

October 27, 2025
SymBio Pharmaceuticals Limited
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(Securities Code: 4582)

**SymBio Presents Positive Efficacy Data for Brincidofovir
in Head and Neck Cancer at ESMO 2025 (Berlin, Germany)**

Brincidofovir (BCV) was shown to induce PD-L1 expression, a key predictive biomarker of immune checkpoint inhibitor (ICI), and demonstrated greater efficacy when combined with an ICI.

SymBio Pharmaceuticals Limited today announced that promising preclinical efficacy data for brincidofovir (BCV) in head and neck cancer were presented at the European Society for Medical Oncology Congress 2025 (ESMO Congress 2025, Berlin, Germany) on October 20, 2025.

Preclinical findings from the research include:

- High-dose BCV monotherapy showed antitumor activity comparable to the standard treatment (ICI + cisplatin).
- Low-dose BCV combined with an ICI showed antitumor activity comparable to the standard treatment.
- BCV combined with an ICI led to a statistically significant increase in the infiltration of cytotoxic T lymphocytes into the tumor tissue, resulting in cancer cell death.

These results suggest that BCV, which has lower toxicity than cisplatin, could represent a potential treatment option to explore for head and neck cancer.

Statement from Tetsu Kamitani, MD, PhD, the presenter of the efficacy data at ESMO Congress 2025: “Because BCV shows lower toxicity compared with cisplatin used in standard therapy, these results indicate it may offer a new treatment option for head and neck cancer and bring hope to many patients suffering from the disease.”

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Summary of the presentation

Title: Preclinical efficacy of brincidofovir (BCV) against head and neck squamous cell carcinoma (HNSCC)

Presenter: Tetsu Kamitani (Translational Research Dept., SymBio Pharmaceuticals Ltd.,)

Presentation Number: 1394P



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(Note)

ESMO Congress 2025

The European Society for Medical Oncology (ESMO) is a leading global authority in cancer treatment and research. Founded in 1975, it serves as an essential forum where oncology specialists, researchers, medical professionals, and pharmaceutical industry representatives share the latest advancements and research findings in cancer treatment.

Head and Neck Cancer

In oncology, the term “head and neck” refers to the region encompassing the face and neck, located between the skull base (the lower part of the head) and the clavicle. This region includes the nose, paranasal sinuses, oral cavities, pharynx, larynx, salivary glands, and thyroid gland. Cancers arising in these areas are collectively referred to as “head and neck cancers.” The estimated annual incidence is over 900,000 cases worldwide and approximately 35,000 cases in Japan. Additionally, it is known that Epstein-Barr virus (EBV) and human papillomavirus (HPV) are known to be involved in the carcinogenesis of nasopharyngeal carcinoma and oropharyngeal carcinoma, respectively.

Standard treatment for head and neck cancer

Currently, chemotherapy centered on platinum agents such as cisplatin is used to treat

head and neck cancer. However, platinum agents have strong toxicity and are difficult to administer to patients with reduced renal function, including elderly patients. Under current standard treatment, it is common to combine these platinum agents with ICIs, and the content of SymBio's presentation suggests the possibility of an alternative approach in which BCV is combined with an ICI instead of a platinum agent for head and neck cancer.

BCV's Business Strategy Based on Three Therapeutic Pillars

Since acquiring the global license to BCV in September 2019, SymBio has been conducting collaborative research with world-class research institutions to unlock BCV's potential in three therapeutic areas. Currently, our management resources and development efforts are centered on three therapeutic pillars: (1) viral infections post-HSCT, (2) hematologic and solid tumors, and (3) neurodegenerative diseases. By expanding our business globally, we aim to maximize the business value of BCV. For the first pillar, we have initiated a global Phase 3 clinical trial for adenovirus infection post-HSCT and aim to submit an application for marketing approval in the second half of 2028. For the second pillar, in the area of hematologic cancers, we have initiated a Phase 1b/2 clinical trial for NK/T-cell lymphoma, are currently enrolling patients, and aim to submit for regulatory approval in 2028. Furthermore, within solid tumors, we are considering the initiation of clinical trials for indications such as brain tumors and head and neck cancer. In the field of neurodegenerative diseases, we plan to advance clinical trials targeting multiple sclerosis (MS) and progressive multifocal leukoencephalopathy (PML) in the future.

