News Release

August 10, 2022

PeptiDream Inc.
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PeptiDream Affiliated Company, PeptiAID Inc., Announces Complete Clinical Research of PA-001, a Candidate Compound for COVID-19 Treatment, Demonstrating Favorable Safety Profile

KANAGAWA, JAPAN – August 10, 2022 – PeptiDream Affiliated Company, PeptiAID Inc. (President: Keiichi Masuya, Headquarters: Kawasaki City, Kanagawa Prefecture, Japan, “PeptiAID”) announced the favorable safety and pharmacokinetic results from the final report of the clinical study for PA-001 injection, a candidate compound for COVID-19 treatment.

For more information, see PeptiAID’s Press Release(attached below).

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PeptiAID Inc.

PeptiAID Complete Clinical Research of PA-001, a Candidate Compound for COVID-19 Treatment, Demonstrating Favorable Safety Profile

KANAGAWA, JAPAN –August 10, 2022 - PeptiAID Inc. (President: Keiichi Masuya, Headquarters: Kawasaki City, Kanagawa Prefecture, Japan, "PeptiAID") today announced the favorable safety and pharmacokinetic results from the final report of the clinical study for PA-001 injection, a candidate compound for COVID-19 treatment.

As announced in the press release on February 4, 2022, PeptiAID conducted an early-stage exploratory clinical study of PA-001 according to the Clinical Trials Act in Japan. In this clinical study, adverse events, injection site reaction and vital signs of the single ascending dose administration of PA-001 from Step1 (0.3mg/kg) to Step5 (8mg/kg) by intravenous injection in 30 healthy Japanese adult male volunteers, were evaluated.

PA-001 was found to be safe without any compound related adverse event and demonstrated clear dose-dependent pharmacokinetics profile.
PeptiAID is currently preparing to initiate clinical trials for PA-001 in the United States and is anticipating that some requirements in the Phase I trial can be reduced by leveraging the safety data obtained from this study to accelerate clinical development. As disclosed in the FY2022 Q2 Financial Results Presentation of PeptiDream Inc., a PhI/IIa clinical trial is planned to start in 2023 to obtain PoC as early as possible.

In addition, similar to its antiviral activity against the conventional Wuhan strain and Alpha, Beta, Gamma Delta and Omicron variants, PA-001 demonstrated high activity against the Omicron BA.1 and BA.2 subvariants.

Comment by Keiichi Masuya, Ph.D., Representative Director, President, PeptiAID Inc.
"We are very excited that a high safety profile was observed for PA-001 in this First-in-Human study. We envisioned that PA-001 has two advantages due to the unique mechanism of action compared to existing drugs. First is that it is effective to mutants. We confirmed PA-001 has antiviral effects from the Wuhan strain to BA.2 and BA.5 subvariants and expect similar potency against BA.2.75 subvariants based on our analysis of the mutated sites of these strains. Second, we expect PA-001 to have a synergistic effect when used with existing drugs such as antibody cocktails and enzyme inhibitors. Also we do not expect PA-001 to inhibit antibodies induced by vaccines. We aim to accelerate the development of PA-001 by utilizing the obtained safety data and deliver effective therapeutics to patients as early as possible."

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■PeptiAID Inc.■
PeptiAID Inc. is a joint venture established in November 2020 by PeptiDream, Fujitsu, Mizuho Capital, Takenaka Corporation, and Kishida Chemical who agreed on the social significance of "delivering effective therapeutic agents for COVID-19 to medical facilities around the world as quickly as possible." PeptiAID, which obtained PeptiDream's COVID-19 candidate compound, aims to conduct pre-clinical studies and early phase clinical trials required for confirming proof of concept (POC) in the shortest possible period. In addition to fully leveraging PeptiDream's peptide-related technology and know-how, PeptiAID will harness

Fujitsu’s high-performance computing (HPC) technologies as well as its Digital Annealer, which is an architecture that rapidly solves combinatorial optimization problems, to further accelerate the relevant research.

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