

December 16, 2022
SymBio Pharmaceuticals Limited
Fuminori Yoshida
Representative Director
President and Chief Executive Officer
(Securities Code: 4582)

SymBio files lawsuit for infringement of TREAKISYM® patents

TOKYO, Japan, December 16, 2022 -- SymBio Pharmaceuticals Limited (Headquarters: Tokyo, "SymBio" or the "Company") today announced that the Company, together with Eagle Pharmaceuticals, Inc. (Headquarters: New Jersey, U.S.A., "Eagle"), the Company's licensor, jointly filed a complaint in the Tokyo District Court against Towa Pharmaceutical Co., Ltd. (Headquarters: Osaka, "Towa") seeking remedies for the infringement of Eagle's patents for TREAKISYM® injection solution 100mg/4mL (generic name: bendamustine hydrochloride hydrate, hereinafter "TREAKISYM®"). Towa obtained manufacturing and marketing approval for its generic version of TREAKISYM® in Japan. The remedies sought by the Company and Eagle include an injunction against the manufacture or sale of Towa's generic product and compensation for damages.

Summary

1. Date of claim

December 16, 2022

2. Cause of action and background

In February 2022, four generic companies obtained approval from the Ministry of Health, Labor and Welfare for the manufacturing and marketing of their respective generic versions of TREAKISYM®. Given the potential infringement of Eagle's patents related to TREAKISYM® in Japan which are exclusively licensed to SymBio, SymBio notified each of the companies of potential patent infringement and requested they take appropriate measures to avoid such infringement. Of the four companies, Towa began selling its bendamustine generic product in June 2022. Eagle and the Company have therefore commenced the litigation seeking an injunction against the manufacture and sale of Towa's generic version of TREAKISYM® and compensation for damages arising from the infringement.

3. Summary of the lawsuit

Claim for injunction against the manufacture and sale of the generic products and compensation

for damages based on patent infringement.

4. Defendant

Towa Pharmaceutical Co., Ltd.

2-11 Shimbashi-cho, Kadoma, Osaka, Japan

President and Representative Director: Itsuro Yoshida

5. Future outlook

The Company does not anticipate the information presented herein to have any material impact on its financial outlook for the fiscal year ending December 2022.

[Contact]

Investor Relations

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