# ICOAT MEDICAL COMPLETES ENROLLMENT IN FIRST IN HUMAN STUDY OF TUM012 IN KIDNEY TRANSPLANTATION

- **All 18 of the intended patients have been successfully included into iCoat Medical's First-in-Human trial ATMIRe**
- **So far no serious or relevant adverse events linked to the Investigational Medicinal Product (IMP) have been observed**
- **TUM012 is the first drug being developed for kidney transplantations based on iCoat Medical's patented coating technology platform**
- **Topline data from ATMIRe is expected in Q3 2023**

Malmö, Sweden, 10th May 2023. iCoat Medical "iCoat", a pioneer in drug development to attenuate ischemia-reperfusion injury (IRI), today announced it has completed enrollment in its First In Human study of TUM012 in kidney transplantation. Top-line data is expected to be shared during the third quarter of 2023.

Peder Waern, CEO, iCoat Medical says, "This First In Human study of TUM012 in kidney transplantation is a transformative moment for iCoat Medical. We remain fully committed to advancing the pipeline and our clinical activities to develop innovative therapies for the many patients affected by IRI".

ATMIRe is a randomized, placebo-controlled, double-blinded, single-center study of TUM012 administered ex vivo to deceased donor kidney allografts prior to the transplantation. A total of 18 patients were randomized 1:2 to receive either placebo- or TUM012-treated kidneys. Patients are evaluated during a primary study period through three months with additional safety evaluation at six and twelve months. In the primary endpoint of the study, the safety and tolerability of ex-vivo allograft treatment will be assessed. iCoat Medical anticipates sharing top-line data during the third quarter of 2023.

Chief Medical Officer Alireza Biglarnia says "We are pleased to have reached this stage in our clinical development. TUM012 holds necessary potential for improving outcomes in kidney transplantation and expanding our understanding of its therapeutic benefits in attenuating IRI-related injuries not only in kidney transplantation but also in other medical conditions".

IRI is a harmful event, that occurs when the blood supply to a tissue or organ is temporarily interrupted and then restored. This condition inevitably occurs in several medical conditions such as organ/tissue transplantation, stroke, myocardial infarction, and cardiac surgery which can lead to tissue damage and early injurious inflammation with severe consequences for patient outcomes. iCoat Medical's coating technology holds the potential to effectively protect organs and tissues from IRI and to improve patient outcomes across various medical conditions.

In 2022, the U.S. Food and Drug Administration and EMA granted Orphan Drug Designation to

TUM012 for the treatment of solid organ transplantation.

Currently, there are no approved therapies for the prevention of IRI in organ transplantation.

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

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**iCoat Medical completes enrollment in First In Human study of TUM012 in kidney transplantation**