

## FOR IMMEDIATE RELEASE

## For Cast Orthopedics Receives Qualified Infection Disease Product (QIDP) Designation from FDA for Second Pipeline Program

Denver, CO – November 4, 2025 – ForCast Orthopedics, a development-stage company focused on modernizing care for complex orthopedic infections, today announced that the US Food and Drug Administration (FDA) has granted Qualified Infectious Disease Product (QIDP) Designation for the Company's second pipeline program, FC002, for the treatment of periprosthetic joint infection (PJI).

FC002 combines ForCast's proprietary Wearable Intra-Articular Infusion System (WIIS) delivery platform with tobramycin to enable targeted treatment of gram-negative PJI cases. The QIDP designation for FC002 builds on the Company's success to date with its lead program, FC001, which pairs the WIIS platform with vancomycin to target PJI cases with gram-positive bacteria, and has also received QIDP designation from the FDA.

"Receiving this second QIDP designation from the FDA is an important regulatory milestone for ForCast and validates our aim to address the full spectrum of PJI cases," said Peter Noymer, PhD, Executive Chairman and CEO of ForCast Orthopedics. "This further underscores the potential of our WIIS platform to improve infection treatment strategies and to deliver better outcomes for all PJI patients."

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 prothesis and form a protective biofilm that can be resistant to standard systemic antibiotics.

"This is a truly meaningful advancement in PJI care", added Jared Foran, MD, Chief Scientific Officer and co-founder of ForCast Orthopedics. "Coverage for both gram-positive and gram-negative pathogens is critical to being able to effectively treat all PJI patients, and we are pleased that the FDA recognizes the positive impact that we can have with our WIIS platform."

QIDP designation, provided under the Generating Antibiotic Incentives Now Act (GAIN Act), offers certain incentives for the development of new antifungal and antibacterial drugs that treat serious or life-threatening infections. These incentives include Fast Track designation, priority review, and additional market exclusivity if the product is approved by the FDA.

## **About ForCast Orthopedics**

For Cast is a development-stage company with a focus on pioneering the treatment of periprosthetic joint infection (PJI) with targeted antibiotic therapies. The Company's mission is



to modernize the standard of care for PJI and to provide better treatments and improved outcomes for the growing population of joint replacement patients.

## Contact:

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