**ORCA Therapeutics B.V. to Start Repeat-Dosing in Phase 1/2a Study of ORCA-010 in Treatment-Naïve Prostate Cancer Patients.**

's-Hertogenbosch, the Netherlands, 07 September, 2021.

**ORCA Therapeutics B.V.,** a clinical-stage biopharmaceutical company developing oncolytic viruses to treat cancer, is pleased to announce the successful completion of the single-dose escalation cohorts of the Phase I/IIa clinical study of ORCA-010 in treatment-naïve patients with localized prostate cancer. Upon review of all safety data from the fully enrolled, the independent Data and Safety Monitoring Board (DSMB) unanimously recommended the continuation of the study without modification. From this recommendation, ORCA Therapeutics will initiate the repeat-dose administration with the highest dose level of ORCA-010 tested in the single dose part of the study.

Following this recommendation, ORCA Therapeutics B.V. has commenced enrollment for the repeat-dose administration Phase IIa part of the study, with the first patient scheduled for enrollment in Q3 2021. In total, twelve treatment-naïve patients with localized prostate cancer, including patients scheduled for radical prostatectomy, will be treated with a repeat dose administration of ORCA-010.

Initial results showed that ORCA-010 exhibits strong single-agent antitumor activity in the patients. Further, MRI data reflected an impressive and significant decrease in prostate volume returning to normal size in patients with significantly enlarged prostate.

ORCA-010 development data will be presented at the 28$^{th}$ Annual Congress of the European Society of Gene and Cell Therapy (Oct. 19– 22, 2021, virtual) and at the 36$^{th}$ Annual Meeting of the Society for Immunotherapy of Cancer (Nov. 10–14, 2021, Washington DC).

"12% of all men will be diagnosed with prostate cancer in their lifetime. We are encouraged by the excellent safety profile and preliminary efficacy of ORCA-010 and are excited to continue enrollment in the repeat dose cohort of this Phase 1/2a study, our first clinical study with ORCA-010," said Kees Groen, ORCA Therapeutics' CEO.

Following these excellent results, ORCA Therapeutics has initiated preparations for a study in patients with unresectable/medically inoperable esophageal cancer.

ORCA Therapeutics B.V.'s two-part Phase I/IIa 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 has enrolled nine 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/

Please contact

**Kees Groen, PhD., CEO**
**ORCA Therapeutics B.V.**
**+31 653648230**
**info@ORCA-therapeutics.com**