

ICOAT MEDICAL SUCCESSFULLY COMPLETED LONG-TERM FOLLOW-UP PART OF ITS CLINICAL STUDY ATMIRE

iCoat Medical, a clinical stage pharmaceutical company focusing on reducing and preventing ischemia reperfusion injuries (IRI) during organ transplantation, today announced it has completed the long-term follow-up part of its First-in-Human Phase 1 /2a study ATMIRe with leading candidate drug iCM012. All endpoints were successfully met.

“We are very pleased that the follow-up results emphatically confirmed what we have previously seen from the ATMIRe study. The results, which are planned for presentation at a scientific conference later this year, give us great hope for the upcoming Phase 2b study EMPIRe,” said iCoat Medical’s CEO Peder Waern.

ATMIRe was a randomized, double-blinded, placebo-controlled phase 1/2a study (NCT05246618), conducted at a single center in Sweden, enrolling 18 de novo kidney transplant patients. Primary endpoints were safety and tolerability over 12 months. Secondary endpoints included delayed graft function (DGF) and estimated glomerular filtration rate (eGFR) at 12 months.

iCM012 demonstrated a favorable safety profile and showed promising efficacy in mitigating IRI and preserving allograft function within a 12-month follow-up. These findings strongly support further investigation in a larger, multicenter trial to confirm its therapeutic potential in kidney transplantation.

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.

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 successfully completed long-term follow-up part of its clinical study ATMIRe](#)