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ASIA EDITION

# FDA approves Prometic's inter-alpha-inhibitor-proteins

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**Rare Pediatric Disease Designation granted for the treatment of patients with necrotizing enterocolitis (NEC)**




**Singapore-** Prometic Life Sciences Inc. announced that the U.S Food and Drug Administration (FDA) has granted a Rare Pediatric Disease Designation to its Inter-Alpha-Inhibitor-Proteins ("IaIp") for the treatment of Necrotizing Enterocolitis ("NEC"). In addition to the Rare Pediatric Disease Designation, IAIP has also been granted an Orphan Drug Designation by the FDA.

"This is the second pediatric designation which our plasma-derived therapeutics have received from the FDA, demonstrating the capacity of our plasma purification platform to generate a variety of drug candidates targeting unmet medical needs for children with rare diseases," said Mr. Pierre Laurin, President and Chief Executive Officer of Prometic. "The combination of pediatric and orphan drug designations provides us with valuable commercial incentives to continue expanding our pipeline of orphan drugs. We look forward to working closely with the FDA to bring this innovative therapy to pediatric patients. The costs associated with this clinical program will not impact our FY2018."

IaIp are endogenous proteins that control excessive inflammatory responses to toxins, infectious organisms, tissue and organ damage. An inverse correlation between IaIp levels in blood plasma and disease severity / mortality has been demonstrated in humans with sepsis. In a gold-standard animal model proven to emulate NEC in humans, the supplementation of IaIp significantly increased the study subjects' survival rates.

The FDA grants Rare Pediatric Disease Designations for serious or life-threatening diseases wherein the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years, including age groups often called neonates, infants, children, and adolescents. If and when approved, Prometic's IaIp replacement therapy could be eligible to receive a rare pediatric disease priority review voucher.