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Regrow Biosciences gets USFDA Nod for Phase II trials of 'OSSGROW' for Osteonecrosis in the US

~OSSGROW is India's first FDA (DCGI) approved product that has treated over 1000 patients across 200 hospitals in the country~

National, 19 May 2022: - 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, Mr. 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.

About Regrow Biosciences:

Regrow Biosciences Pvt. Ltd. is an Indian-centric global biotech company (www.regrow.in) with an R&D center and GMP manufacturing facility near Pune, India, and offices in India, the US, and Singapore. The company is dedicated to researching, developing, and commercializing cell and stem cell-based products to target degenerative and life-threatening diseases. The company has crossed several milestones in its decade-long journey, with many firsts like market authorization and a commercial license for OSSGROW® and CARTIGROW® in 2017. UREGROW® was developed in collaboration with BIRAC, the Department of Biotechnology, the Ministry of Science and Technology, and the Government of India. Today with a strong pool of 340 doctor-partner networks across 46 cities, the Regrow Biosciences has transformed the lives of 1500 patients in India. In addition, the company also provides premium services for Cord Blood Stem Cell banking (Biocell®) across 600 Indian cities and has catered to more than 50,000 young parents.