THE U.S. FOOD AND DRUG ADMINISTRATION HAS GRANTED ICOAT MEDICAL ORPHAN DRUG DESIGNATION FOR TUM012 IN THE UNITED STATES

Today, iCoat Medical announces that the U.S. Food and Drug Administration has issued a positive decision on the company's application for Orphan Drug Designation of TUM012 for solid organ transplantation in the United States.

Commenting on the announcement, Peder Waern, CEO of iCoat Medical, said:
"The positive decision from the U.S. Food and Drug Administration on our Orphan Drug Designation application for TUM012 is another important regulatory milestone for us. Transplantation is a lifesaving procedure which can significantly improve the quality of life for very sick patients. Unfortunately, many patients are unable to receive the transplant they need because of the lack of suitable organs. We believe TUM012 has the potential to revolutionize the transplant process and to significantly increase the quality and number of transplantations. Our pre-clinical data generated with TUM012 in kidney transplantation on pigs have been highly encouraging and we look forward to continuing progressing it through our ongoing First In Human – trial, which we expect to conclude in 2023".

The U.S. Food and Drug Administration grants Orphan Drug Designation to drugs intended for the treatment of life threatening or chronically debilitating rare diseases where no therapeutic options are either authorized or where the drugs will be of significant benefit to those affected by the condition. Rare diseases are those defined as having a prevalence of no more than 200,000 persons in the United States. The designation provides development and commercial incentives, including seven years of market exclusivity, protocol assistance on the development of the drug, including clinical studies, and certain exemptions from or reductions in regulatory fees.

For more information, please contact:

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