

Enrollment Passes Halfway Milestone in Clinical Trial Evaluating the Effect of an Exclusive Human Milk Diet Including a Specialty Fortifier in Term Infants Born with Single Ventricle Congenital Heart Defects

DUARTE, Calif., Aug. 9, 2018 – Prolacta Bioscience[®], the pioneer in human milk-based neonatal nutritional products for premature infants, announced today that enrollment has passed the halfway milestone in a randomized controlled study evaluating how growth and clinical outcomes are affected when an exclusive human milk diet (EHMD)¹ including a specialty fortifier is provided in the immediate post-surgical period to term infants who have undergone surgery to address a serious heart defect known as single ventricle cardiac physiology. To date, 58 out of 100 patients have been enrolled.

Single ventricle cardiac physiology, a set of conditions in which the heart has only one adequate ventricle or pumping chamber, occurs in 5 out of 100,000 live births² and causes a range of clinical problems.² The condition is usually fatal unless treated by a series of surgeries,³ and babies with this heart defect often have difficulty breathing, feeding and growing.^{3,4}

“Having seen the benefits of an EHMD in the youngest and most fragile premature infants, we are committed to creating specialized human milk-based nutritional formulations to meet the needs of other infants with very specific medical needs,” said Scott Elster, president and CEO of Prolacta Bioscience.

Prolacta has developed a first-of-its-kind human milk-based specialty fortifier specifically to meet the nutritional needs of fragile term infants undergoing cardiac surgery. The new fortifier contains the highest caloric density of any 100 percent human milk-based fortifier ever created by the company.

“This population of frail term infants who are going through cardiac surgery has particular nutritional challenges and increased caloric demands,” said Principal Investigator Cynthia Blanco, M.D., University of Texas Health Science Center. “We hypothesize that early administration of an EHMD that includes a human milk-based fortifier precisely formulated to support these infants may result in improved growth, better wound healing, reduced episodes of feeding intolerance and necrotizing enterocolitis (a destructive inflammation of the intestines), and reduced length-of-stay in the hospital. We further speculate that these babies may have improved long-term neurodevelopmental outcomes as a result of this feeding protocol. Ultimately, results like these could potentially have long-term health and economic benefits.”

All infants in the trial must have received only maternal human milk or donor human milk if they received any enteral nutrition prior to randomization. Once randomized, infants in the EHMD group will receive only human milk prior to surgery and then an EHMD including the specialty fortifier, started as

soon as possible post-surgery and then throughout the 30-day feeding period following surgical repair or until hospital discharge, whichever comes first. Infants in the control group will receive a standard diet (per standard of care at each hospital) that includes mother's own milk, donor human milk, or cow milk-based formula pre-surgery and human milk and/or formula post-surgery. Follow-up on these infants will take place for up to two years.

The study, "A Randomized Controlled Trial to Evaluate Growth Velocity and Clinical Outcomes of Infants With Single Ventricle Physiology Fed an Exclusive Human Milk Diet With Early Nutritional Fortification Following Surgical Repair," is being conducted at the University of Texas Health Science Center at San Antonio, San Antonio, Texas (lead center); Texas Children's Hospital, Houston, Texas; Cook Children's Medical Center, Fort Worth, Texas; Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio; University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma; UF Health Shands Children's Hospital, Gainesville, Florida; Children's Hospital of Orange County, Orange, California; Lurie Children's Hospital, Chicago, Illinois; and Columbia University New York Presbyterian Children's Hospital, New York City, New York.

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.

www.prolacta.com

Media Contact:

Loren Kosmont
Lkosmont@prolacta.com
310-721-9444

¹ 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.

² Adult Congenital Heart Association. *Single Ventricle Defects and the Fontan*. Accessed Nov. 13, 2016.

³ Cadet JV, *Children's Hospital of Philadelphia: Treating Single Ventricle Defects*. *Cardiovascular Business*. July 26, 2010. Accessed Nov. 13, 2016.

⁴ American Heart Association. *Single Ventricle Defects*. Updated Oct. 21, 2015. Accessed Nov. 13, 2016.