Sus Clinicals

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SUS CLINICALS, INC. RECEIVES CLEARANCE FROM THE U.S. FOOD & DRUG ADMINISTRATION

Grant of Enforcement Discretion Supports Commercial Launch

Cincinnati, Ohio, April 1, 2022 -- Sus Clinicals, Inc.™ received clearance to commercialize the genetically-engineered animal used in the Oncopig Cancer Model™ from the U.S. Food & Drug Administration. Following an exhaustive review, the FDA determined that the commercialization of the specific "Oncopig" used for tumor inductions and other oncology research by Sus Clinicals does not require further regulatory oversight.

Sus Clinicals accelerates qualification of life-saving cancer therapeutics through proprietary pig-based pre-clinical testing services. In collaboration with top research institutions, its large animal predictive model can more quickly identify drugs, diagnostics and devices that have the highest potential for success in human clinical trials, allowing clients to focus their resources and advance more quickly to in-market success.

The FDA's Center for Veterinary Medicine (CVM) provides regulatory oversight of genetically-engineered animals used in biomedical research. CVM has said that it may exercise "enforcement discretion" on a case-by-case basis if, after a risk-based review, it determines that the product is low risk to humans, animals and the environment.

Sus Clinicals has licensed technology from the University of Illinois related to the Oncopig Cancer Model (OCM). The OCM approach involves introducing site- and time-specific tumors in the test animals, allowing researchers to evaluate efficacy as well as any toxicity concerns in ways that can be highly predictive of results in humans.

"We've had extensive experience with the Oncopig, having bred hundreds of animals and successfully conducted numerous tumor induction studies," said Lawrence Schook, Ph.D., the Edward William and Jane Marr Gutgsell Professor *Emeritus*, Department of Animal Science and Radiology, University of Illinois and Chief Scientific Officer and co-founder of Sus Clinicals.

"Based on this extensive experience, we requested enforcement discretion, and provided hundreds of pages of documentation as to the use of the genetically-modified 'Oncopig'" said Dr. Schook. "Our experience with the review team at the FDA was very positive. They were thorough and professional, asking excellent questions, with their multi-disciplinary team carefully reviewing all the documentation."

With FDA clearance in hand, Sus Clinicals is actively bringing on board customers from across various sectors in oncology, including medicines, diagnostics, devices and immunotherapies. "We had our first customer under contract within two months of having FDA clearance," said Jeffrey D. Weedman, Chief Executive Officer and co-founder. "We are very gratified with the interest we have received to date, and look forward to bringing more customers on board in the coming months, leveraging our predictive large animal model to help them accelerate promising cancer research."

Sus Clinicals is headquartered in Cincinnati, Ohio, with scientific facilities in Chicago and Urbana, Illinois.

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