Sirnaomics to Treat Hepatocellular Carcinoma with STP705, Its New siRNA Therapeutic Candidate

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Sirnaomics, Inc. announced that FDA had granted orphan drug designation to its siRNA therapeutic candidate, STP705, for the treatment of Hepatocellular Carcinoma (HCC).

Sirnaomics, Inc., a leading biopharmaceutical company in the discovery and development of RNAi therapeutics, announced today that the Office of Orphan Product Development division of the FDA has granted orphan drug designation to its leading therapeutic candidate, STP705, for the treatment of Hepatocellular Carcinoma (HCC). This is the third such designation for this drug candidate, following the designation for Primary Sclerosing Cholangitis and Cholangiocarcinoma.

Sirnaomics lead product candidate, STP705 is a siRNA (small interfering RNA) therapeutic that takes advantage of the Company's proprietary dual-targeted inhibitory property and polypeptide nanoparticle (PNP)-enhanced delivery to directly knock down both TGF-β1 and COX-2 gene expression. Sirnaomics has opened Investigational New Drug (IND) applications under the jurisdiction of the US FDA and Chinese FDA for clinical studies for Non-melanoma skin cancers (NMSC), Cholangiocarcinoma (CCA), and Hypertrophic Scar (HTS) Reduction.

"We are very pleased to reach another significant milestone and very excited to develop our lead product candidate for the treatment of HCC with tremendous unmet needs" stated Patrick Lu, Ph.D., President, and CEO. "This third grant of orphan drug designation for STP705 to treat HCC further consolidates our long-term strategy positioning us to take advantage of the regulatory arbitrage by achieving approval in the US and then moving to the large market in China."

"Receipt of the orphan drug designation for Hepatocellular Carcinoma is a very important step for Sirnaomics. It provides the pathway allowing us to develop STP705 in a devastating oncology disease for which there is currently no effective therapy," stated Dr. Michael

Molyneaux, MD, MBA, Chief Medical Officer. "This orphan drug designation aligns with our mission to alleviate human suffering and target diseases with high unmet clinical need and we anticipate the start of our clinical study for HCC in the second half of 2020."

About STP705 (Cotsiranib)

Sirnaomics leading product candidate, STP705, is a siRNA (small interfering RNA) therapeutic which takes advantage of a dual-targeted inhibitory property and polypeptide nanoparticle (PNP)-enhanced delivery to directly knock down both TGF-β1 and COX-2 gene expression. The product candidate has received multiple IND approvals from both the US FDA and Chinese NMPA, including treatments of Cholangiocarcinoma, Non-Melanoma skin cancer, and Hypertrophic Scar. STP705 has also received Orphan Drug Designation for treatment of Cholangiocarcinoma and Primary Sclerosing Cholangitis. Preclinical animal models using STP705, have demonstrated a dramatic improvement in T-cell penetration into tumors in the liver with single-agent action as well as improvement in the efficacy of an anti-PD-L1 antibody checkpoint inhibitor in an HCC model. This effect may improve other immune checkpoint inhibitor efficacies in addition to those targeting the PD-1/PD-L1 axis.