



## Growing Number of Hospital NICUs Turning to Prolacta's 100 Percent Human Milk-Based Nutrition for the Premature Infants in Their Care

### 2018 Prematurity Awareness Month Marks Progress in the Standard of Care for Premies Nationwide

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**DUARTE, Calif., Nov. 15, 2018** – When Prolacta Bioscience® was founded in 1999, the idea seemed logical: An exclusive human milk-based diet (EHMD)<sup>1</sup> – including a fortifier made from donor breast milk instead of cow milk – would be the best nutrition for extremely premature infants, better than a diet including cow milk-based formula or fortifier. But it remained to be proven that an EHMD would, in fact, lead to reduced complications, improved growth rates and better outcomes for the one in 10 premature babies born annually in the U.S.

This November, as preemie families and neonatal intensive care units (NICUs) observe Prematurity Awareness Month, Prolacta is gratified that the benefits of an EHMD have been substantiated, and that NICUs nationwide are changing the standard of care for extremely premature infants. Today, nearly 40 percent of all Level III and IV NICUs combined in the U.S. have come to rely on Prolacta's 100 percent human milk-based neonatal nutritional products to feed the most fragile premature infants in their care.

NICUs are embracing an EHMD and using Prolacta's products in recognition of the clinical evidence supporting this diet: When used as part of an EHMD, Prolacta's neonatal nutritional products have been clinically proven to improve health outcomes<sup>2,3,4</sup> and reduce hospital costs<sup>5,6</sup> for critically ill, extremely premature infants weighing between 500 and 1250 g (1 lb 2 oz to 2 lb 12 oz) at birth, in the NICU, as compared to cow milk-based fortifier or cow milk-based preterm formula.

"As awareness has grown about the connection between cow milk nutrition and serious complications in premature infants, increasing numbers of neonatal specialists are adopting an EHMD as the new standard of care, and families are calling for it," said Scott Elster, president and CEO of Prolacta Bioscience. "We are proud to provide NICUs with human milk-based nutritional products that can reduce the anguish and expense that come with complications suffered by preterm infants."

In clinical studies, premies fed an EHMD not only experienced fewer complications<sup>7</sup> and required fewer days of hospitalization,<sup>6</sup> but they also showed improved growth rates. Early and appropriate advancement of fortification with an EHMD has been associated with weight gain and length and head circumference growth meeting targeted standards.<sup>8</sup>

## About Prolacta Bioscience

Prolacta Bioscience, Inc. is a privately held life sciences company dedicated to Advancing the Science of Human Milk®. The company pioneered the development of human milk-based neonatal nutritional products to meet the needs of critically ill premature infants in the NICU. Prolacta leads the industry in the quality and safety of nutritional products made from donor breast milk and operates the first and only pharmaceutical-grade manufacturing facility for the processing of human breast milk.

[www.prolacta.com](http://www.prolacta.com)

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<sup>1</sup> An exclusive human milk diet (EHMD) is achieved when 100 percent of the protein, fat and carbohydrates in an infant's diet are derived from human milk. This diet includes a human milk-based human milk fortifier.

<sup>2</sup> Sullivan S, Schanler RJ, Kim JH, et al. *An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products.* *J Pediatr.* 2010;156(4):562-567. doi:10.1016/j.jpeds.2009.10.040. The randomized study of 207 infants weighing 500 to 1250 g compared the benefits of an exclusive human milk diet to a diet of both human milk-based and cow milk-based products.

<sup>3</sup> Cristofalo EA, Schanler RJ, Blanco CL, et al. *Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants.* *J Pediatr.* 2013;163(6):1592-1595. doi:10.1016/j.jpeds.2013.07.011. The multicenter randomized controlled study examined 53 extremely premature infants weighing 500 to 1250 g who were fed either a bovine milk-based preterm formula or an exclusive human milk diet, comparing the duration of parenteral nutrition, growth and morbidity.

<sup>4</sup> Abrams SA, Schanler RJ, Lee ML, Rechtman DJ. *Greater mortality and morbidity in extremely preterm infants fed a diet containing cow milk protein products.* *Breastfeed Med.* 2014;9(6):281-285. doi:10.1089/bfm.2014.0024. This cohort study included 260 extremely preterm infants born weighing less than 1250 g who received a diet that ranged from 100% cow milk to 100% human milk.

<sup>5</sup> Ganapathy V, Hay JW, Kim JH. *Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants.* *Breastfeed Med.* 2012;7(1):29-37. doi:10.1089/bfm.2011.0002. This cost-effectiveness analysis of 2,560 extremely premature infants less than 28 weeks' gestational age in 257 hospitals nationwide compared the impact of an exclusive human milk diet composed of mother's milk fortified with a human milk-based fortifier versus a diet composed of mother's milk fortified with cow milk-based fortifier.

<sup>6</sup> Assad M, Elliott MJ, Abraham JH. *Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet.* *J Perinatol.* 2016;36(3):216-220. doi:10.1038/jp.2015.168. The study retrospectively looked at 293 preterm infants between gestational ages of 23 and 34 weeks and birth weights between 490 and 1700 g in the Level III NICU. The study compared the clinical and financial impacts between infants that were fed an exclusive human milk diet; cow milk-based fortifier and maternal milk; a mixed combination of maternal milk, cow milk-based fortifier and cow milk-based formula; or formula between March 2009 and March 2014.

<sup>7</sup> Hair AB, Peluso AM, Hawthorne KM, et al. *Beyond necrotizing enterocolitis prevention: improving outcomes with an exclusive human milk-based diet.* *Breastfeed Med.* 2016;11(2):70-74 doi: 10.1089/bfm.2015.0134. The multicenter retrospective study looked at 1,587 infants weighing less than 1250 g at birth who received a cow milk-based diet of mother's own milk fortified with cow milk-based fortifier and/or preterm formula compared to infants who received a human milk-based feeding protocol.

<sup>8</sup> Hair AB, Hawthorne KM, Chetta KE, Abrams SA. *Human milk feeding supports adequate growth in infants  $\leq$  1250 grams birth weight.* *BMC Res Notes.* 2013;6:459 doi: 10.1186/1756-0500-6-459. The study looked at growth among infants weighing less than 1250 g who were fed an exclusive human milk-based diet including a human milk-based fortifier until 34 weeks postmenstrual age as compared to historical growth standards.