Swedish MPA looks favorably on iCoat Medical's continued and expanded development of iCM012

iCoat Medical, a clinical stage pharmaceutical company focusing on reducing and preventing ischemia reperfusion injuries (IRI) during organ transplantation, today announced that it will continue the development of its leading candidate drug iCM012 according to plan. Based on input from the Swedish Medical Products Agency (*Läkemedelsverket*, LMV), the development of iCM012 in kidney transplantation will advance into a late stage clinical study. In addition, preclinical work will proceed aiming for clinical studies of transplantation of other solid organs.

For the iCM012 lead indication kidney transplantation, iCoat recently completed the Phase 1/2a study ATMIRe with encouraging safety and preliminary efficacy result. The company is now preparing the global pivotal clinical study EMPIRe, expected to start H1 2024.

"We are happy to get this feedback from the Swedish Medical Products Agency and their positive view of proceeding with the clinical development of iCM012 in kidney transplantation," said Peder Waern, CEO at iCoat Medical.

In addition to the development of iCM012 for kidney transplantation, preclinical research in transplantation of other solid organs, as well as in open-heart surgery, is progressing, which are intended to be the next indications to advance towards clinical development. "They also support continued preclinical work, which, together with the promising results from the completed first-in-human ATMIRe study, should be able to form the basis for future Phase I/IIa studies of transplantation of other solid organs, as well as in open heart surgery. This allows us to push forward with our novel asset iCM012 which will have a significant impact to reduce and prevent ischemia reperfusion injury", he continued.

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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/

About iCM012
iCM012 is an innovative pharmaceutical compound designed for ex vivo allograft treatment aiming to mitigate IRI and safeguard organ functionality post transplantation. iCM012 has been granted Orphan Drug Designation by the US Food and Drug Administration (FDA) and by European Commission.

About Phase 1/2a trial ATMIRe in kidney transplantation
ATMIRe was a randomized, placebo-controlled, double blinded first-in-human trial including uremic patients awaiting *de novo* first kidney transplantation at Skåne University Hospital in Malmö, Sweden. Eighteen patients were randomized (2:1) in 2 arms (iCM012 n= 12 / placebo= n=6) with safety and tolerability as primary endpoints. The main trial period was 3 months followed with another 9 months of additional safety assessment.

About IRI and the kidney transplant market
IRI is a serious complication that arises during organ transplantation resulting in detrimental short- and long-term graft outcomes. In kidney transplantation, IRI contributes to DGF which occurs in about 20-40% of deceased donor kidney transplantations.

Total number of kidney transplants in 2021 amounted to 36,000 in Europe and the US. Kidney transplants have increased over time with most kidneys originating from deceased donors. iCM012 can provide value for all transplanted kidney recipients but the population with higher risk of IRI, such as recipients of kidneys with high KDPI scores, will benefit the most.

The total annual market potential for iCM012 in the initial target population amounts to up to $850M-1.2B in Europe and the US, using a price estimated based on possible cost savings incurred from reducing short- and long-term effects of IRI and DGF