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New Clinical Trial for Patients With Asbestos-Associated Lung Cancer

Investigational Therapy May Help Avoid Lung Removal Surgery for Patients with Pleural Mesothelioma

Mesothelioma Center at NewYork-Presbyterian Hospital and Columbia University Medical Center Now Recruiting Participants

NEW YORK (May DAY, 2008) — The Mesothelioma Center within the Herbert Irving Comprehensive Cancer Center at NewYork-Presbyterian Hospital and Columbia University Medical Center is now recruiting patients for a new clinical research study of a new targeted radiation and chemotherapy protocol for pleural mesothelioma, a cancer of the lung's lining that is almost always caused by previous exposure to asbestos.

The standard treatment for pleural mesothelioma is currently surgery to remove the patient's lung — a potentially debilitating consequence.

"Current surgical and chemotherapy treatments of patients with malignant pleural mesothelioma are unsatisfactory, and have not been shown to significantly prolong survival. In this study, we will investigate whether a combination of chemotherapy and radiation targeted directly at the lung's lining can improve outcomes while avoiding

surgery," says Dr. Robert Taub, the study's principal investigator, director of the Mesothelioma Center at NewYork-Presbyterian/Columbia and professor of clinical medicine at Columbia University College of Physicians and Surgeons. "In addition, this approach has shown to have minimal toxic side effects compared to systemic chemotherapy."

"This trial is also significant because our center is the only one nationwide that is offering this experimental therapy to treat pleural mesothelioma," added Dr. Taub. "We are very focused on offering these patients the best treatment that medical technology can offer while simultaneously working to preserve quality of life."

Researchers also anticipate that the radiation therapy will kill the cancer cells on surface of the lung while sparing other parts of the lung and surrounding vital tissues.

"Delivery of radiation therapy directly into the pleural cavity is a strategy that has been employed since 1945. Today, direct injection of radioactive P32 may prove to be a significant and effective therapeutic approach for selected mesothelioma patients," adds Dr. Rashid Fawwaz, study co-investigator, radiologist at NewYork-Presbyterian/Columbia and professor of clinical radiology at Columbia University College of Physicians and Surgeons.

"Overall, it is hoped that this study will decrease the need for patients to undergo radical surgery," states Dr. Joshua Sonett, study co-investigator, chief of general thoracic surgery, surgical director of the Lung Transplant Program and surgical director of the High-Risk Lung Assessment Program at NewYork-Presbyterian/Columbia and professor of clinical surgery at Columbia University College of Physicians and Surgeons.

Participating patients will receive several rounds of targeted chemotherapy using the drugs cisplatin and doxorubicin via surgically implanted catheters. Some patients will be randomly selected to receive additional systemic (intravenous) chemotherapy using the drugs cisplatin and pemetrexed. All patients will receive targeted radiotherapy using the P-32 radioisotope. Patients may elect to receive additional surgical treatment, including removal of the affected lung lining or lung. Subsequently, patients will be offered outpatient systemic chemotherapy with cisplatin and pemetrexed.

The investigators previously led a prospective study that employed a similar protocol for patients with pleural mesothelioma as well as those with the more retractable sarcomatous disease. Completed in 2002, the study reported a median survival of 70 months, and a three-year survival of 67 percent (*American Journal of Clinical Oncology*, February 2008).

Patients aged 18 and older that have not had recent radiation therapy or chemotherapy, and have not received prior Alimta chemotherapy, may be eligible for the current study. Those interested in enrolling should contact Dr. Robert Taub, Dr. Joshua Sonett or study coordinator Lilian Batista at (212) 305-6837.

The study is being conducted at the Mesothelioma Center within the Herbert Irving Comprehensive Cancer Center at NewYork-Presbyterian Hospital and Columbia University Medical Center.

Drs. Taub, Fawwaz and Sonett are joined by co-investigators Drs. Mark Ginsberg and Lyall Gorenstein — both of NewYork-Presbyterian Hospital and Columbia University Medical Center.

From 1940 through 1979, approximately 28 million U.S. workers were exposed to asbestos at work. An estimated 3,000 people died of mesothelioma in the late 1990s. It is unknown how asbestos causes the disease.

Columbia University Medical Center

Columbia University Medical Center provides international leadership in basic, pre-clinical and clinical research, in medical and health sciences education, and in patient care. The medical center trains future leaders and includes the dedicated work of many physicians, scientists, nurses, dentists, and public health professionals at the College of Physicians & Surgeons, the Mailman School of Public Health, the College of Dental Medicine, the School of Nursing, the biomedical departments of the Graduate School of Arts and Sciences, and allied research centers and institutions. Established in 1767, Columbia's College of Physicians & Surgeons was the first institution in the country to grant the M.D. degree. Among the most selective medical schools in the country, the school is home to the largest medical research enterprise in New York State and one of the largest in the United States. For more information, please visit www.cumc.columbia.edu.

Herbert Irving Comprehensive Cancer Center

The Herbert Irving Comprehensive Cancer Center at Columbia University Medical Center and NewYork-Presbyterian Hospital encompasses pre-clinical and clinical research, treatment, prevention and education efforts in cancer. The Cancer Center was initially funded by the NCI in 1972 and became a National Cancer Institute (NCI)—designated comprehensive cancer center in 1979. The designation recognizes the Center's collaborative environment and expertise in harnessing translational research to bridge scientific discovery to clinical delivery, with the ultimate goal of successfully introducing novel diagnostic, therapeutic and preventive approaches to cancer. For more information, visit www.hiccc.columbia.edu.

NewYork-Presbyterian Hospital

New York-Presbyterian Hospital, based in New York City, is the nation's largest not-for-profit, non-sectarian hospital, with 2,242 beds. The Hospital has nearly a million patient visits in a year, including more than 220,000 visits to its emergency departments — more than any other area hospital. New York-Presbyterian provides state-of-the-art inpatient, ambulatory and preventive care in all areas of medicine at five major centers: New York-Presbyterian Hospital/Weill Cornell Medical Center, New York-Presbyterian Hospital/Columbia University Medical Center, Morgan Stanley Children's Hospital of New York-Presbyterian, New York-Presbyterian Hospital/Allen Pavilion and New York-Presbyterian Hospital/Westchester Division. One of the largest and most comprehensive health-care institutions in the world, the Hospital is committed to excellence in patient care, research, education and community service. It ranks sixth in U.S.News & World Report's guide to "America's Best Hospitals," ranks first on New York magazine's "Best Hospitals" survey, has the greatest number of physicians listed in New York magazine's "Best Doctors" issue, and is included among Solucient's top 15 major teaching hospitals. The Hospital's mortality rates are among the lowest for heart attack and heart failure in the country, according to a 2007 U.S. Department of Health and Human Services (HHS) report card. The Hospital has academic affiliations with two of the nation's leading medical colleges: Weill Cornell Medical College and Columbia University College of Physicians and Surgeons. For more information, visit www.nyp.org.