June 10, 2025
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio Announces Enrollment of the First Patient in International Phase Ib/II Clinical Trial of IV Brincidofovir for Malignant Lymphoma

SymBio Pharmaceuticals Limited today announced that the first patient has been enrolled in the global Phase Ib/II clinical study of the intravenous formulation of brincidofovir (IV BCV) in malignant lymphoma. This multicenter international collaborative study is being conducted in Japan, Hong Kong, and Singapore, and enrollment of 15 subjects is planned to be completed by the end of 2025.

NK/T-cell lymphoma and peripheral T-cell lymphoma, the diseases investigated in the study, are refractory diseases. Existing therapies have limited efficacy and severe side effects, so there is a strong demand for the development of new therapeutic drugs.

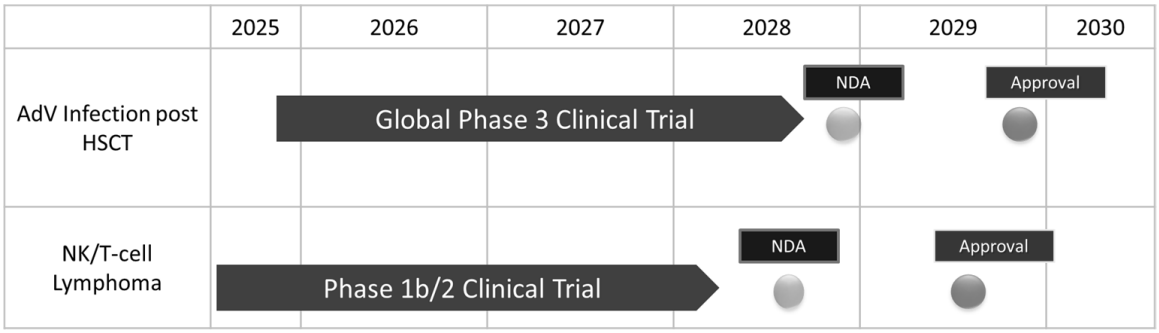
Statement from Fuminori Yoshida, President and CEO: “In collaboration with the National Cancer Centre of Singapore and the University of California, San Francisco, IV BCV has shown high anti-cancer activity, and we will work to provide a new treatment option for NK/T-cell lymphoma and peripheral T-cell lymphoma, which are under-represented disease areas, as soon as possible.”

Notes

1: Study Overview

This study consists of a Phase Ib clinical trial to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of the intravenous formulation brincidofovir in patients with malignant lymphomas, such as NK/T-cell lymphoma and peripheral T-cell lymphoma, as well as a Phase II trial to assess its efficacy against NK/T-cell lymphoma. In addition, we plan to apply for the approval of NK/T-cell lymphoma as part of this phase II study. By establishing an appropriate dosage, we aim to secure approval within the shortest possible timeframe.

Clinical Trial Plan for IV BCV (as of June 10, 2025)



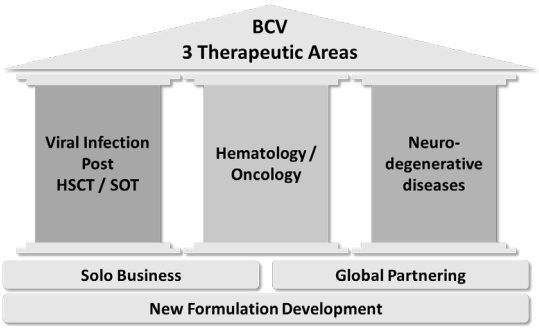
2: NK/T-cell Lymphoma

NK/T-cell lymphoma is a rare cancer classified as a malignant lymphoma and is a lymphoma of NK or T-cell origin. This disease is characterized by its frequent occurrence around the nasal cavity and on the skin, and in most patients, the EB virus infects the tumor cells and is associated with its development and other symptoms. This disease is relatively common in Southeast Asia, China, and Japan. Currently, no standard treatment has been established for this disease, and there is a strong demand for the development of new therapeutic agents.

3: Peripheral T-cell Lymphoma (PTCL)

PTCL is a rare cancer classified as a rapidly progressing aggressive lymphoma, a group of diseases that includes a wide variety of disease types. Multi-agent chemotherapy and radiation therapy are commonly used as primary treatment but have limited efficacy. Although several therapeutic agents have come into clinical use for relapsed or refractory PTCL in recent years, there is still no standard treatment for this disease, and there is a strong need for the development of new therapeutic agents.

4: BCV's Business Strategy: Focused on Three Therapeutic Areas



Since obtaining the global license for the drug in 2019, SymBio has been advancing collaborative research with world-class research institutions. In terms of target disease areas, the company is focused on three therapeutic areas: viral infections following hematopoietic stem cell transplantation, as well as hematologic and solid cancers as the second pillar, and neurodegenerative diseases as the third pillar, aiming to maximize the business value of BCV.

Our collaborative research with the National Cancer Centre Singapore confirmed the high anticancer activity of IV BCV against NK/T-cell lymphoma and PTCL. Accordingly, this clinical trial is being conducted primarily in Japan and across the Asia region, targeting NK/T-cell lymphoma and PTCL. Moving forward, this trial is positioned as a critical step for the company's global business expansion in the hematologic and solid cancer fields, which represent its second strategic pillar.
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2024 European Hematology Association (report on anticancer activity against PTCL):
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