



ORCA Therapeutics BV Announces Treatment of First Patient in a Phase I/IIa Study with ORCA-010 in Treatment-Naïve Patients with Localized Prostate Cancer.

's-Hertogenbosch, the Netherlands, December 23, 2019.

ORCA Therapeutics BV, a privately held clinical-stage biopharmaceutical company developing oncolytic viruses, today announced that the first patient has been dosed in a Phase I/IIa study with ORCA-010 in treatment-naïve patients with localized prostate cancer. ORCA-010 is a genetically modified adenovirus being developed to treat cancer. This Phase I/IIa study is considered the proof-of-concept study to assess the safety, tolerability and antitumor activity upon administration of this oncolytic virus. The initiation of the study follows Health Canada approval of the company's clinical trial application.

The study entitled, "A Phase I/IIa Study Evaluating the Safety and Tolerability of Intratumoral Administration of ORCA-010 in Treatment-Naïve Patients with Localized Prostate Cancer", is composed of two parts. The first part comprises a dose-escalation to assess the safety, tolerability, pharmacokinetics, and preliminary antitumor activity of ORCA-010. It is used to define the recommended dose for the second part of the study comprising of a repeat-dose cohort of patients. The principal investigator of the study is Dr. Richard Casey of The Fe/Male Health Centre in Oakville, Canada.

Based on the 14-day safety and tolerability data, the Data Safety Monitoring Board (DSMB) positively advised on dosing of the other patients in the cohort with ORCA-010.

"We expect that this study will generate important insights about the utility of ORCA-010 in patients with a properly functioning immune system," said Dr. Kees Groen, CEO of the company. "This research furthers the adequate application of oncolytic viruses."

## **About Orca Therapeutics BV**

ORCA Therapeutics B.V. is developing a pipeline of innovative anticancer immunotherapies based on the highly promising approach of oncolytic viruses. ORCA's lead product ORCA-010 is a new oncolytic adenovirus based on the Company's proprietary T1 technology. ORCA-010 has up to ten thousand fold higher oncolytic potency as compared to current state of the art oncolytic adenoviruses in a broad panel of cancer cell lines.

For more information, please visit our website at [www.orca-therapeutics.com](http://www.orca-therapeutics.com)