

iCoat Medical’s upcoming Phase 2b study EMPIRe with iCM012 fundamental to updated clinical development plan

iCoat Medical, a clinical stage pharmaceutical company focusing on reducing and preventing ischemia reperfusion injuries (IRI) during organ transplantation, today announced that it will proceed with its Phase 2b study EMPIRe as the next step in the clinical development of iCM012 in deceased-donor kidney transplantation.

“We have had fruitful and constructive discussions with the regulatory authorities, and a phase 2b study demonstrating efficacy is judged by iCoat to be regarded as the logical next step by regulatory authorities, building on the promising data generated by the already completed Phase 1/2a study ATMIRe. It will give valuable information about the design of any additional study that might potentially be required”, said iCoat Medical’s CEO Peder Waern.

The randomised, controlled, double-blind phase 2b efficacy study, which is planned to start in 2024, 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 later be discussed with the regulatory authorities.

“For the company and investors, an extensive phase 2b study design will lower the overall financial risk and at the same time optimize the design of the iCM012 development program to obtain market approval. Effectively, our updated clinical development plan is expected to further increase the potential for substantial long-term value creation of iCoat Medical”, said Peder Waern.

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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/>