News Release

Takeda Submits New Drug Applications in Japan for Cell Culture-Based Pandemic Influenza Vaccines with its Hikari Plant

Osaka, Japan, March 27, 2013 –Takeda Pharmaceutical Company Limited ("Takeda") announced today that it has submitted New Drug Applications ("NDAs") for cell culture-based pandemic influenza vaccines (H5N1 and prototype*) to the Ministry of Health, Labour and Welfare ("MHLW") in Japan, using its Hikari Plant as the manufacturing facility.

In December 2010, Takeda and Baxter International Inc. (Headquarters: Illinois, U.S.A., "Baxter") entered into a Development, License and Technology Transfer Agreement in which Baxter licensed exclusive rights to its proprietary cell culture-based pandemic influenza vaccines technology for the Japanese market to Takeda. Based on the agreement, Takeda has been conducting development activities jointly with Baxter and constructing the manufacturing facility for cell culture-based influenza vaccines at its Hikari Plant, a state-of-the-art influenza facility, in order to establish the supply source in Japan.

Takeda and Baxter jointly submitted NDAs in September 2012 to the MHLW for cell culture-based pandemic influenza vaccines with Baxter's plant in Europe as the manufacturing site. The NDAs submitted today cover vaccine product produced at Takeda's Hikari Plant and for which Takeda has conducted testing to demonstrate equivalence to vaccine manufactured at Baxter's facility.

The Japanese government had previously offered a subsidy to support the investment associated with the development and production of pandemic influenza vaccine in Japan, and it selected Takeda as one of recipients of that subsidy.

Takeda has a proven track record of stable supply of pediatric vaccines in Japan for more than sixty years and is committed to developing and producing pandemic influenza vaccine in Japan as its social mission under the support of the government's subsidy. Takeda is aiming to obtain the approval of the NDAs within fiscal 2013 through close coordination with the regulatory authorities.

* To facilitate registration of a vaccine in the event of a pandemic caused by an influenza strain other than H5N1.

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