable patients by improved safety – ensures accurate dosing, reducing the risk of under or overdosing compared to diluting or adjusting adult formulations. It makes it easier for healthcare providers to administer in emergency settings. It minimizes preparation time in neonatal and paediatric intensive care units (NICU & PICU), allowing for quicker intervention*".

Peter DeYoung, CEO, Piramal Global Pharma commented, "*We are thrilled to announce the approval of Neoatricon®, the first and only authorized treatment for hypotension in neonates, infants, and children. This milestone marks an important step for Piramal Critical Care as we expand into a new therapeutic area. Our partnership with BrePco Biopharma has allowed us to bring forward an innovation that will significantly improve health outcomes for paediatric patients."*

With this approval, Neoatricon® establishes a new standard in paediatric critical care.

Neoatricon®1.5 mg/mL is most suitable for neonates (including those of extremely low gestational age), infants and children below 10 kg body weight when use of this inotrope is indicated to provide cardiovascular support. *PLGB 43267/0003*
Neoatricon® 4.5mg/ml is a paediatric strength dopamine formulation, most suitable for infants and children weighing 10 kg or above, and adolescents, when use of this inotrope is indicated to provide cardiovascular support. *PLGB 43267/0004*

About BrePco Biopharma Limited: Ireland-based BPCO develops products for the unique needs of paediatric patients. The development of Neoatricon® was part funded by the European Commission within the 7th Framework Programme ("FP7"). www.bcopharma.com

About Piramal Critical Care: Piramal Critical Care (PCC), a division of Piramal Pharma Limited, is a global leader in anaesthesia, pain management, intrathecal therapy, and critical care medicine. PCC products are available in more than 100 countries, including the US and the European markets. Piramal Critical Care has a focus on improving outcomes for patients with high quality products manufactured in-house or in partnership with leading pharmaceutical development and manufacturing organizations around the world. For more information and updates, please visit: www.piramalcriticalcare.com

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