October 18, 2019

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

Notice Regarding Inappropriate Conduct of Clinical Trial Monitor

A clinical trial monitor engaged as a facility supervisor in a clinical trial conducted by SymBio Pharmaceuticals Limited ("the Company") was found to have engaged in inappropriate conduct. We sincerely apologize for the inconvenience and concern this incident has caused to the parties involved. We provide below an overview of the incident, its impact on clinical trial participants, and the measures that the Company has implemented to prevent recurrence.

1. Description of incident

A clinical trial monitor filled in the signature of the principal investigator on certain Safety Information Reports and submitted the reports to the relevant medical institutions.

2. Details and findings of investigation

Upon becoming aware of the monitor's conduct, the Company promptly reported the incident to the pharmaceutical regulatory authority and initiated an investigation to assess the scope of the conduct. The Company thoroughly reviewed all relevant documents maintained by the Company and the trial sites that were overseen by the clinical trial monitor, and validated the accuracy of the source documents.

The investigation showed that the conduct of the monitor took place with respect to two medical institutions. The Company determined that the monitor's conduct was clearly inappropriate and exceeded the monitor's authority. The Company communicated with the principal investigators involved and has handled the matter in accordance with the instructions from the medical institutions. There have been no reports of any negative health impact on clinical trial participants in connection with the monitor's conduct and, with the exception of the conduct of this individual clinical trial monitor involving two medical institutions, no other issues were identified.

3. Development and implementation of measures to prevent recurrence

As the opinion of the principal investigator is critical information to evaluate the safety of an investigational new drug, the actions of the monitor are unacceptable from the point of view of the need to ensure safety for clinical research volunteers. To prevent recurrence, the Company, after

consulting with appropriate regulatory agency in Japan, has implemented the following measures:

(1) The Company will provide additional training for the Research & Development Division to ensure full compliance. The Company will also integrate compliance training into the monthly training provided to clinical trial monitors.

(2) The Company has implemented a review system whereby supervisors will review all activity of clinical trial monitors.

The Company takes this incident seriously and has implemented corrective actions to prevent recurrence of similar incidents going forward and to restore trust as soon as possible.

[Contact]

Investor Relations
Tel: +81 (0)3 5472 1125