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Safety and Efficacy of a Novel Intervention for Acute Childhood Diarrhea

Clinical trial published in BMJ Global Health demonstrates the potential of PTM202 in a key subset of children with infectious diarrhea

Product shown to be safe and well-tolerated in a vulnerable patient population

BOULDER, CO. and DENVER, CO, January 30, 2018 – The Colorado School of Public Health at the University of Colorado Anschutz Medical Campus and PanTheryx, a leading medical nutrition company, announced today the publication of results from a randomized, double-blind, placebo-controlled trial to assess the safety and efficacy of the novel nutrition-based solution, PTM202, for the treatment of pediatric infectious diarrhea. Infectious diarrhea is the second leading cause of death among children under 5 years of age; greater than the number of childhood deaths caused by AIDS, malaria, and measles combined. The clinical trial was conducted in Guatemala and involved more than 300 children presenting with acute non-bloody diarrhea. The study was conducted in a very challenging environment due to the severity of living conditions. Overall, the results support the use of PTM202 as a safe therapeutic tool against diarrhea.

The full results from this study are published in BMJ Global Health. No difference in diarrhea duration was observed between intervention and placebo in the total population. However, the results demonstrate a significant reduction in the treatment group among children with at least one targeted pathogen (p-value=0.02), an effect most pronounced in urban subjects (p-value=0.007) who had significantly fewer stool pathogens (2.7 total pathogen count versus 4.8) and better nutritional status. The results demonstrate the potential of PTM202 to target specific pathogens occurring in children with acute non-bloody diarrhea and shorten illness duration using a novel, safe, nutrition-based intervention and may represent a new tool to ameliorate the effects of acute diarrheal disease globally. There were no adverse events associated with PTM202.

“Infectious diarrhea is a leading cause of global childhood morbidity and mortality, yet there are few treatment options available for these children,” said Stephen Berman, M.D., FAAP, professor of pediatrics and public health and director of the Center for Global Health at CU Anschutz. “As a
physician, I am excited by the potential that nutrition-based solutions have for addressing infectious diarrhea that impact the lives of millions of patients worldwide.”

PTM202 is an innovative nutrition-based diarrheal treatment that is derived from bovine colostrum and hen’s eggs. It contains key immunoglobulins that target common causes of diarrhea, such as \textit{E. coli}, Salmonella, Rotavirus and Shigella. PTM202 was created with major global health issues in mind, but is also effective against less severe cases of diarrhea and safe for use in countries like the United States, where the average child experiences 7-15 episodes of diarrhea by the time they reach five years old.

“These findings demonstrate that PTM202 is a safe and effective therapeutic tool for addressing diarrhea in children across a wide range of settings and pathogens,” said Mark Grabowsky, M.D., Vice President for the Public Sector at PanTheryx. “We’ve proven we can materially affect one of the most challenging gut health issues on the planet, and the concepts demonstrated in this trial give me great confidence in our future ability to target additional pathogens and address other serious GI-related health conditions with our patented technology.”

\textbf{About PanTheryx}
Founded in 2007, PanTheryx™ is a medical nutrition company based in Boulder, Colorado, and is dedicated to improving global health and quality of life through innovative life science. Utilizing its broad-based patented technology platform, PanTheryx is focused on the development and commercialization of medical nutrition products that target the gastrointestinal microbiome. For more information, please log on to \url{www.pantheryx.com}.

\textbf{About the Center for Global Health}
The Center for Global Health is an interdisciplinary collaboration between the \url{Colorado School of Public Health}, the University of Colorado School of Medicine/Department of Pediatrics and Children’s Hospital Colorado, which enables them to leverage innovative and creative advances in the global standard of health through teaching, research, practice, and service. For more information, visit \url{Center for Global Health} and connect with the Center on \url{Facebook}. 