Orca Therapeutics Announces Positive DSMB Review in Phase 1/2a Study of ORCA-010 in Treatment-Naïve Prostate Cancer Patients

's-Hertogenbosch, the Netherlands, 15 October 2020.

Orca Therapeutics BV, 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-dose patient cohort 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.

Following this recommendation, Orca Therapeutics has initiated enrollment in the intermediate-dose arm of the dose-escalation phase of this study. Two additional, pre-specified DSMB reviews will occur after the completion of enrollment in the intermediate-dose study arm and the high-dose study arm, respectively.

At an earlier stage, ORCA-010 demonstrated strong single-agent antitumor activity in the first patient treated with the lowest dose in this study. MRI data is impressive reflecting significant decrease in prostate volume returning to normal size as well as less tumor tissue surface area. Further of highlighted interest, the researchers reported an ongoing decrease in PSA.

"We are encouraged by the safety profile and preliminary efficacy of ORCA-010 so far and are excited to continue enrollment in the intermediate dose cohort of this Phase 1/2a study, our first clinical study with ORCA-010," said Kees Groen, Orca's CEO.

Orca's two-part Phase 1/2a study is a multi-center, open-label, dose-escalation study of ORCA-010 in 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 12 additional patients.

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

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