March 15, 2023

Perseus Proteomics Inc.
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To all stakeholders,

PPMX-T003: Announcement on Submission pf Clinical Trial Notification of Investigator-led Clinical Trial for Aggressive NK-cell Leukemia

Perseus Proteomics Inc. (The Company) is pleased to announce that the clinical trial notification of the Phase I/II investigator-led clinical trial among aggressive NK-cell leukemia (ANKL) patients using our in-development anti-transferrin receptor antibody PPMX-T003 as a therapeutic was submitted to the PMDA by Hiroshima University Hospital (Director, Yoshiki Kudo) today.

ANKL is a blood cancer categorized as malignant lymphoma, and originates in NK (natural killer) cells, one of immune cells. It is fulminant type of refractory hematological malignancy, where symptoms will progress rapidly once developed. Due to the rarity of the disease with few reported cases, there is a need to discover its causes and establish the effective standard treatment as soon as possible. Under such circumstances, the research and development on PPMX-T003 as a new therapeutic drug of ANKL was adopted as Project Promoting Support for Drug Discovery Support Program for Orphan drug prior to the Designation by AMED in March 2022. Following the adoption, this investigator-led clinical trial will be conducted for the purpose of assessing the safety and tolerability in administering PPMX-T003 to ANKL patients, as well as efficacy and pharmacokinetics. The investigator-led clinical trial will be initiated after the review by PMDA and registration of participating patients.

The Company expects the clinical trial costs of 100 million yen to be incurred in the fiscal year ending March 31, 2024. The Company will receive the subsidy of 100 million yen from AMED in the same fiscal year, however, it will book the subsidy as long-term deposits received until the actual amount will be determined at the inspections to be conducted by AMED.

■ About PPMX-T003:

PPMX-T003 is an antibody targeting transferrin receptor (TfR) that is related to iron intake into cells. TfR is highly expressed in cells that require much more iron than usual cells, such as cancer cells that proliferate at a significant pace, and erythroblasts, which are nucleated cells in bone marrow from which RBCs derive. When PPMX-T003 binds to TfR, it inhibits cell proliferation by inhibiting iron uptake into cancer cells.

As PPMX-T003 is expected to have therapeutic effects for a wide variety of cancers including ANKL and acute myeloma leukemia (AML), its development has been the main target of the Company. The Company has been also conducting the phase I clinical trial for polycythemia vera, where RBCs increase at an abnormal level.

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