

August 29, 2023  
Symbio Pharmaceuticals Limited  
Fuminori Yoshida  
Representative Director  
President and Chief Executive Officer  
(Securities Code: 4582)

**Notice of Change of Global Chief Medical Officer and  
Appointment of Senior Vice President of Symbio Pharma USA, Inc.**

TOKYO, August 29, 2023 -- Symbio Pharmaceuticals Limited (Headquarters: Tokyo, hereinafter “Symbio”) today announced that effective September 11, 2023, Dr. Nkechi E. Mbanefo-Azie, MD, FISDA , MBA, (hereinafter “Nkechi Azie”) will be joining Symbio as Global Chief Medical Officer (“CMO”) and concurrently, as Senior Vice President of R&D of Symbio Pharma USA, Inc. (wholly owned US subsidiary; CEO & President: Stephane Berthier; hereinafter “SPU”)

With the addition of Dr. Nkechi Azie, along with Dr. Stephane Berthier who joined as CEO and President of SPU on August 1, 2023, the foundation of SPU with a mission to lead the global business of brincidofovir (BCV), will be further strengthened to accelerate the global development and commercialization of BCV.

Statement from Dr. Nkechi Azie: “Symbio is poised to tackle some life-threatening and debilitating unmet medical needs. I am honored and thrilled to join the company as they tackle these needs to bring much needed relief to the waiting patients around the world. Working with Symbio’s team of highly experienced professionals I am convinced that together we can realize Symbio’s vision.”

Statement from Fuminori Yoshida, President and CEO of Symbio: “I’m thrilled to welcome Dr. Nkechi Azie to our management team as CMO. Nkechi will bring to Symbio her extensive knowledge and experience of global pharmaceutical development and a strong expertise in infectious disease to advance our BCV pipeline. With the strong management team in place, Symbio will further accelerate the global development and commercialization of BCV to enable its transformation into a global specialty pharmaceutical company.”

Dr. Koji Fukushima, currently Corporate Officer and CMO, will remain as Corporate Officer, Deputy CMO and Medical Lead for the transplantation Area.

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**Symbio Pharma USA, Inc. (summary)**

Name	Symbio Pharma USA, Inc. (SPU)
Address	Durham, North Carolina, USA
CEO and President	Stephane Berthier
Establishment Date	May 10, 2016
Shareholders	A 100% subsidiary of Symbio Pharmaceuticals Limited
Business Activities	Research and development of pharmaceutical products

**1. Appointment of Global Chief Medical Officer of Symbio**

Name	Title
Nkechi E. Mbanefo-Azie	Global Chief Medical Officer (SVP, R&D Head of SPU)

**2. Date of appointment: September 11, 2023**

**3. Profile of the newly appointed Global Chief Medical Officer**

1998	Associate Research Director, Clinical Pharmacovigilance, Pharmacia (US)
2003	Director, Ant-infective Clinical Development, Pfizer (US)
2006	Medical Director, Medical Sciences, Astellas (US)
2008	Senior Medical Director, Medical, Astellas (US)
2016	Senior Vice President, Head Medical Affairs, The Medicines Company (US)
2019	Vice President, Clinical Dev. & Medical Affairs / Medical Sciences, Scynexis Inc. (US)
2023	Senior Vice President, R&D Head of Symbio Pharma USA and Global Chief Medical Officer of Symbio Pharmaceuticals Limited
1988	Bachelor of Medicine, Bachelor of Surgery University of Nigeria College of Medicine
1997	Infectious Disease & Clinical Pharmacology Fellowship Indiana University Medical Center
2012	Executive MBA, Notre Dame University (US)
Qualification	MD, MBA, FIDSA

**About the Anti-viral Drug Brincidofovir**

Brincidofovir (BCV) has a new mechanism of action as a lipid conjugate of cidofovir (CDV). CDV is an antiviral drug already approved and marketed in the United States and the European Union, but unapproved in Japan. BCV is expected to be an effective treatment against a wide spectrum of dsDNA virus infections (cytomegalovirus, adenovirus, Epstein-Barr virus, herpes virus, BK virus, papillomavirus, smallpox virus and monkeypox virus, etc.), with superior features such as high activity antiviral effect in comparison with CDV and other antiviral drugs.

Due to the breakthrough nature of the BCV molecule, in which a specific length of lipid chain is attached

to the CDV, BCV is converted into a molecule that acts directly within the cell, thereby dramatically increasing the efficiency of cellular uptake and showing a high antiviral activity.

In September 2019, Symbio entered into a license agreement with Chimerix for the exclusive worldwide rights to develop, market, and manufacture BCV for all diseases except orthopoxviruses (such as smallpox and monkeypox).

The tablets and oral suspension (oral formulation) were approved on June 4, 2021, for the treatment of smallpox in adults and pediatric patients, including neonates.

In addition to its high antiviral activity, BCV is also expected to have anti-tumor effects. We are currently conducting collaborative studies with the National Cancer Center of Singapore, the University of California, San Francisco, and other institutions to confirm its anti-cancer activity and to identify synergistic effects when combined with its antiviral activity.

Clinical trials and major R&D collaborations with prominent research institutions are underway as follows:

- Initiated a Phase II clinical trial in patients with adenovirus infection after hematopoietic stem cell transplantation (March 2021) and received Fast Track designation from the FDA (April 2021). Proof of Concept (POC) of antiviral efficacy established based on data up to cohort 3 (May 2023).
- Initiated a non-clinical trial at the University of California, San Francisco Neurosurgery Brain Tumor Center to evaluate the anti-tumor effect of BCV on refractory brain tumors (September 2021).
- With regard to multiple sclerosis, an intractable disease that has recently been proven to be associated with the EB virus, Symbio has entered into a Cooperative Research and Development Agreement (CRADA) with the National Institute of Neurological Disorders and Stroke (NINDS), affiliated with the National Institutes of Health (NIH), to examine BCV's efficacy against the EB virus in the treatment of multiple sclerosis, and to obtain information needed to conduct future clinical trials (March 2023).
- CRADA with the National Institute of Allergy and Infectious Diseases (NIAID), affiliated with the NIH, to evaluate the efficacy of BCV for EB virus-associated lymphoproliferative diseases (April 2023).
- Research on the involvement of infection by reactivation of latent viruses in various neurological severity diseases of the brain, including Alzheimer's disease, has been ongoing for the past several years, and a simple three-dimensional mimicry of human neural stem cell cultures and brain tissue established by Tufts University in the United States, the A Sponsored Research Agreement was signed (December 2022) to examine the effect of BCV on HSV infection using a herpes simplex virus (HSV) infection/reactivation model established by Tufts University in the U.S., which uses human neural stem

cells cultured to mimic brain tissue in three dimensions.

### **About SymBio Pharmaceuticals Limited**

SymBio Pharmaceuticals Limited was established in March 2005 by Fuminori Yoshida who previously served concurrently as Corporate VP of Amgen Inc. and founding President of Amgen Japan. In May 2016, the Company incorporated its wholly-owned subsidiary in the U.S., called SymBio Pharma USA, Inc. (Headquarters: Durham, North Carolina, representative: Stephane Berthier). The Company's underlying corporate mission is to “deliver hope to patients in need” as it aspires to be a leading global specialty biopharmaceutical company dedicated to addressing underserved medical needs.