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FOR IMMEDIATE RELEASE

## **First FDA-Approved Study of Stem Cells to Treat Hearing Loss Begins at Children's Memorial Hermann Hospital**

HOUSTON -- January 12, 2012 -- Children's Memorial Hermann Hospital and [Cord Blood Registry® \(CBR\)](#) are launching the first FDA-approved, Phase I [safety study](#) on the use of cord blood stem cells to treat children with sensorineural hearing loss.

The study, which will use patients' stem cells from their own stored umbilical cord blood, is the first-of-its-kind, and has the potential to restore hearing. This follows evidence from published laboratory studies that cord blood helps repair damaged organs in the inner ear.

The year-long study will follow 10 children, ages 6 weeks to 18 months, who have sustained post-birth hearing loss. Children who are deaf as a result of a genetic anomaly or syndrome are not eligible. To ensure consistency in cord blood stem cell processing, storage, and release for infusion, [CBR](#) is the only stem cell bank providing clients for the study.

“Children only have 18 months to acquire language skills and, if a child does not hear well, they will not acquire the language skills to speak normally,” said James Baumgartner, M.D., sponsor of the study and guest research collaborator at The University of Texas Health Science Center at Houston (UTHealth) Medical School.

Parents will be interviewed by phone to determine eligibility of their children for the study. Those who meet the criteria will be admitted to Children's Memorial Hermann Hospital to undergo a series of blood tests, hearing and speech tests, and an MRI that will view the tracts that send signals from the inner ear to the brain.

The Principal Investigator is Samer Fakhri, M.D., surgeon at Memorial Hermann-Texas Medical Center and associate professor and program director in the Department of Otorhinolaryngology – Head & Neck Surgery at UTHealth. Linda Baumgartner, MS, CCC-SLP, Auditory-Verbal Therapist, is a co-investigator.

“Currently, the only treatment options for sensorineural hearing loss are hearing aids or cochlear implants,” Dr. Fakhri said. “We hope that this study will open avenues to additional treatment options for hearing loss in children.”

Researchers will obtain and process the patients’ stored cord blood for treatment. The cells then will be given to the patients via IV infusion, and patients will be observed for several hours in the hospital.

Patients will return to the hospital to repeat all tests except the MRI at one month and one year, and all tests with an MRI at six months.

“This study is exciting because it might offer a non-surgical option for some children with profound loss,” Linda Baumgartner said. “More importantly, this is the first treatment with the potential to restore normal hearing.”

Since more infants are surviving premature birth, physicians and researchers are seeing a rising number of very young children with significant hearing loss. About 15 percent of children in the U.S. also suffer from low-frequency or high-frequency hearing loss that can impact the child’s speech, language, and social development and can increase their risk of developing learning disabilities, according to Dr. Fakhri.

“We share Dr. Fakhri’s and Dr. Baumgartner’s passion and commitment to understanding more about the potential applications of cord blood to help repair nerve tissue,” said Heather Brown, vice president of scientific and medical affairs at CBR. “It is exciting to be at the forefront of research to match children who have cord blood stored, with this team of groundbreaking doctors studying autologous stem cell therapies for hearing loss.”

The study is supported by CBR and TIRR Foundation.

For information on participation in the study, visit [www.cordblood.com/hearingloss](http://www.cordblood.com/hearingloss).

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#### **About Children’s Memorial Hermann Hospital**

With 11 hospitals located in the Texas Medical Center and throughout greater Houston, Memorial Hermann is a vital healthcare resource known for world-class clinical expertise, quality patient care, and leading-edge technology and innovation. Children’s Memorial Hermann is a 240-bed hospital dedicated to pediatric and neonatal care with an additional 68 beds dedicated to women’s services. The hospital’s compassion and healing expertise has distinguished it as one of the finest children’s hospitals in the

nation. In partnership with the University of Texas Medical School, Children's Memorial Hermann specialists provide care for more than 120,000 patient visits annually, including the tiniest premature infants, children, and adolescents. Memorial Hermann takes a holistic approach to healthcare, offering programs and services that address the physical, social, psychological and spiritual aspects of well-being.

**About Cord Blood Registry Center for Regenerative Medicine**

Cord Blood Registry® (CBR®) is the world's largest and most experienced stem cell bank. The company founded the CBR Center for Regenerative Medicine<sup>SM</sup> to support and advance medical research in regenerative treatments and help to link client families with clinical researchers with trials currently in place or on the horizon. CBR has consistently led the industry in technical innovations and safeguards more than 400,000 cord blood and cord tissue collections for individuals and their families. The company was the first family bank accredited by AABB and the company's quality standards have been recognized through ISO 9001:2008 certification—the global business standard for quality. CBR also has released more client cord blood units for specific therapeutic use than any other family cord blood bank. For more information, visit [www.cordblood.com](http://www.cordblood.com).