

Approval of a Cell Culture Pandemic Influenza Vaccine (Prototype)

26th March, 2015

The Chemo-Sero-Therapeutic Research Institute (Head Office: Kumamoto, Director General: Seiji Miyamoto, hereinafter “Kaketsuken”), announced today that it has received manufacturing and marketing approval for a cell culture pandemic influenza vaccine (prototype) (General name: Emulsion Cell Culture Influenza HA Vaccine (Prototype)). This is a result of a co-development with GlaxoSmithKline K.K. (Head Office: Shibuya-ku, Tokyo, President: Philippe Fauchet), and GlaxoSmithKline Vaccines* (Belgium, hereinafter “GSK”).

Prototype vaccine is a model vaccine developed and manufactured using a model virus for pandemic vaccine production, and is a mock vaccine with immunogenicity and safety confirmed in humans. Pandemic influenza outbreak cannot be predicted. In addition, after the outbreak, there will be an urgent need for the manufacture and supply of vaccines. Receiving approval for the Prototype Vaccine means that if a pandemic occurs, by changing the manufacturing virus strain to that against the pandemic influenza, it would become possible to promptly manufacture and supply a pandemic vaccine using the same manufacturing and quality control methods.

The pandemic influenza vaccine by the “cell culture method” is expected to allow shortened manufacturing time and rapid supply of a vaccine following occurrence of a pandemic. Until now, GSK and Kaketsuken have collaborated to develop a cell culture pandemic influenza vaccine, combining the EB66[®] cell line licensed from Valneva SE (France), and cell culture / purification technology held by both companies, and GSK’s adjuvant technology.

In March, 2014, Kaketsuken received manufacturing and marketing approval for an H5N1 influenza vaccine, “General name: Emulsion Cell Culture Influenza HA Vaccine (H5N1 strain)”. This was followed by submission for manufacturing and marketing approval of the Prototype Vaccine in September, 2014, and today’s approval. In July, 2012, the Prototype Vaccine was designated as an orphan drug.

Kaketsuken was selected for the first and second open calls of the “Development and

* Registered as GlaxoSmithKline Biologicals S.A.

Production System Installation Project for Cell Culture-based Pandemic Influenza Vaccine”, established by the Ministry of Health, Labour and Welfare, and, as such, has received monetary support for the establishment of pandemic influenza vaccine manufacturing facilities and conduct of clinical trials, etc. The pandemic vaccine manufactured based on the Prototype Vaccine’s license is assumed to be used in accordance with the “governmental action plans for measures against pandemic influenza” and “guidelines for measures against pandemic influenza”.

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Reference

Kaketsuken:

Kaketsuken is a Japanese pharmaceutical manufacturer, involved in the development and supply of vaccines and blood plasma products. Kaketsuken has developed many pharmaceuticals for supply to the Japanese market, including influenza vaccines, a DPT/IPV combined vaccine, and a Hepatitis B vaccine. As part of the national response to pandemic influenza, Kaketsuken received manufacturing approval for an egg culture H5N1 (pre) pandemic influenza vaccine on October 27, 2010. Kaketsuken also has experience producing vaccines against the “H1N1 pandemic influenza”, during the outbreak in 2009.

With the approval of the Prototype Vaccine, Kaketsuken will continue to further develop vaccines against infectious diseases, and contribute to human health.

GSK:

With vast experience and track record in the manufacture and supply of influenza vaccines, and the development of adjuvants, GSK received manufacturing approval for one of its egg culture H5N1 (pre) pandemic vaccine in all 27 nations of the EU in May 2008, followed by receiving approval of a similar vaccine from the US FDA in November, 2013.

EB66[®] cells:

The EB66[®] cells used to develop the Vaccine were established using Valneva SE technology, and exclusively licensed to GSK for influenza vaccine development and sub-licensed to Kaketsuken. EB66[®] cells allow for serum free suspension culture, and can be used to manufacture highly effective human and animal vaccines.