

MEDIA BRIEF

Regrow Biosciences gets USFDA nod for Phase II trials of ‘OSSGROW’



Regrow Biosciences, an Indian-centric global biotech company, is glad to announce a breakthrough achievement of getting 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 accomplishment reflects the brand’s commitment to delivering a safe, effective, and durable solution to patients suffering from Osteonecrosis, also

known as Avascular Necrosis. Furthermore, Regrow Biosciences moves one step closer to attaining a global market monopoly estimated at \$5 Bn through this milestone feat.

Osteonecrosis is a prevalent disease in Asia. However, 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. Furthermore, 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.

Speaking on the recent success, **Satyen Sanghvi, Chief Scientific Officer and Executive Director at Regrow Biosciences Private Limited**, said, "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."

Osteonecrosis, mainly seen in the hip joint, is a progressive bone disease that leads to the death of bone tissue due to interrupted blood supply. The initial stages are asymptomatic; however, the disease progresses quite rapidly, affecting the structure and eventually the function of the joint. The advanced stage involves the collapse of the femoral head and arthritis. This necessitates the patients who are barely in their 30s and 40s to undergo hip replacement surgery causing severe loss of productivity and decreased quality of life.