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Progress of Lilly MDR-TB Partnership Highlighted as Part of World TB Day
Expansion of production capability, transfer of manufacturing technology and training of health care professionals are underway

The completion of a \$7 million expansion of a drug manufacturing facility in the United Kingdom; the successful initiation of transferring manufacturing technology to companies in India, China, and South Africa; and the start of a new research and treatment training class in Russia are some of the milestones achieved in the first 10 months of a global partnership to fight the spread of multi-drug resistant tuberculosis (MDR-TB), said an Eli Lilly and Company (NYSE: LLY) official.

MDR-TB is a type of tuberculosis (TB) that often develops in patients who do not complete the proper treatment for TB. The disease can occur when a physician does not prescribe proper treatment regimens or when a patient is unable to adhere to therapy with first-line drugs. Once a strain of MDR-TB develops, it can be spread to others just as "normal" TB.

In June 2003, Lilly announced a \$70 million partnership with the World Health Organization (WHO); the U.S. Department of Health and Human Services' Centers for Disease Control and Prevention (CDC); Brigham and Women's Hospital (BWH), an affiliate of Harvard Medical School; Purdue University; and the International Council of Nurses to battle this growing public health threat. At the core of the partnership is increasing the availability and proper use of two life-saving antibiotics developed by Lilly, Capastat[®] (capreomycin) and Seromycin[®] (cycloserine), which are used for treatment of MDR-TB.

"In a very short period, we have taken some important steps to increase the number of trained personnel and availability of drugs to treat the expanding crisis of MDR-TB," said Dr. Gail

Cassell, vice president, scientific affairs and distinguished research scholar in infectious diseases, Eli Lilly and Company. "However, new statistics from the WHO reveal this crisis is broadening, requiring us to be even more diligent in our efforts to control its spread."

To date, the partnership's successes to meet this goal include:

Increasing drug supply

- A newly-completed \$7 million expansion of Lilly's manufacturing facility in Speke, an operation south of Liverpool in the United Kingdom, will double the company's capacity for producing Capastat.
- To support this increased capacity, Lilly has contracted with Human Serum Production and Medicine Manufacturing Co., Ltd., Hungary, which has validated and shipped its first batch of Capastat-filled vials.
- Lilly continues to supply both Capastat and Seromycin at discounted prices to WHO Green Light Committee-approved MDR-TB DOTS-Plus programs around the world. The value of this discount is approximately \$25 million (USD) over the 6-year life of the project.

Technology transfer

- Lilly has signed technology transfer agreements with companies in India (Shasun Chemical and Drugs, Ltd.) and South Africa (Aspen Pharmacare Holdings, Ltd) and is negotiating a similar agreement in China (Zhejiang Hisun Pharmaceutical Co., Ltd.). In addition to making available the necessary manufacturing know-how, Lilly is providing financial assistance for the purchase of equipment and/or conversion of manufacturing facilities and technical training for various steps in manufacturing processes. Currently, the companies are in various stages of facility conversion and initial production. The first validated production could occur within the next six months with shipments for disbursement to WHO-approved MDR-TB DOTS-Plus programs occurring before the end of 2004.
- In December 2003, Purdue University broke ground for its new manufacturing facility, the Allen Chao Center for Industrial Pharmacy, which will produce Seromycin.

University officials also visited Lilly's manufacturing partners in both India and China to determine training requirements for both facilities and to meet with local universities in those countries to discuss possible collaborative efforts. In May, Purdue University will be hosting its first training for five employees of Zhejiang Hisun Pharmaceutical Co., Ltd. (China), and four employees from Shasun Chemical and Drugs, Ltd. (India), in West Lafayette, Ind. The university will train employees in Good Manufacturing Practices and proper regulatory documentation.

Prevention, treatment and surveillance

Through funding from Lilly:

- Harvard University/Partners in Health has established a MDR-TB research and training program in Tomsk, Russia. As a part of the training, health care workers from Russia and other countries of the former Soviet Union with high burdens of MDR-TB were trained in treating the illness, while research data obtained is being used globally to improve and potentially develop new treatments. The first class completed training in January and the next class begins training this week.
- The International Council of Nurses (ICN) is developing TB and MDR-TB treatment guidelines for nurses around the world. The ICN will launch this effort in May.
- The U. S. Centers for Disease Control and Prevention have begun development of a laboratory-based electronic surveillance system to monitor resistance to drugs used for treating MDR-TB in Russian patients.
- The WHO is developing software to standardize data collection of patient outcomes at Green Light Committee-approved treatment sites. Strengthening of data management will assist in improving logistics, training and drug management (i.e., better forecasting of drugs needed at treatment sites).

For more information about the Lilly MDR-TB partnership, visit the Lilly Website at www.lillyMDR-TB.com.

This topic and other relevant information about World TB Day will be discussed during today's NewsMaker Forum, a Lilly-sponsored media briefing conference call. The Lilly NewsMaker

Forum will occur today at 9:15 a.m. (eastern time). Reporters can access the media briefing conference call by dialing:

United States: (888) 428-4480

International: (612) 288-0318

Today's guests are Dr. Paul Farmer, chief of the Division of Social Medicine and Health Inequalities at Brigham and Women's Hospital and co-founder of Partners in Health; Dr. Maria Freire, chief executive officer of the Global Alliance for TB Drug Development; and Dr. Gail Cassell, vice president, scientific affairs and distinguished research scholar in infectious diseases, 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. Additional information about Lilly is available at www.lilly.com.

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