Takeda Pharmaceutical Company Limited
1-1, DOSHOMACHI 4-CHOME,CHUO-KU, OSAKA 540-8645, JAPAN

News Release

Contact:
Public Relations
+81-3-3278-2037 (Tokyo)

Takeda Voluntarily Recalls its Anti-inflammatory Enzyme Preparation, Dasen® in Japan

Osaka, Japan, February 21, 2011 – Takeda Pharmaceutical Company Limited ("Takeda") announced today its decision to voluntarily recall Dasen® 5 mg tablets, 10 mg tablets, and 1% granules (generic name: serrapeptase), anti-inflammatory enzyme preparations sold in Japan, starting on February 21.

In the double-blind studies that have been conducted to compare Dasen with placebo ("Studies"), no statistical significant differences were found. Based on the results of the Studies, the Committee on Reevaluation of the Pharmaceutical Affairs and Food Sanitation Council ("Committee") of the Ministry of Health, Labour and Welfare of Japan ("MHLW") held a meeting on January 19, 2011 in order to discuss the possibility of categorizing Dasen as the product for the future reevaluation with additional studies to be conducted, including the contents of such studies if that is the case.

As a result, the Committee pointed out the necessity of conducting additional studies in a manner that reflects current clinical treatment practices, and to prove the efficacy of Dasen. In accordance with the instruction of the MHLW, Takeda has been studying the feasibility of conducting such studies. Takeda believes that the efficacy of Dasen would be confirmed through additional clinical trials with a revised study design, however, it has reached a conclusion that it would be difficult to conduct additional studies as requested.

Takeda has been marketing Dasen in Japan since 1968 and the product has been prescribed by physicians to a number of patients for over 40 years. Takeda will ensure that accurate information will be communicated promptly to healthcare providers to minimize confusion in the medical practice or among patients upon recall of the product.

The sales of Dasen in Japan in the 2009 fiscal year were Yen 6.7 billion and the impact of this issue on the fiscal 2010 financial year is estimated to be minimal at this moment.

<Background of Studies>
The current indications* of the product were approved in 1995, based on the results of reevaluation as announced by the then Ministry of Health and Welfare, on the conditions that the required data at that time would be prepared before the next reevaluation. Takeda therefore conducted specific clinical trials: one trial included patients with chronic bronchitis (protocol: TSP/CCT-901) and two were conducted with patients with sprained ankle (protocol: TSP/CCT-902, CCT-910). The results were submitted to the MHLW which are available on the website of The Japan Pharmaceutical Information Center (JAPIC). http://www.clinicaltrials.jp/user/ctiMenu.jsp

* Currently approved indications of Dasen

- Remission of swelling in the following diseases or symptoms:
  After operation and trauma, chronic sinusitis, galactostasis (in cases where breast massage or pumping is performed)
- Difficulty of expectoration in the following diseases with hard-to-eliminate sputum and frequent hacking:
  Bronchitis, pulmonary tuberculosis, bronchial asthma
- Difficulty of expectoration after anaesthesia

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About Takeda
Located in Osaka, Japan, Takeda is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the global leaders of the industry, Takeda is committed to strive towards better health for patients worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, www.takeda.com.

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