



PRESS RELEASE

ORCA Therapeutics receives approval from Spanish Interministerial Council of Genetically Modified Organisms to use ORCA-010 in a Phase I/IIa study in treatment-naïve prostate cancer patients.

's-Hertogenbosch, 4 December 2019.

ORCA Therapeutics B.V., a clinical stage company developing oncolytic viruses, announced today (4 December 2019) they have received an approval letter from the Spanish Interministerial Council of Genetically Modified Organisms to use ORCA-010, a genetically modified adenovirus, in a Phase I/IIa study evaluating the safety and tolerability of intratumoral administration of ORCA-010 in treatment-naïve patients with localized prostate cancer. The application for clearance of ORCA-010 to be used in a clinical study in Spain was submitted in June 2019.

The approval to use ORCA-010 in a clinical study in a European country is a key milestone in the development of ORCA-010 and will contribute to preparations for clinical investigations with ORCA-010 in Europe. "We are excited to receive this approval and look forward to also investigate ORCA-010 in Spain and other European countries" says Kees Groen, CEO of ORCA Therapeutics.

About ORCA-010

ORCA Therapeutics has successfully designed a virus, ORCA-010, that kills cancer cells, while leaving normal cells unharmed. ORCA-010 is up to ten thousand-fold more effective at killing a wide variety of cancer cells than competitor oncolytic viruses. Extensive laboratory and animal experiments have demonstrated that ORCA-010 can attack different cancer types. ORCA has developed a scalable process for the production of ORCA-010, and the product is protected by patents.

The first clinical study with ORCA-010 in treatment-naïve patients with localized prostate cancer was approved in Canada and is currently enrolling patients. ORCA-010 is aimed to be used in solid tumors, as first-line treatment, with intratumoral or intravenous injection. Maximally three treatment cycles with 2-4 weeks interval are anticipated, either given alone or in combination with other cancer therapies.

About ORCA Therapeutics

ORCA Therapeutics is a Dutch biopharmaceutical company developing innovative oncolytic immunotherapies for the treatment of cancer. The company has a strong platform of technologies to engineer highly potent oncolytic adenoviruses. ORCA's lead product ORCA-010 is a powerful oncolytic adenovirus that exhibits strong oncolytic potency in different cancer types in vitro and in vivo.

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