PRESS RELEASE

ImCheck Receives FDA Fast Track Designation for ICT01 in Combination with Azacitidine and Venetoclax in First-Line Acute Myeloid Leukemia for Patients Unfit for Induction Chemotherapy Treatment

ICT01, a humanized anti-butyrophilin 3A monoclonal antibody designed to selectively activate Vγ9Vδ2 T cells, has shown encouraging clinical data in AML in its ongoing Phase 1/2a EVICTION study

Marseille, France, September 18, 2024, 11 am CET – ImCheck Therapeutics announced today that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ICT01 in combination with azacitidine and venetoclax for the treatment of acute myeloid leukemia (AML) patients 75 years or older, or who have comorbidities that preclude use of standard intensive induction chemotherapy. Based on encouraging results from the Phase 1 dose-escalation portion of the EVICTION study evaluating ICT01 monotherapy in relapsed/refractory hematological malignancies (European Society for Medical Oncology Congress 2023), ImCheck initiated in October 2023 a randomized dose-optimization cohort (NCT04243499), evaluating two doses of ICT01 in combination with azacitidine and venetoclax, the current standard of care for newly diagnosed patients with AML who are deemed unfit for induction chemotherapy.

"The growing body of data on ICT01 together with the FDA's Fast Track designation further validates our development of ICT01 in first-line AML patients and highlights the critical need for therapies that generate higher response rates and improve overall survival for these patients," said Stephan Braun, MD, PhD, Chief Medical Officer of ImCheck Therapeutics. *"We are highly encouraged by ICT01's potentially broad applicability in solid tumor and hematological cancer indications and look forward to sharing updates from the EVICTION study at upcoming scientific conferences."*

The FDA designed Fast Track status to facilitate the development and expedite the review of therapeutic candidates that have the potential to treat serious conditions and address an unmet medical need. A therapeutic candidate that receives Fast Track designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan. Candidates with Fast Track designation may also be eligible for Priority Review and Accelerated Approval if supported by clinical data, with the goal of bringing approved therapies to patients earlier.

EVICTION is an open-label multicohort Phase 1/2a trial studying ICT01, a humanized anti-butyrophilin 3A monoclonal antibody that selectively activates γ9δ2 T cells; the study comprises cohorts investigating ICT01 as a monotherapy and combination therapy in solid and hematological tumors. As reported at ESMO 2023, the Phase 1 dose-escalation cohort in relapsed/refractory hematological cancers included 26 patients who failed all available treatment options, 24 of which had AML, one with diffuse large B-cell lymphoma and one with follicular lymphoma. No dose-limiting toxicities were revealed for ICT01 administered at doses ranging from 200 µg to 75 mg every 21 days. Based on encouraging safety, pharmacokinetic and pharmacodynamic data, a dose-optimizing and efficacy-estimating part was initiated for

patients with newly diagnosed AML who are older or deemed unfit for standard chemotherapy, which has enrolled 29 patients to date. Emerging pharmacodynamic and pharmacokinetic data for ICT01 in combination with azacitidine-venetoclax showed reproducible activation and migration of γ9δ2 T cells from the blood within hours of dosing, suggesting effective target engagement as the basis for the observed efficacy.

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About IMCHECK THERAPEUTICS

ImCheck Therapeutics is designing and developing a new generation of immunotherapeutic antibodies targeting butyrophilins, a novel super-family of immunomodulators.

As demonstrated by its lead clinical-stage program ICT01, which has a mechanism of action to simultaneously modulate innate and adaptive immunity, ImCheck's "first-in-class" activating antibodies may be able to produce superior clinical results as compared to the first-generation of immune checkpoint inhibitors and, when used in combination, to overcome resistance to this group of agents. In addition, ImCheck's antagonist antibodies are being evaluated as potential treatments for a range of autoimmune and infectious diseases.

ImCheck benefits from support from Prof. Daniel Olive (INSERM, CNRS, Institut Paoli Calmettes, Aix-Marseille University), a worldwide leader in γ9δ2 T cells and butyrophilins research, as well as from the experience of an expert management team and from the commitment of leading US and European investors.

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