



Lilly Suspends Phase III Trial in Metastatic Melanoma

INDIANAPOLIS, Dec. 13, 2010 /PRNewswire/ -- Eli Lilly and Company announced today that it has suspended its global Phase III study evaluating tasisulam, an investigational, small-molecule anti-cancer compound, as a second-line treatment for those with unresectable or metastatic melanoma.

Lilly, in consultation with an independent data monitoring committee, recommended a "full clinical hold," because of safety concerns. A full clinical hold ensures that no new or existing patients in the trial receive additional doses of the compound, allowing researchers the time to fully analyze existing data.

Lilly notified regulatory agencies and contacted all trial investigators to provide details on how to manage individuals enrolled in the trial.

"We are thoroughly reviewing the clinical trial data to understand what modifications to the study protocol or dosing would be needed to improve patient safety on this trial," said Richard Gaynor, M.D., vice president, oncology product development and medical affairs for Lilly.

Lilly continues to develop tasisulam as part of an extensive clinical development program across a wide range of tumors, including soft tissue sarcoma, breast, ovarian and renal cancers, as well as non-small cell lung cancer and acute leukemia. At this time, these trials continue without modification because the dosing of tasisulam is different. Lilly is closely evaluating patient safety within these trials on an ongoing basis.

"We remain committed to Lilly Oncology's active fight against cancer, especially for patients facing cancers where the need for new treatments is especially great," added Gaynor.

The Phase III trial sought to compare the efficacy, safety and tolerability of tasisulam versus paclitaxel, as a second-line treatment for those with metastatic melanoma. The study enrolled more than 300 patients in 18 countries. The primary endpoint of this study is overall survival.

Tasisulam was granted orphan drug status for stage 2b-IV melanoma by the U.S. Food and Drug Administration in late 2009.

Notes to Editor

About Melanoma

Melanoma is the deadliest form of skin cancer and is frequently attributed to exposure to ultraviolet (UV) radiation.(1) Although U.S. incidence rates for many cancers have been on the decline, new cases of melanoma have been increasing for the past 30 years.(1) Recent estimates suggest that more than 68,000 people are diagnosed annually in the U.S. with melanoma.(2)

Melanoma has a pathological staging system, starting at 0 and rising to the severity of stage IV.(2) The cancer can metastasize, or spread rapidly, moving from the skin to the blood and lymphatic vessels, and then on to the rest of the body(1) becoming the most deadly form of the disease.(3)

About Lilly Oncology

For more than four decades, Lilly Oncology, a division of Eli Lilly and Company, has been dedicated to delivering innovative solutions that improve the care of people living with cancer. Because no two cancer patients are alike, Lilly Oncology is committed to developing novel treatment approaches. To learn more about Lilly's commitment to cancer, please visit www.LillyOncology.com.

About Eli Lilly and Company

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Ind., Lilly provides answers — through medicines and information — for some of the world's most urgent medical needs.

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This press release contains forward-looking statements about the potential of tasisulam for the treatment of metastatic melanoma and reflects Lilly's current beliefs. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. There is no guarantee that the product will continue to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's filings with the United States Securities and Exchange Commission. Lilly undertakes no duty to update forward-looking statements.

(1) American Cancer Society, "Detailed Guide: Skin Cancer - Melanoma - What Are the Key Statistics About Melanoma?" March 5, 2010. Available at: <http://www.cancer.org/Cancer/SkinCancer-Melanoma/DetailedGuide/melanoma-skin-cancer-key-statistics> Accessed on April 30, 2010.

(2) American Cancer Society, "Detailed Guide: Skin Cancer — Melanoma: How Is Melanoma Staged?" March 5, 2010. Available at: http://www.cancer.org/docroot/CRI/content/CRI_2_4_3X_How_is_melanoma_staged_50.asp?rnav=crl. Accessed on May 5, 2010.

(3) American Academy of Dermatology, "Malignant Melanoma" 2010. Available at: http://www.aad.org/public/publications/pamphlets/sun_malignant.html. Accessed on April 30, 2010.

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