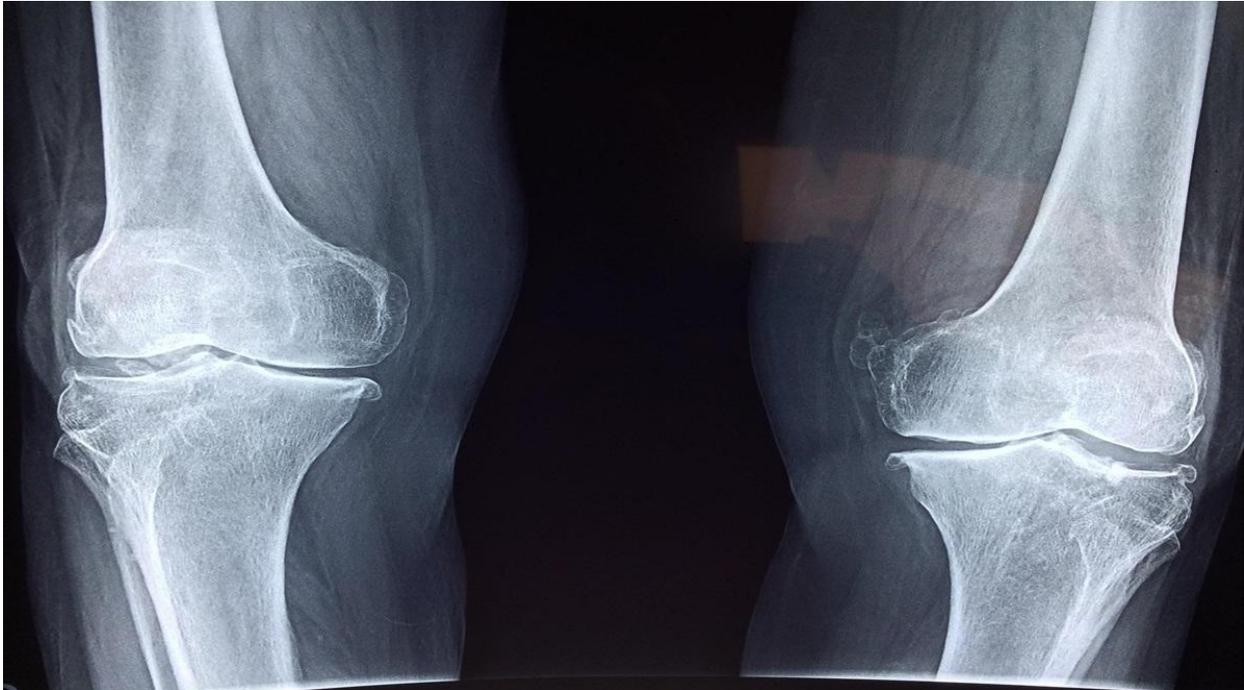




## **Regrow Biosciences gets USFDA Nod for Phase II trials of 'OSSGROW' for Osteonecrosis**





Regrow Biosciences announced on Thursday that it has received a USFDA nod for conducting a phase II trial of its lead product 'OSSGROW,' an orphan drug that helps in effectively treating Osteonecrosis, in the US market. The drug is meant for patients suffering from Osteonecrosis, also known as Avascular Necrosis. According to the company's press statement, Regrow Biosciences has moved one step closer to attaining a global market monopoly estimated at \$5 Billion through this milestone feat.

Although Osteonecrosis is a prevalent disease in Asia, it is a rare disease in the United States and Europe. Regrow Biosciences has been granted Orphan Drug Designation (ODD) for OSSGROW® from the USFDA and EMA. The company also informed that after completing Phase 3 clinical trials in India, OSSGROW® received marketing authorization from the Indian FDA (DCGI) in 2017; the product has successfully treated more than 1000 patients across 200 hospitals.

“Regrow Biosciences welcomes the positive feedback from USFDA from its Pre-IND (Pre-Investigational New Drug) meeting to develop the world's first biological bone cell therapy product – OSSGROW®, indicated to treat Osteonecrosis or Avascular Necrosis. The Pre-IND feedback and recommendation for Phase 2 clinical trial in a small patient population are very encouraging for the brand, as the company is now working towards IND filing. This positive feeling is backed by the safety and efficacy data of OSSGROW® across 200 hospitals in India for more than five years,” Satyen Sanghvi, Chief Scientific Officer and Executive Director at Regrow Biosciences Private Limited, said in a statement on Thursday.

Osteonecrosis is a progressive bone disease that leads to the death of bone tissue due to interrupted blood supply. According to health experts, during the initial stages the patient is asymptomatic, however, as the disease progresses, it affects the structure and eventually the function of the joint. Meanwhile, the advanced stage involves the collapse of the femoral head and arthritis.