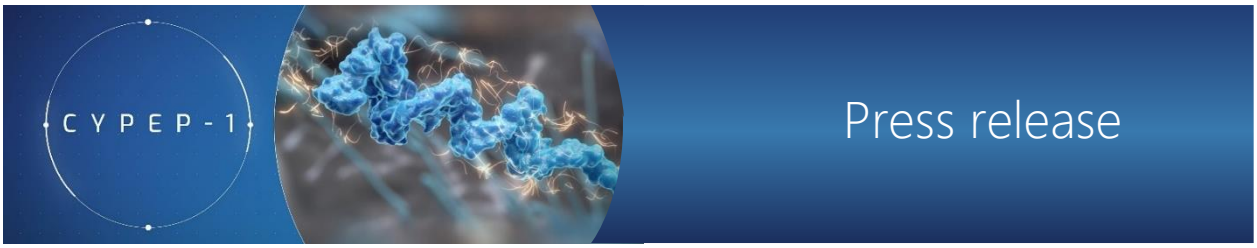
Cytovation Announces Dosing of First Patient in its Phase I/II CICILIA Trial Investigating CyPep-1 in Patients with Solid Cancers

CyPep-1 is a novel lytic immunotherapy that both selectively binds and destroys tumor cells and promotes an anti-tumor immune response



Bergen, Norway, and Schiphol, the Netherlands (May 26, 2020) – Cytovation AS ("Cytovation"), a clinical-stage biotechnology company focused on developing CyPep-1, a next-generation lytic immunotherapy, is pleased to announce that the first patient has today been successfully dosed in its Phase I/II CICILIA clinical trial. The CICILIA trial will investigate CyPep-1 in patients with advanced solid cancers (ClinicalTrials.gov Identifier: NCT04260529).

The aim of the open-label, dose-escalation Phase I/II trial is to evaluate the safety, efficacy and pharmacokinetics of CyPep-1 given as intratumoral injection. Up to 21 patients with advanced (unresectable Stage III) or metastatic (Stage IV) solid tumor malignancies will be recruited. Two renowned clinical centers in the Netherlands are currently open for recruitment: the Netherlands Cancer Institute (NKI) in Amsterdam and Erasmus MC (EMC) in Rotterdam. Three additional university medical centers in the Netherlands will be opened shortly: the UMCU in Utrecht, the LUMC in Leiden and the MUMC in Maastricht.

This marks the first time a patient suffering from an advanced solid tumor will be dosed in a clinical trial with a lytic agent specifically targeting and lysing tumor cell membranes based on their altered molecular composition compared to healthy cells. CyPep-1's mode of action enables it to selectively bind to and disrupt cancer cells by forming pores that destabilize and rupture the membrane to kill the cell. Upon lysis, tumor antigens are released into the circulation and induce a systemic, tumor-specific immune response by *in-situ* immunization, which offers the possibility of long-lasting immunity against the tumor.

Mr. Kjell-Inge Arnevig, CEO of Cytovation said: *"We are thrilled about the progress we are making enrolling the first patient into the CICILIA trial. Treatment strategies that aim at recruiting the immune system to attack and kill tumor cells hold great promise and are currently a main focus in global oncology research. CyPep-1 may represent a unique, dual, tumor-agnostic approach that has a direct tumor-killing effect and boosts the effect of established immunotherapies across multiple tumor types. CICILIA is our first clinical trial in malignant*

tumors and we have an ongoing clinical trial investigating CyPep-1 in benign tumors, which is expected to read out in the coming months. We expect the result from this study to provide important support for the clinical proof-of-concept of this novel candidate. We look forward to providing updates on the clinical development of CyPep-1 in due course."

"Today's announcement defines the first major milestone in the clinic for CyPep-1." commented Veroni Baas, Project Director of the CICILIA trial at CATO SMS, the CRO supporting Cytovation in this trial. *"Our dedicated team supported the start-up of Cytovation's first-in-human trial. Given these COVID-19 times, this encouraging start is extraordinary. We are glad to closely support Cytovation and to see how CyPep-1 progresses in the upcoming months."*

About Cytovation: Cytovation builds on over 15 years of cutting-edge research from two leading Norwegian institutions; University of Bergen and Haukeland University Hospital. Led by a highly experienced management team and world-renowned experts in tumor biology, an extensive research program focused on engineering synthetic peptides with unique properties. CyPep-1, the company's lead candidate, is being developed as a first-in-class lytic agent for the treatment of solid tumors in both injectable and cream formulations. Through its unique pharmacological properties, CyPep-1 selectively targets and lyses tumor cell membranes based on their altered molecular composition. This mode of action kills cancer cells, releases tumor antigens, and potentially induces a tumor-specific immune response by in-situ immunization.

About CATO SMS: CATO SMS is a full-service clinical and regulatory contract research organization (CRO), specializing in complex areas such as (immuno-)oncology, advanced therapeutics and orphan diseases. CATO SMS has a center of excellence solely dedicated to oncology. With over 320 dedicated professionals with offices and operations in over 25 countries around the globe, the company brings a powerful blend of capabilities focused on supporting small and mid-sized biotech, top-tier pharmaceutical companies and investigator groups with their innovative research. We offer regulatory consulting and oncology drug development affairs in addition to clinical trial management services, with offices in close proximity from the FDA and EMA.

Contact info: Cytovation AS
Kjell-Inge Arnevig, CEO
kjell@cytovation.com

Møllendalsveien 65 C
5009 Bergen
Norway
+47 90474508
www.cytovation.com

Contact info: CATO SMS
Lindy Bosch, Business Development Director
l.bosch@sms-oncology.com

Walaardt Sacréstraat 401-403
1117 BM Schiphol
The Netherlands
+31 (0)20 - 4350 580
www.sms-oncology.com