ICOAT MEDICAL ANNOUNCES POSITIVE RESULTS FROM PHASE 1/2A TRIAL ATMIRE IN KIDNEY TRANSPLANTATION

- *ATMIRe met the primary endpoint in the first-in-human trial of drug candidate iCM012 in deceased-donor kidney transplantation*
- *iCM012 was well tolerated with no serious adverse events related to the treatment*
- *The excellent primary function and the absence of Delayed Graft Function (DGF) in iCM012 treated expanded-criteria donor (ECD) kidneys with high Kidney Donor Profile Index (KDPI) support the therapeutic potential of iCM012 in organ transplantation*
- *Pivotal iCM012Phase 2/3 trial is planned for H1 2024*

iCoat Medical, a clinical stage pharmaceutical company focusing on reducing and preventing ischemia reperfusion injuries (IRI) during organ transplantation, today announced the results of ATMIRe, a Phase 1/2a trial of iCM012 in kidney transplantation. The results show that *ex vivo* allograft treatment with iCM012 was safe and well tolerated in the patients undergoing deceased-donor kidney transplantation. Furthermore, compiled data from this first-in-human trial indicate that iCM012 has the potential to preserve and improve allograft function in kidneys at high risk for IRI. These data support continuous clinical development of iCM012 and the upcoming pivotal trial EMPIRe, planned for in the US and Europe in H1 2024.

ATMIRe is a randomized, placebo-controlled, single-center Phase 1/2a trial of iCM012, the first drug being developed for kidney transplantations based on iCoat Medical's patented coating technology platform, administered into the transplant (ex vivo) to deceased-donor kidney allografts prior to the transplantation. Patients were monitored for an initial three-month period, followed by another extended nine-month safety assessment. The primary objective of the trial was safety and tolerability of *ex vivo* allograft treatment with iCM012 to reduce IRI in deceased-donor kidney transplantation. The trial was performed at the Department of Transplantation at Skåne University Hospital in Malmö, Sweden.

"We are pleased to have reached this stage in our clinical development. The results from our first in human trial are encouraging and in the line with our pre-clinical data from the porcine transplant studies. We are currently working to finalize the preparations for the next step in the clinical development of iCM012 – the initiation of a pivotal Phase 2/3 trial during the first half of 2024," said Peder Waern, CEO at iCoat Medical. *"This further strengthen our believe that iCoat Medical's coating technology holds the potential to effectively protect organs and tissues from IRI and improve patient outcomes across various medical conditions."*

A total of 18 patients were randomized 1:2 to receive either placebo (n=6) or iCM012 (n=12)-treated kidneys. Recipient baseline characteristics were balanced between the two treatment groups. However, the distribution of donor kidney quality (assessed by KDPI) among the groups were uneven, despite the randomization process. The placebo group received a smaller fraction (1 /6) of ECD kidneys, while the iCM012 group received a higher proportion (6/12) of ECD kidneys with KDPI > 84%.

The ATMIRe trial met the primary endpoint by showing a favorable safety profile of iCM012. Adverse events were equally distributed between the two treatment groups. There were no serious adverse events related to iCM012 treatment.

Consistent with the results from previous pig transplant studies, the iCM012-treated kidneys exhibited low inflammatory response and less cell damage compared to the placebo group, as determined by a variety of urine markers for tubular cell injury. The initial kidney function (assessed by cystatin-c based eGFR slope) in iCM012 treated ECD-kidneys improved to the same extent as standard-criteria kidneys in placebo group.

Furthermore, there were no cases of DGF in the trial population. These initial findings in combination with excellent primary function of iCM012 treated ECD kidneys are encouraging given a reported DGF incidence of up to 40% for ECD kidneys with high KDPI score.

"We are encouraged by the favorable outcome of this first-in-human trial of iCM012 in deceased-donor kidney transplantation," said Alireza Biglarnia, Chief Medical Officer at iCoat Medical. *"Apart from a convincing safety profile, iCM012 appears to be effective in preservation of initial function of ECD kidneys at high risk for DGF. These findings are a crucial steppingstone for the upcoming multi-center trial to demonstrate efficacy and safety of iCM012 to preserve and improve overall allograft function in deceased-donor kidney transplantation."*

More information about the trial is available at ClinicalTrials.gov under NCT05246618.

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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 transplate 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

Image Attachments

Peder Waern ICoat Medical

Attachments

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iCoat Medical announces positive results from Phase 1/2a trial ATMIRe in kidney transplantation