

Enrollment Completed in Major Lung Cancer Trial

January 16, 2002

Trial Involves LY900003 (ISIS 3521), Developed By Isis Pharmaceuticals And Licensed to Eli Lilly and Company

CARLSBAD, Calif., Jan. 16 /PRNewswire-FirstCall/ -- Enrollment has been completed in a late-phase clinical trial of LY900003 (ISIS 3521) in patients with non-small cell lung cancer, which affects more than one million people worldwide. LY900003 (ISIS 3521) is an investigational cancer compound of Isis Pharmaceuticals, Inc. and is being developed through an alliance between Eli Lilly and Company (NYSE: LLY) and Isis Pharmaceuticals, Inc. (Nasdaq: ISIP).

The U.S. and European Phase III clinical trial is designed to evaluate the ability of LY900003 (ISIS 3521) to prolong patients' lives in combination with the chemotherapy agents carboplatin and paclitaxel. Isis initiated the study in non-small cell lung cancer in October 2000. In August 2001, Isis exclusively licensed the investigational antisense agent to Lilly.

"Enrollment in this trial was relatively swift, with the planned 600 patients enrolled in just 15 months," said F. Andrew Dorr, M.D., Isis' vice president and chief medical officer. "We are pleased to achieve this clinical milestone in the development of LY900003 (ISIS 3521) for patients with non-small cell lung cancer."

Added Jack Harris, M.D., executive director of oncology and critical care products at Lilly and leader of the LY900003 product team, "New therapies which prolong survival in patients with non-small cell lung cancer are urgently needed. We believe that LY900003 (ISIS 3521) could be a new weapon in fighting this terrible disease."

LY900003 (ISIS 3521) is an antisense agent. Antisense compounds use the specificity of the genetic code to prevent the production of disease-causing proteins. In contrast, conventional drugs bind to disease-causing proteins that have already been produced. "As a representative of a new class of drugs, LY900003 (ISIS 3521) works through a fundamentally different mechanism, and may enhance treatment when used in combination with traditional drugs," said Harris, adding that clinical trials are planned to evaluate LY900003 (ISIS 3521) in combination with the anticancer medications Gemzar[®] (gemcitabine hydrochloride) and cisplatin.

According to the American Cancer Society, lung cancer is the leading cause of cancer death for both men and women. In 2001, approximately 169,500 new cases of lung cancer were diagnosed and 157,400 Americans died due to the disease. More people die of lung cancer than of colon, breast and prostate cancers combined. Non-small cell lung cancer is the most prevalent form of lung cancer, accounting for approximately 75 percent of lung cancer diagnoses in the U.S.

Isis Pharmaceuticals, Inc. is exploiting its expertise in RNA to discover and develop novel human therapeutic drugs. The company has commercialized its first product, Vitravene[®] (fomivirsen), to treat CMV-induced retinitis in AIDS patients. In addition, Isis has 13 products in its development pipeline, with two in late-stage development and seven in Phase II human clinical trials. LY900003 (ISIS 3521), an inhibitor of PKC-alpha, is in Phase III trials for non-small cell lung cancer, and alicaforsen (ISIS 2302), an ICAM-1 inhibitor, is in Phase III human clinical trials for Crohn's disease. Isis has a broad patent estate, as the owner or exclusive licensee of nearly 900 issued patents worldwide. Isis' GeneTrove[™] division uses antisense to assist pharmaceutical industry partners in validating and prioritizing potential gene targets through customized services and access to an extensive gene function database. Ibis Therapeutics[™] is a division focused on the discovery of small molecule drugs that bind to RNA.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaboration 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.

This press release contains forward-looking statements about the potential of the investigational compound LY900003 (ISIS 3521) in the treatment of non-small cell lung cancer and the potential of antisense drug discovery and development efforts that reflect the current beliefs of Lilly and Isis. However, as with any pharmaceutical under development, there are substantial risks and uncertainties in the process of pharmaceutical discovery, development and regulatory review. There are no guarantees that future clinical trials will confirm the preliminary results referred to in this release or that LY900003 (ISIS 3521) will receive regulatory approvals or prove to be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly and Isis' filings (for Isis please refer to Form 10Q for the period ended September 30, 2001) with the United States Securities and Exchange Commission. Lilly and Isis undertake no duty to update forward-looking statements.

Gemzar[®] (gemcitabine hydrochloride, Lilly), GeneTrove[™] and Ibis Therapeutics[™] are trademarks of Isis Pharmaceuticals, Inc.

Vitravene[®] (fomivirsen) is a registered trademark of Novartis AG.

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