

FOR IMMEDIATE RELEASE**ForCast Orthopedics Receives Orphan Drug Designation from FDA for the Treatment of Periprosthetic Joint Infection (PJI)**

Denver, CO – June 27, 2023 – ForCast Orthopedics today announced that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation for ForCast’s lead program, FC001, for the treatment of periprosthetic joint infection (PJI).

PJI is a rare but serious complication of joint replacement procedures that can threaten the function of the joint, the preservation of the limb and even the life of the patient. PJI is challenging to treat because the infecting bacteria adhere to the prosthesis and form a protective biofilm that can be resistant to standard systemic antibiotics.

FC001 is being developed to address these challenges by delivering a targeted antibiotic therapy directly into the infected joint using ForCast’s proprietary technology.

The FDA's Office of Orphan Drug Products grants orphan status to support the development of medicines for rare disorders that affect fewer than 200,000 people in the United States. Orphan drug designation provides certain benefits, including market exclusivity upon regulatory approval, assistance during the development process, exemption from certain FDA fees, and tax credits for qualified clinical trials.

“We are extremely pleased to receive Orphan Drug designation from the FDA,” said Peter Noymer, PhD, Executive Chairman and CEO of ForCast Orthopedics. “Along with the recent designation of FC001 as a Qualified Infectious Disease Product (QIDP) by the FDA, this helps to further validate the potential superiority of our approach to treating PJI relative to the current standard of care.”

“This is a great achievement for ForCast, and an even greater signal to PJI patients about our commitment to improving the treatment options available to them”, added Jared Foran, MD, Chief Scientific Officer and co-founder of ForCast Orthopedics.

About ForCast Orthopedics

ForCast is a development-stage company with a focus on pioneering the treatment of periprosthetic joint infection (PJI) with targeted antibiotic therapy. Our mission is to modernize the standard of care for PJI and improve the quality of life for the growing population of joint replacement patients.

Contact:

Peter Noymer, PhD
Executive Chairman and CEO
pnoymer@forcastortho.com