

## Japan approves Clinigen's world-first therapeutic human breast milk fortifier to manage VLBW infants

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**Prolacta's "PremieFort® Enteral Solution," a human milk-based fortifier for nutritional management in neonates and infant with very low birth weight (VLBW) condition**

Clinigen, a global leader in accelerating patient access to critical medicines, obtained the world's first prescription drug approval for a human breast milk nutritional fortifier on the Japanese market.

Clinigen K.K. and Prolacta Bioscience obtained regulatory approval for 'PremieFort® Enteral Solution' in Japan as the world's first human milk-based nutritional fortifier regulated as a prescription drug. Highlighting the country's leadership in neonatal care and high preterm survival rates, Prolacta designated Clinigen as its exclusive licensee and marketing authorization holder in Japan

Human milk-derived fortifiers are part of specialized nutritional strategies, and their growth emphasizing the need for robust regulatory frameworks to ensure safety, quality, and access. Extensive clinical data, including the JASMINE Phase III trial, supports Clinigen's regulatory strategy to secure pharmaceutical approval in Japan.

Prolacta's "PremieFort® Enteral Solution" is intended for VLBW infants, as well as neonates and infants with conditions such as congenital gastrointestinal disorders or congenital heart diseases. It is also intended for those recovering from gastrointestinal surgery, which indicates a failure to gain weight. The approval acknowledges the critical role of human milk-based nutrition for these at-risk babies.

"Japan's approval reflects a clear regulatory judgment that this category warrants pharmaceutical-level oversight." Dr. Varun Sethi, CEO, Clinigen commented, "The regulatory authorities have carefully reviewed and established the necessary protocols to ensure that PremieFort® Enteral Solution, a human milk-based product has been tested and approved according to medicine standards. Patient access is determined by quality, safety, and efficacy, not geography.

"A complex, new science asset was updated in Japan, opening new markets and helping vulnerable infants." Scott Elster, CEO, of Prolacta said: "We are proud to have secured approval for the world's first human milk-based fortifier for therapeutic use in Japan underscoring the strength of our pharmaceutical-grade manufacturing, quality systems, clinical evidence, and regulatory expertise. This landmark approval enables access to more at-risk infants globally."