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RNL BIO files IND for stem cell product with FDA

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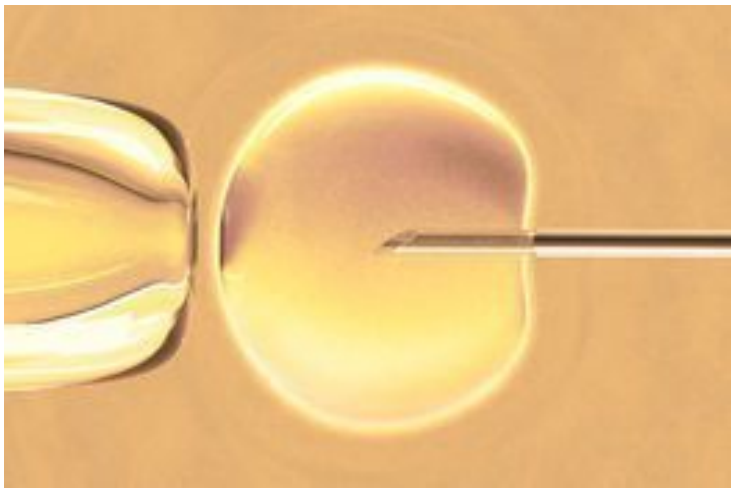

Singapore: RNL BIO, Korea-based stem cell biotechnology company, has filed an Investigational New Drug application (IND) with the US FDA to begin clinical trials with its adipose-derived stem cell product, termed RNL-JointStem, for the treatment of osteoarthritis (OA).

Assuming approval of the IND by the Center for Biologics Evaluation and Research (CBER) at the FDA, RNL BIO plans to initiate its double-blinded, randomized, positive-control Phase II clinical trial during the third quarter of 2013 in Sugarland, Texas.

Dr Jason Dragoo of Stanford University and Dr David Alan Fisher of Indiana University acted as reviewers and completed revision of the protocol now under evaluation by the FDA. Phase I and phase II clinical trials of RNL-JointStem have already been completed under the authority of the Korean Food and Drug Administration (KFDA).

"We are excited about filing an IND for RNL-JointStem because it brings us closer to a clinical trial with RNL-JointStem in the United States," said Mr Jeong-Chan Ra, CEO and chairman, RNL BIO. "Our goal for this trial is to achieve global demonstration that RNL-JointStem is efficacious. If our trial is successful it can lead to a paradigm shift in the treatment of osteoarthritis, using stem cell products derived from a patient's own fat tissue."

"Treatments of this painful chronic condition should relieve pain, not add to it," said Dr Ra. "We hope to confirm the efficacy of RNL-JointStem for cartilage regeneration, pain reduction and joint function improvement for OA patients, and that it will see market approval in due course."