



*Better Health, Brighter Future*

Media Contact:  
Takeda Pharmaceutical Company Limited  
Corporate Communications Department  
Tel +81-3-3278-2037

## News Release

### **Takeda Announces Termination of Fasiglifam (TAK-875) Development**

**Osaka, Japan, December 27, 2013** – Takeda Pharmaceutical Company Limited (Takeda) announced today that it has decided voluntarily to terminate the development activities for fasiglifam (TAK-875), an investigational treatment for type 2 diabetes, due to concerns about liver safety.

Patient safety is Takeda's highest priority. The company has worked with three independent panels of experts to provide for the safety of trial participants and ensure independent safety oversight for the clinical trials throughout the duration of the fasiglifam (TAK-875) Phase 3 development program.

The expert panels include the independent Data Monitoring Committee (DMC), a committee that oversees the fasiglifam global clinical development program, reviews the unblinded clinical data from program trials and provides continual safety oversight of trial subjects and recommendations. The DMC is comprised of clinical experts in endocrinology, cardiology and hepatology as well as a statistician. The independent Liver Safety Evaluation Committee (LSEC) is comprised of five hepatologists with expertise in drug-induced liver injury. While remaining blinded to treatment information, the LSEC regularly evaluates data on liver enzymes elevations and adjudicates cases that impacted the liver. In addition, an independent Executive Committee (EC) provides additional oversight for the fasiglifam (TAK-875) cardiovascular outcomes trial.

After careful consideration of the data emerging from all the clinical trials and in consultation with these panels, the company has reached the conclusion that, on balance, the benefits of treating patients with fasiglifam (TAK-875) do not outweigh the potential risks. For this reason, Takeda has decided voluntarily to terminate the development activities for fasiglifam.

Takeda is in communication with trial investigators and the relevant regulatory authorities regarding the company's decision, to provide them with updated and current information in compliance with local

regulations. Takeda is working with trial investigators and local regulatory authorities to ensure that patients who participated in the fasiglifam (TAK-875) trials are transitioned to appropriate therapies and ensure that trial participants receive appropriate care. Patients enrolled in the fasiglifam (TAK-875) clinical trials are urged to consult their study investigators to address any questions, and before making any changes to their medication. For additional information, please visit [www.takeda.com](http://www.takeda.com).

Takeda remains committed to the development of novel treatments for diabetes, a disease which represents a growing health burden for people worldwide.

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*Forward-looking statements involve risks and uncertainties that could cause actual results or experience to differ materially from that expressed or implied by the forward-looking statements. Some of these risks and uncertainties include, but are not limited to, (1) the economic circumstances surrounding Takeda's business, including general economic conditions in Japan, the United States and worldwide; (2) competitive pressures and developments; (3) applicable laws and regulations; (4) the success or failure of product development programs; (5) actions of regulatory authorities and the timing thereof; (6) changes in exchange rates; (7) claims or concerns regarding the safety or efficacy of marketed products or product candidates in development; and (8) integration activities with acquired companies.*

*The forward-looking statements contained in this press release speak only as of the date of this press release, and Takeda undertakes no obligation to revise or update any forward-looking statements to reflect new information, future events or circumstances after the date of the forward-looking statement. If Takeda does update or correct one or more of these statements, investors and others should not conclude that Takeda will make additional updates or corrections.*