



FOR IMMEDIATE RELEASE

## **FDA-Regulated Study of Cord Blood Stem Cells to Treat Acquired Hearing Loss Launches**

### **Signals Potential of Newborn Stem Cells in Regenerative Medicine for Common Disorders**

SAN BRUNO, CA – [January 16, 2014] – Cord Blood Registry® (CBR®), the world’s largest and most experienced newborn stem cell company, announces the start of a U.S. Food and Drug (FDA)-regulated study being conducted at Florida Hospital for Children in Orlando to investigate the use of a child’s stem cells from their own stored umbilical cord blood as a treatment for acquired sensorineural hearing loss.

In the United States, approximately 15 percent of children suffer from low or high-frequency hearing loss.<sup>1</sup> The most common type of hearing loss, especially at high frequencies, is sensorineural. Acquired sensorineural hearing loss results from damage to hair cells in the inner ear (cochlea) and can be caused by illness, medication, noise exposure, birth injury, or head trauma. A child’s ability to hear affects the development of language skills, and hearing impairments can lead to poor academic and social development.<sup>2</sup>

The groundbreaking phase 1 study has a primary objective of determining the safety of using cord blood stem cells in a select pediatric patient population while also assessing whether this approach to treatment improves inner ear function, speech, and language development. Researchers will follow 10 children, ranging in age from 6 weeks to 6 years, who have been diagnosed with acquired hearing loss for less than 18 months and who have their own cord blood unit processed and stored under CBR’s strict quality controls. Children with a known genetic cause of deafness are ineligible for study participation. Patients will receive one intravenous infusion of their own umbilical cord blood stem cells. All patients will return for follow-up at 1 month, 6 months, and 1 year post-treatment.

The trial, supported by CBR, follows promising evidence from preclinical studies suggesting that the infusion of human umbilical cord stem cells may help repair damaged cells in the inner ear in ways that could lead to hearing improvement.<sup>3</sup>

“As more children survive premature birth, we are observing increasing numbers of very young children with significant acquired hearing loss, and currently there are no therapies available for reversing that damage,” says Linda Baumgartner M.S., CCC-SLP, LSLs cert. AVT, the trial’s Speech and Language Pathologist and hearing loss expert. James Baumgartner, MD, Surgical Director of Florida Hospital for Children’s Comprehensive Pediatric Epilepsy Center and the study’s principal investigator notes that “presently, the only treatment options for acquired sensorineural hearing loss are hearing aids or cochlear implants, neither of which actually repairs the damage. Using cord blood stem cells to help trigger the body’s own repair mechanisms could provide a non-invasive therapeutic option that does not exist today.”

During the last 25 years, cord blood stem cells have been used in more than 30,000 transplants performed worldwide for the treatment of nearly 80 serious diseases and disorders in both adults and children. The evolution of stem cell therapies has paved the way for further research being conducted through FDA-regulated clinical trials to uncover their potential in regenerative medicine applications.

“Cord Blood Registry continues to lead the industry in evaluating the potential of newborn stem cells in neurological damage, supporting FDA-regulated clinical trials in autism, cerebral palsy, pediatric stroke, traumatic brain injury, and now hearing loss,” underscores Heather Brown, Vice President of Scientific & Medical Affairs at CBR. “We are excited to learn from the outcomes of this particular study and from future studies that may evaluate broader populations affected by hearing loss or other neurological impairments for which there are limited treatment options today,” adds Brown.

For further details regarding the study, visit [www.cordblood.com/hearingloss](http://www.cordblood.com/hearingloss)

### **About Cord Blood Registry**

Cord Blood Registry® (CBR®) is the world’s largest newborn stem cell company. Founded in 1992, CBR is entrusted by parents with storing more than 500,000 cord blood and cord tissue units. CBR is dedicated to advancing the clinical application of newborn stem cells by partnering with leading research institutions to establish FDA-regulated clinical trials requiring CBR processed cord blood for conditions that have no cure today. For more information, visit [www.cordblood.com](http://www.cordblood.com)

### **Florida Hospital for Children**

Florida Hospital for Children is a full-service facility served by more than 130 pediatric specialists and a highly trained pediatric team of more than 1,000 caregivers and staff. This unique children's hospital provides patients with private, family-centered pediatric rooms, a dedicated pediatric emergency department and an Advanced Center for Pediatric Surgery. The Walt Disney Pavilion at Florida Hospital for Children, in Orlando, delivers a complete range of pediatric health and research services for younger patients including advanced surgery, oncology, neurosurgery, cardiology and transplant services, full-service pediatrics, and an innovative health and obesity platform. The 200-pediatric bed facility officially opened in March 2011, but Florida Hospital has been caring for children for more than 100 years.

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1 Niskar, AS, et al. Prevalence of hearing loss among children 6 to 19 years of age: the Third National Health and Nutrition Examination Survey. *JAMA*.1998;279:1071-1075.

2 Tierney, CD, et al. Development of children who have hearing impairment. *Pediatr Rev* 29, e72-73; discussion e73 (2008)

3 Revoltella RP, Papini S, Rosellini A, et al. Cochlear repair by transplantation of human cord blood CD133+ cells to nod-scid mice made deaf with kanamycin and noise. *Cell Transplant*.2008;17(6):665-678.