

ICOAT MEDICAL RECEIVES POSITIVE FEEDBACK FROM EMA AROUND PLANNED CLINICAL STUDY EMPIRE AND COMPLETED PRECLINICAL PROGRAM

iCoat Medical, a clinical stage pharmaceutical company focusing on reducing and preventing ischemia reperfusion injuries (IRI) during organ transplantation, today announced it has received positive feedback from EMA’s Committee for Medicinal Products for Human Use (CHMP) around its planned 2b efficacy study EMPIRe and completed preclinical program.

“We are very pleased with the feedback from CHMP that confirms our own belief in the leading candidate drug iCM012, which is developed to improve the outcome of organ transplantations. We are now fully focused to initiate the EMPIRe study,” said iCoat Medical’s CEO Peder Waern.

The randomised, controlled, double-blind phase 2b efficacy study EMPIRe, will include approximately 100 patients and be performed at selected high-quality sites in Europe and the U.S. The potential for conditional approval, given sufficiently convincing data generated by the Phase 2b study, will be discussed with the regulatory authorities.

CHMP supports the study design and proposed endpoints of the EMPIRe study, including Delayed Graft Function (DGF) as primary endpoint. CHMP also concluded that the results from the company’s preclinical program, comprising in vitro and in vivo studies addressing proof-of-concept, PK/PD and safety, appear sufficient for the continued clinical development of iCM012.

For more information, please contact:

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About iCoat Medical

iCoat Medical is a clinical stage, pharmaceutical company focusing on reducing and preventing ischemia reperfusion injuries by developing novel pharmaceutical products. The company is one of the world’s leading R&D-centered organizations within innate immunology and is systematically expanding its pipeline using its proprietary coating-technology platform.

iCoat Medical’s lead candidate iCM012 is developed to improve the outcome of organ transplantations. The company’s unique ex-vivo coating of the grafts has the ambition of being an integral part in the transplant procedures of tomorrow. iCoat Medical has operations in Uppsala, Lund, and Malmö, and is headquartered in Stockholm.

For more information, please visit <https://www.icoatmedical.com/sv/>.

Attachments

[iCoat Medical receives positive feedback from EMA around planned clinical study EMPIRe and completed preclinical program](#)