

FDA approves first-ever stem cell trial on Autism

22 August 2012 | Regulatory | By BioSpectrum Bureau

FDA approves groundbreaking clinical trial on Autism



Singapore: Sutter Institute for Medical Research and Cord Blood Registry (CBR), which is the world's largest stem cell bank, are launching the first FDA-approved clinical trial to assess the use of a child's own cord blood stem cells to treat select patients with autism. This first-of-its-kind placebo controlled study will evaluate the ability of an infusion of cord blood stem cells to help improve language and behavior.

Dr Michael Chez, director, pediatric neurology, Sutter Neuroscience and principal investigator of the study, said that, "This is the start of a new age of research in stem cell therapies for chronic diseases such as autism, and a natural step to determine whether patients receive some benefit from an infusion of their own cord blood stem cells. I will focus on a select portion of children diagnosed with autism who have no obvious cause for the condition, such as known genetic syndromes or brain injury."

The study will enroll 30 children between the ages of two and seven, with a diagnosis of autism who meet the inclusion criteria for the study. Enrolled participants will receive two infusions, one of the child's own cord blood stem cells and one of a placebo, over the course of 13 months.

Both the participants and the lead investigators will be blinded from knowing the content of each infusion. To ensure the highest quality and consistency in cord blood stem cell processing, storage and release for infusion, CBR is the only family stem cell bank providing units from clients for the study.