

'Jointstem,' a Stem Cell Drug for Knee Osteoarthritis in New Drug Application Phase

LOS ANGELES, CA, UNITED STATES, August 23, 2021 /EINPresswire.com/ -- The world's first autologous stem cell drug for severe [Osteoarthritis](#) (OA) using a single intra-articular injection

A successful phase 3 clinical trial with 5-year tracking study added; the innovative drug expected to be available in the next year

Nature Cell Co., Ltd. (Jeong Chan Ra, CEO) announced that RBio Co., Ltd. completed the new drug application (NDA) for [Jointstem](#) on August 20, 2021, to the Ministry of Food and Drug Safety. Nature Cell Co., Ltd. has the exclusive rights for the sales of Jointstem in Korea and for its development and approval in the United States.

Jointstem, the world's first autologous stem cell drug for patients with severe Osteoarthritis of the knee and the revolutionary treatment by only a single intra-articular injection developed by Biostar Stem Cell Research Institute (lead researcher Dr. Jeong Chan Ra). Hundreds of billions of Korean won (KRW) have been invested during the last sixteen years for R & D. After it had been rejected for conditional approval in 2018, Nature Cell Co., Ltd. completed phase 3 of the clinical trial successfully, and added a tracking study on the previous phase 2b clinical trial. It is now in the new drug application phase, which is not a conditional approval.

Considering the 115 days of the administration process time by the Ministry of Food and Drug Safety, and the time for supplementing by the Central Pharmaceutical Affairs Council, it is expected to take six months to one year for the approval.

Dr. Jeong Chan Ra, lead researcher of Jointstem, said "I am happier to have completed the new drug application for Jointstem than to get the approval. The successful phase 3 clinical trial has proved that the opinions opposing against the commercialization of Jointstem were wrong."

Dr. Ra also said, "We will thoroughly and diligently prepare for the upcoming regulatory review of the new drug application. We will do our best to have patients with severe knee OA be treated not only in Korea, but around the world."

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