ORCA Therapeutics B.V. to Start Highest Scheduled Dose in Phase 1/2a Study of ORCA-010 in Treatment-Naïve Prostate Cancer Patients. Consistent Efficacy Data from First Cohort and Start New Indication. Additional funding secured.

's-Hertogenbosch, the Netherlands, 05 March 2021.

ORCA Therapeutics B.V., a clinical-stage biopharmaceutical company developing oncolytic viruses to treat solid tumors, is pleased to announce that, upon review of all safety data from the fully enrolled, low- and mid-dose patient cohorts of the ongoing Phase 1/2a clinical study of ORCA-010 in treatment-naïve patients with localized prostate cancer, the independent Data and Safety Monitoring Board (DSMB) unanimously recommended the continuation of the study without modification. From this recommendation, ORCA Therapeutics will initiate administration of the highest scheduled dose level of ORCA-010 in the single dose part of the study.

Following this recommendation, ORCA Therapeutics B.V. has commenced enrollment in the highest-dose arm of the dose-escalation phase of this study, with the first patient scheduled for administration in March 2021. Upon conclusion of enrollment in the highest study arm, DSMB will conduct an additional review on ORCA-010 prior to starting the repeat dosing part of the trial

At the lowest dose studied, ORCA-010 demonstrated strong single-agent antitumor activity in the first patient. Further, MRI data reflected an impressive and significant decrease in prostate volume returning to normal size, as well as continuing decreases in PSA. This pattern has been confirmed in the second patient who completed the 6-month follow-up MRI, and also showed prostate volume returning to near normal size.

Investors favorably viewed the DSMB recommendations and the recent clinical success by investing in another round of financing to progress ORCA-010's development.
ORCA-010 has garnered the attention of researchers, recently, ORCA Therapeutics B.V. has initiated discussions to prepare for a study in patients with unresectable/medically inoperable esophageal cancer.

"12% of all men will be diagnosed with prostate cancer in their lifetime. We are encouraged by the safety profile and preliminary efficacy of ORCA-010 and are excited to continue enrollment in the highest dose cohort of this Phase 1/2a study, our first clinical study with ORCA-010," said Kees Groen, ORCA Therapeutics' CEO. "We are grateful for the continuous support from our investors. The generous contributions enable ORCA Therapeutics to progress ORCA-010's development for treating prostate cancer."

ORCA Therapeutics B.V.'s two-part Phase 1/2a study is a multi-center, open-label, dose-escalation study of ORCA-010 in approximately 24 treatment-naïve patients with localized prostate cancer:

Part A: Dose-escalation phase to define the safety, tolerability, and optimal dose level of ORCA-010 in treatment-naïve patients with localized prostate cancer. This phase is expected to enroll up to 12 patients in three dose cohorts.

Part B: A subsequent extension of the optimal dose level, as defined in the dose escalation phase, and given as two doses with 2 weeks interval. This phase is expected to enroll approximately 12 additional patients.

For more information please visit http://www.orca-therapeutics.nl/

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