



Lilly Presents New Data in Advanced Melanoma - A Difficult-To-Treat Cancer That Causes Majority of Skin Cancer Deaths

INDIANAPOLIS, May 20, 2010 /PRNewswire via COMTEX News Network/ -- Lilly released results today from a Phase II study evaluating Lilly Oncology's tasisulam, a novel anti-cancer agent, in patients with metastatic melanoma, the deadliest form of skin cancer.(1) Study results will be presented during the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) held in Chicago, Ill. on June 6, 2010.

"While great strides have been made in treating some cancers over the past decade, others - such as melanoma - continue to be challenging to treat," said John M. Kirkwood, M.D., co-leader of the Melanoma Program of the University of Pittsburgh Cancer Institute. "Ongoing research is critical if we are to find appropriate treatments for patients who need them most."

The Phase II study (Abstract #8541) evaluated the use of tasisulam as a second-line treatment in patients with unresectable or metastatic melanoma. The trial's primary objective was to determine overall response rate and its two secondary objectives were to determine progression-free survival and overall survival. Of the 68 patients enrolled in the study, eight demonstrated partial response, 24 had stable disease (no progression after two cycles), 25 had progressive disease, and 11 did not have their disease progression completely evaluated. The median progression-free survival was 2.6 months and the median overall survival was 9.6 months.

Tasisulam was given in 21-day cycles using a dosing algorithm based on body weight. The most common grade 3/4 hematologic toxicities were thrombocytopenia (low platelet count), neutropenia (low white blood cell count) and anemia (low red blood cell count). Non-hematologic toxicities included fatigue, mucositis (inflammation of the mucous membrane) and stomatitis (inflammation of the mucous lining).

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

"Encouraging results from these studies are confirmation that Lilly Oncology is moving in the right direction towards finding innovative solutions for difficult-to-treat cancers," said Richard Gaynor, M.D., vice president, product development and medical affairs at Lilly Oncology. "These studies are in keeping with Lilly's dedication to addressing patient populations that are most in need."

In total, there will be 13 studies presented at ASCO evaluating Lilly pipeline molecules. Lilly has one of the largest oncology pipelines in the industry, with more than 20 molecules being evaluated for use in a wide range of cancers.

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.(2) 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.(3) 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)

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 first-in-class and best-in-class 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.

(Logo: <http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO>)

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

(2) American Cancer Society, "Detailed Guide: Skin Cancer - Melanoma - What Are the Key Statistics About Melanoma?" March 5, 2010. Available at: http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_melanoma_50.asp?rnav=cri. Accessed on April 30, 2010.

(3) 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=cri. Accessed on May 5, 2010.

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