

Clinical Trial Evaluating the Effect of Prolact CR® on Length of Stay and Bronchopulmonary Dysplasia Among Very Low Birth Weight Infants Surpasses the Halfway Point

DUARTE, Calif., May 25, 2017 – Prolacta Bioscience®, the pioneer in human milk-based neonatal nutritional products for premature infants, announced today that it passed the halfway point in a clinical trial evaluating the effect of adding [Prolact CR®](#), a caloric fortifier made from 100 percent human milk cream, to an exclusive human milk-based diet (EHMD)¹ for very low birth weight (VLBW) premature infants. The study is evaluating the length of stay and incidence of bronchopulmonary dysplasia (BPD) and has enrolled 127 of the 210 participants weighing between 500 and 1,250g (1 lb 1 oz to 2 lbs 12 oz).

The randomized controlled study is evaluating whether adding the human milk cream-based caloric fortifier can decrease the length of hospital stay and reduce BPD, a form of debilitating chronic lung disease not uncommon in VLBW babies. The milk cream caloric fortifier is added as a supplement to an EHMD, which includes the use of 100 percent human milk-based fortifier Prolact+ H²MF®, and is the recommended diet for VLBW infants.

“Due to the increased energy and macronutrient requirements of VLBW infants in general, and those with BPD in particular, unfortified human milk does not meet their nutritional needs,” said Amy Hair, M.D., lead investigator, Assistant Professor of Pediatrics at Baylor College of Medicine, and the Director of Neonatal Nutrition at Texas Children’s Hospital. “VLBW infants require 20 to 40 percent more calories than their age-matched counterparts. These infants also are at higher risk for postnatal growth failure due to disruptions in their feeding regimens. An earlier randomized clinical trial looking at growth suggested that Prolact CR® reduced the incidence and severity of BPD in the group receiving additional nutrients provided from fat.”

The study, “A Randomized Trial of the Use of Human Milk Cream to Decrease Length of Stay in Extremely Premature Infants,” is currently being conducted at Akron Children’s Hospital at Boardman, Boardman, Ohio (Linda Cooper, M.D.); Innsbruck Medical University, Innsbruck, Austria (Ursula Kiechl-Kohlendorfer, M.D.); Michigan State University-Sparrow Hospital, Lansing, Mich. (Padmani Karna, M.D.); University of Texas Health Science Center at San Antonio, San Antonio, Texas (Cynthia Blanco, M.D.); Winnie Palmer Hospital for Women & Babies, Orlando, Fla. (Jose Perez, M.D.); Wasatch Neonatal LC, Orem, Utah (Dale Gerstmann, M.D.); St. Joseph’s Women’s Hospital, Tampa, Fla. (Jenelle Ferry, M.D.); St. John Medical Center, Tulsa, Okla. (Craig Anderson, D.O.); Cook Children’s Medical Center, Fort Worth, Texas (David Riley, M.D.); St. Louis Children’s Hospital, St. Louis, Mo. (Stephanie Attarian, M.D.); The University of Oklahoma Health Sciences Center, Oklahoma City, Okla. (Andrea Willeitner, M.D.); and Texas Tech University Health Sciences Center El Paso, El Paso, Texas (Lewis Rubin, M.D.).

Potential future sites include: Texas Health Harris Methodist Hospital Fort Worth, Fort Worth, Texas; MultiCare Tacoma General Hospital, Tacoma, Wash.; Westchester Medical Center, Valhalla, N.Y.; Sharp Mary Birch Hospital for Women & Newborns, San Diego, Calif.; and Scott & White Memorial Hospital, Temple, Texas.

“This clinical trial is the result of secondary findings that were observed in an earlier trial, and underscores the need for continued study of the unique properties in human milk,” said Scott Elster, CEO of Prolacta. “We look forward to seeing how Prolact CR[®] affects lengths of stay and BPD with the hope of uncovering new therapeutic benefits for this fragile patient population.”

This new clinical trial seeks to verify observations on length of stay and BPD with the use of Prolact CR[®] from a prior multi-center, randomized trial ([“Premature Infants 750-1,250g Birth Weight Supplemented with a Novel Human Milk-Derived Cream are Discharged Sooner,”](#) published in Breastfeeding Medicine in 2016). This analysis found that infants who received Prolact CR[®] were discharged, on average, 12 days earlier than those who did not receive the cream supplement. In the initial trial, infants who developed BPD may have derived an even greater benefit, a finding which prompted this new study.

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 neonatal intensive care unit (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 milk.

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1 An EHMD is when 100% percent of the protein, fat and carbohydrates in an infant’s intake are derived solely from human milk.