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Takeda Pharmaceutical Company Limited

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Takeda Pharmaceutical Company Limited

Takeda Announces Termination of Orteronel (TAK-700) Development for Prostate Cancer in Japan, U.S.A. and Europe

Osaka, Japan, June 19, 2014 –Takeda Pharmaceutical Company Limited (TSE:4502) announced today that it has voluntarily decided to end the development program for orteronel (TAK-700) for prostate cancer. The decision follows the results of two Phase 3 clinical trials in metastatic, castration resistant prostate cancer (mCRPC). The studies found while orteronel plus prednisone could extend the time patients lived before their cancer progressed, it did not extend overall survival in these patients. After careful consideration of the data from these trials, the company has determined that the drug has not demonstrated a clinical profile sufficient to move forward in mCRPC, given the availability of other therapies.

On May 14, 2014, Takeda announced results from ELM-PC4, a pivotal, international, double blind, randomized Phase 3 trial in men with mCRPC who had not received chemotherapy, which showed that orteronel plus prednisone improved radiographic progression free survival (rPFS) compared to prednisone alone, one of the study's two primary endpoints, but did not show a statistically significant improvement in the study's second primary endpoint of overall survival (OS). A previously reported Phase 3 trial, ELM-PC5, in men with mCRPC that had progressed during or following chemotherapy, was unblinded in 2013 after a pre-specified interim analysis indicated that orteronel plus prednisone would likely not meet the primary endpoint of improved overall survival when compared to the control arm. The interim analysis did show an advantage for orteronel plus prednisone for the secondary endpoint, radiographic progression-free survival over the control arm. There were no significant safety concerns in either study.

Takeda is in communication with trial investigators and the relevant regulatory authorities, 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 orteronel (TAK-700) trials are transitioned to appropriate therapies so that trial participants receive appropriate care. Patients enrolled in the orteronel (TAK-700) 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.

Takeda remains committed to oncology and to the treatment of prostate cancer.

About Millennium: The Takeda Oncology Company

Millennium: The Takeda Oncology Company, a leading biopharmaceutical company based in Cambridge, Mass., markets a first-in-class proteasome inhibitor and has a robust pipeline of oncology product candidates. Additional information about Millennium is available through its website, www.millennium.com.

About Takeda Pharmaceutical Company Limited

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 people worldwide through leading innovation in medicine. Additional information about Takeda is available through its corporate website, www.takeda.com.

This press release contains forward-looking statements. Forward-looking statements include statements regarding Takeda's plans, outlook, strategies, results for the future, and other statements that are not descriptions of historical facts. Forward-looking statements may be identified by the use of forward-looking words such as "may," "believe," "will," "expect," "project," "estimate," "should," "anticipate," "plan," "assume,"

"continue," "seek," "pro forma," "potential," "target," "forecast," "guidance," "outlook" or "intend" or other similar words or expressions of the negative thereof. Forward-looking statements are based on estimates and assumptions made by management that are believed to be reasonable, though they are inherently uncertain and difficult to predict. Investors are cautioned not to unduly rely on such forward-looking statements.

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.

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