## **PRESS RELEASE**



### FOR IMMEDIATE RELEASE

First Patient Dosed in EVICTION Trial Evaluating ImCheck's Lead Anti-Cancer Drug, ICT01: A Novel Gamma Delta T Cell-Activating Immunotherapy

-- First-in-human, international, multi-center trial to test
Butyrophylin 3A-targeted antibody in advanced solid and hematologic tumors --

Marseille, France, March 26, 2020 – ImCheck Therapeutics announced today that it has dosed the first patient in a Phase I/IIa clinical trial evaluating ICT01, a first-in-class gamma delta ( $\gamma\delta$ ) T cell-activating monoclonal antibody (mAb) targeting the extracellular domain of Butyrophilin 3A (BTN3A), a member of the butyrophilin superfamily of immuno-modulatory targets. **EVICTION** (**EV**aluation of **ICT**01 in Immuno-**ON**cology) is a first-in-human, two-part, open-label clinical trial to assess the safety, tolerability and activity of ICT01 as monotherapy and in combination with an immune checkpoint inhibitor in patients with advanced, relapsed/refractory cancer, including both solid and hematologic tumors that express BTN3A. The trial has been approved by regulators in France, Belgium, and Spain, with clinical trial applications pending or planned in the United Kingdom, Germany, and the United States.

"It is very exciting to lead the EVICTION trial that is testing ICT01 in patients with relapsed or refractory solid or hematologic malignancies. ICT01, with its unique mechanism of action, has the potential to be the next generation in immuno-oncology and provide a much needed option for cancer patients," commented Aurélien Marabelle, MD, PhD, Clinical Director of the Cancer Immunotherapy Program at the Gustave Roussy Cancer Centre, Villejuif, France and Principal Investigator for EVICTION.

"Our entry into the clinic is a significant milestone for ImCheck and is the result of rigorous translational research needed for a first-in-human trial. We would like to express our deep gratitude to the investigators and their teams for their incredible diligence and support during a very challenging and difficult time with the COVID-19 pandemic," said Paul Frohna, MD, PhD, Chief Medical Officer at ImCheck Therapeutics. "The results from our biomarker studies incorporated into this trial will begin to characterize the phenotypes and genotypes of responders/non-responders as part of our precision medicine-guided strategy for the ICT01 clinical development program."

"The timeline from the discovery of the butryrophilin superfamily of targets to the development of a lead antibody candidate and entry into clinical evaluation is remarkable when you consider the groundbreaking potential of the science. I applaud the ImCheck team for the focus and commitment needed for this achievement," added Prof. Daniel Olive, MD, PhD, Professor of Immunology at Aix Marseille University Institut Paoli-Calmettes and Scientific Founder of ImCheck.

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## **About ICT01**

ICT01 is a humanized, monoclonal antibody that activates  $\gamma 9\delta 2$  T cells, which are part of the innate immune system that is responsible for immunosurveillance for malignancy and infection, by targeting BTN3A (also known as CD277). BTN3A is expressed on the surface of innate and adaptive immune cells (T cells, B cells and NK cells) and is overexpressed on a number of solid tumors (e.g., bladder, breast, colon, gastric, melanoma, ovarian and prostate) and hematologic cancers (e.g., leukemia &

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lymphoma). BTN3A appears essential for the activation of the anti-tumor immune response of  $\gamma9\delta2$  T cells.

ICT01 selectively activates circulating  $\gamma9\delta2$  T cells that leads to migration of  $\gamma9\delta2$  T cells out of the circulation and into target tissue (e.g., tumors or infection site). ICT01 has been shown to have antitumor activity against a range of cancers in *in vitro* and *in vivo* tumor models.

### **About EVICTION Trial**

EVICTION is a first-in-human, dose escalation (Part 1) and cohort expansion (Part 2) study of ICT01 monotherapy in patients with relapsed or refractory solid or hematologic cancers that have exhausted standard of care treatment options. A third group of cancer patients will test ICT01 in combination with an anti-PD-1 inhibitor (immune checkpoint inhibitior). More information on the EVICTION trial can be found at: <a href="https://www.clinicaltrials.gov/ct2/show/NCT04243499">https://www.clinicaltrials.gov/ct2/show/NCT04243499</a>.

The study is being managed in Europe by ILife Consulting (a Paris-based CRO) in collaboration with Precision for Medicine (the CRO managing US sites). Precision for Medicine is also providing central lab capabilities for biomarker sample handling and flow cytometry. HalioDx (Marseille), a leader in Immuno-oncology testing with Immunoscore® and related assays, will be responsible for analyzing tumor biopsies as part of the precision medicine-guided analysis of baseline and on-treatment samples.

### **About IMCHECK THERAPEUTICS**

ImCheck Therapeutics is designing and developing a new generation of immunotherapy antibodies positioned at the crossroads of two high-potential immunological fields:  $\gamma 9\delta 2$  T cells and a novel super-family of immunomodulators, butyrophilins.

Due to their mechanism of action, and notably their ability to simultaneously modulate innate and adaptive immunity, ImCheck's "first-in-class" activating antibodies may be able to produce superior anti-cancer efficacy as compared to the first-generation of immune checkpoint inhibitors and, when used in combination, overcome the resistance to this class of agents. Activated  $\gamma 9\delta 2$  T cells also have therapeutic potential in infectious diseases (e.g., bacteria and viruses), while antagonist antibodies have potential as treatments for a range of autoimmune diseases.

Co-founder of the Marseille Immunopole cluster, ImCheck benefits from support from Prof. Daniel Olive (INSERM, CNRS, Institut Paoli Calmettes, Aix-Marseille Université), a worldwide leader in  $\gamma\delta$  T cells and butyrophilins research; from the experience of an expert management team; and from the commitment of leading US and European investors.

For further information on ImCheck: http://www.imchecktherapeutics.com and @ImCheckThx

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