



Prolacta Bioscience® Initiates Clinical Trial to Evaluate the Effect of a Specially Fortified Exclusive Human Milk Diet to Improve Growth in Infants Born with Single Ventricle Congenital Heart Defect

DUARTE, Calif., Feb. 16, 2017 – Prolacta Bioscience, the pioneer in human milk-based neonatal nutritional products, announced today that the first patient has been enrolled in a clinical study to evaluate the effect of a specially fortified exclusive human milk diet (EHMD)¹ to improve growth in infants who have undergone surgery for a serious heart defect known as single ventricle cardiac physiology. Prolacta developed a first-of-its-kind, human milk-based fortifier to address the post-surgical nutrition needs of this fragile infant population.

Single ventricle cardiac physiology occurs in five out of 100,000 live births,² and results in a range of clinical problems resulting from the heart having only one adequate ventricle or pumping chamber.² The condition is usually fatal unless treated by a series of surgeries.³ Babies with single ventricle cardiac physiology often have difficulty breathing, feeding and growing.^{3,4}

“These medically frail newborns are at high risk for growth failure, due to increased caloric demands due to their heart and pulmonary conditions. This presents unique nutritional challenges,” said Principal Investigator Cynthia Blanco, M.D., University of Texas Health Science Center. “We believe a densely fortified human milk diet may be a real benefit to these infants with an ultimate goal of optimizing their nutritional status prior to their second surgery.”

“While not preemies, these babies have a similar need for rich nutrition delivered in small volumes,” said Scott Elster, CEO of Prolacta. “This study is the first to explore the benefits of human milk-based fortifiers in a population of fragile infants other than preemies. The medical centers will be using a new formulation that we developed specifically for these babies, and we hope that it will make a difference to their health and healing.”

The randomized controlled study will evaluate a minimum of 84 infants, starting at age seven days or younger, who require surgery to correct a single ventricle cardiac physiology present at birth, and who were fed an EHMD prior to study enrollment. The study will measure growth rate and clinical outcomes for up to 30 days following surgery in these infants. One group will be fed an EHMD that includes a new formulation of Prolacta’s highest caloric density exclusive human milk-based fortifier, while the other group will receive a standard diet that includes some cow milk-based nutrition. The hypothesis is that infants fed the EHMD will have short-term benefits, including improved growth, reduced episodes of feeding intolerance, sepsis and necrotizing enterocolitis (damaged intestinal tissue), reduced stay in the hospital and potentially improved long-term neurodevelopmental outcomes.

The study is titled, “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.” It is expected to take place at 12 centers: University of Texas Health Science Center at San Antonio (lead center), San Antonio, Texas; University of Texas Southwestern Medical Center, Dallas, Texas; Texas Children’s Hospital, Houston, Texas; Cook Children’s Medical Center, Fort Worth, Texas; Children’s Hospital of Philadelphia, Philadelphia, Pa.;

Cincinnati Children’s Hospital Medical Center, Cincinnati, Ohio; Children’s Hospital of Orange County, Orange, Calif.; Ann & Robert H. Lurie Children’s Hospital of Chicago, Chicago, Ill.; Columbia University Medical Center, New York, N.Y.; Emory University Hospital, Atlanta, Ga.; University of Oklahoma Health Sciences Center, Oklahoma City, Ok.; and UF Health Shands Children’s Hospital, Gainesville, Fla.

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 milk.

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

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

³ Cadet, J.V., “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.