

Announcement of Discontinuation of Development of a Norovirus Vaccine in an Overseas Consolidated Subsidiary and Recording of Extraordinary Loss

Denka Company Limited (Head Office: Chuo-ku, Tokyo; President and CEO: Toshio Imai) hereby announce that we have decided to discontinue the development of the norovirus vaccine that was under development by the consolidated subsidiary Icon Genetics GmbH (Head Office: Halle, Land Sachsen-Anhalt, Germany; CEO: Kazuyuki Hiruta; hereinafter referred to as “Icon”), and recorded a extraordinary loss during the cumulative third quarter of the fiscal year ended March 2024.

This does not affect the manufacture of seasonal influenza vaccines by the egg method and their supply.

1. Background

For the development of vaccines including norovirus and diagnostic raw materials, we have acquired Icon, which has protein expression technology involving genetic recombination using plants, in 2015 and has been developing various diagnostic raw materials and a norovirus vaccine. Regarding the development of the norovirus vaccine, a Phase I clinical trial was started in September 2020, and since the expected evaluation criteria were met, we proceeded with preparations for a Phase II clinical trial.

However, due to the significant impact of the new coronavirus pandemic on the clinical trial environment in Europe, it was revealed that there would be a significant delay in the schedule after the Phase II clinical trial, and also that the development costs, including clinical trials, would be much higher than had initially been expected. It is also assumed that the rapid advances in the development of vaccines for new modalities (*) such as mRNA will also result in intense competition for norovirus vaccines.

As a result of re-evaluation of the business potential based on such changes under these circumstances, it was determined that it would be reasonable to discontinue the in-house development of the norovirus vaccine and allocate management resources to other focused businesses such as virus drug products for cancer treatment and test reagents, and we decided to discontinue the development of the norovirus vaccine by our company.

(*) Modality... Basic technologies in manufacturing and development of pharmaceutical products, or classification of drugs based on them

2. Future Plan

Although the internal development of the norovirus vaccine is discontinued, our purpose is to explore methods to effectively utilize the development results to date, including out-licensing to other companies. Regarding the development of diagnostic raw materials using the technology of Icon, we are already on track with the switching of raw materials of multiple products, and we are eager to continue the development.

We will continue to consider the development of other vaccines than norovirus in parallel with vaccines developed by other modalities such as joint development of seasonal influenza vaccines using next-generation mRNA technology.

3. Recording of Extraordinary Loss

Due to the discontinuation of the development of norovirus vaccine, initially expected earnings are no longer viable. Therefore, 6,786 million yen was recorded as a Extraordinary loss such as impairment of goodwill pertaining to Icon in the cumulative third quarter of the fiscal year ended March 2024. Regarding the influence on our consolidated performance forecast, please also refer to the “Notice Concerning the Correction of the Consolidated Performance Forecast for the Full Year ended March 2024” disclosed at the same time today.

4. Overview of Icon Genetics GmbH

(1) Company Name	Icon Genetics GmbH
(2) Address	Halle, Land Sachsen-Anhalt, Germany
(3) Representative	Kazuyuki Hiruta, CEO
(4) Details of Business	Provision of research and development/contract research services for biopharmaceuticals
(5) Capital	25,000 Euros
(6) Year of Establishment	1999
(7) Shareholder Composition	Denka Company Limited 100%

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