



*Better Health, Brighter Future*

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# News Release

## **Takeda Announces the New Drug Application Approval of Cell Cultured Influenza vaccine H5N1 “TAKEDA” 1mL and Cell Cultured Influenza vaccine (Prototype) “TAKEDA” 1mL in Japan for Prevention of Pandemic Influenza**

**Osaka, Japan, March 31, 2014** – Takeda Pharmaceutical Company Limited (“Takeda”) announced today that the Japanese Ministry of Health, Labour and Welfare (MHLW) has approved the New Drug Application (NDA) of Cell Cultured Influenza vaccine H5N1 “TAKEDA” 1mL (generic name: Cell Cultured Influenza vaccine (H5N1Strain)) and Cell Cultured Influenza vaccine (Prototype\*) “TAKEDA” 1mL (generic name: Cell Cultured Influenza vaccine (Prototype)) for prevention of pandemic influenza to be manufactured in the Hikari Plant (Hikari City, Yamaguchi Prefecture). Takeda’s NDA was submitted to MHLW in March 2013.

In 2010, Takeda and Baxter International Inc. (Headquarters: Deerfield, 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 vaccine technology for the Japanese market. Under this agreement, Takeda has been conducting pandemic influenza vaccine development activities jointly with Baxter. The vaccine will be manufactured at a newly-established facility at for cell culture-based influenza vaccines at Takeda’s Hikari Plant, which was partially funded by a subsidy from the Japanese Government.

The NDA approval means that Takeda is now able to manufacture and supply pandemic influenza vaccines in Japan using cutting edge manufacturing technologies licensed from Baxter. With a proven track record of providing pediatric vaccines in Japan for more than 60 years, Takeda will continue to fulfill its social mission as a pharmaceutical company by helping to protect the Japanese population in the event of an influenza pandemic.

“Today’s decision by the MHLW represents an important milestone in our collective efforts to strengthen pandemic preparedness in Japan,” said Rajeev Venkayya, MD, Head of Takeda’s Vaccine Business Division. “Takeda remains committed to advancing public health in Japan and across the globe.”

This approval does not change the outlook for Takeda's consolidated results for FY fiscal 2013.

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

## References

### H5N1

Japanese Brand Name	Cell Cultured Influenza vaccine H5N1 “TAKEDA” 1mL
Generic name	Cell Cultured Influenza vaccine (H5N1Strain)
Dosage and Administration	Usually, the vaccine 0.5mL is intramuscularly or subcutaneously administered twice with 3 weeks or longer intervals.
Indication	Prevention of influenza (H5N1)

### Prototype

Japanese Brand Name	Cell Cultured Influenza vaccine (Prototype) “TAKEDA” 1mL
Generic name	Cell Cultured Influenza vaccine (Prototype)
Dosage and Administration	Usually, the vaccine 0.5mL is intramuscularly or subcutaneously administered twice with 3 weeks or longer intervals.
Indication	Prevention of pandemic influenza

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