BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

FDA grants Fast Track designation for Paradigm Biopharmaceuticals Phase III Osteoarthritis Program

April 14, 2022 | News

FDA Fast Track designation for Pentosan Polysulfate Sodium (Zilosul/PPS) offers pathways to expedite development of Paradigm's osteoarthritis clinical program

Australia's Paradigm Biopharmaceuticals, a clinical stage biopharmaceutical company focused on repurposing existing molecules for new indications with unmet clinical needs, is excited to announce that the FDA has granted Fast Track Designation for the company's phase III program investigating Pentosan Polysulfate Sodium (PPS) for the treatment of osteoarthritis (OA).

The FDA Fast Track program offers a number of benefits to help advance development and expedite the review of novel therapies for serious conditions for which there is an unmet medical need, with the aim of providing important new therapies to patients more quickly. This Fast Track Designation from the FDA acknowledges that OA can be a serious disease and that preliminary data demonstrates that Zilosul™ has the potential to address unmet medical challenges associated with the disease.

OA is a chronic degenerative disease characterized by a progressive loss of cartilage, leading to pain, loss of joint function and disability. It is the most prevalent form of joint disease, affecting up to 16% of the population in the developed world, with more than 72 million people in the US, EU5, Canadaand Australia suffering from OA.