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Will RNL stem cell drug trial get Korean FDA nod?

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Singapore: RNL Bio filed an Investigational New Drug (IND) application with the Korean Food and Drug Administration (KFDA) to start phase II and III clinical trials of RNL-Astrostem stem cell drug in patients with cerebral palsy. The study will assess efficacy of stem cells treatment in 45 cerebral palsy subjects over 11 months and will be conducted through Kyung Hee University Hospital at Gangdong and Bethesda Hospital.

RNL-Astrostem has already completed a phase I trial, including tests to rule out toxicity or tumorigenicity, at Seoul National University's Clinical Research Institute. The results of the study have been published in the February 2011 issue of the journal, Stem Cells and Development, under the tile, ' Safety of intravenous infusion of human adipose tissue-derived mesenchymal stem cells in animals and humans'.

RNL Bio believes that with successful trials and approval of the KFDA, it will be possible to commercialize RNL-Astrostem by 2014, revolutionizing the possibility to cure cerebral palsy, which is caused by non-progressive brain damage from single or multiple defects on the nerve or muscular system and results in disorder in motion and sensory integration.

In the clinical study, the investigators employed a variety of methods to assess efficacy, including Kaufman Assessment Battery for Children (K-ABC), Gross Motor Function Measure (GMFM), box and block test, Modified Asworth Scale (MAS), finger tapping test, Brain SPECT and MRI.

Dr JC Ra, president of RNL Bio Stem Cell Technology Institute, said, "It is our mission to find cures for incurable diseases, such as the terrible pediatric curse of cerebral palsy, through autologous stem cell technology."