



## **superDimension Receives FDA 510(k) Clearance for Marker Delivery Kit**

*Electromagnetic Navigational Bronchoscopy Reaches 20,000 Treatments*

### **PRESS RELEASE**

Minneapolis, MN, April 4, 2011 - **superDimension, Ltd.**®, a privately- owned company that develops minimally invasive interventional pulmonology devices, today announced it has received FDA 510(k) clearance for the superDimension marker delivery kit. The kit is designed for use with the Company's Electromagnetic Navigational Bronchoscopy (ENB) system, which has treated a total of 20,000 total patients since commercial launch.

David S. Wilson, MD, Columbus Regional Hospital, said, "This kit will enable both pulmonologists and surgeons to place radiosurgical markers deep in the lungs, facilitating the treatment of early stage lung cancer through external beam radiation and minimally invasive video assisted surgeries. This is an exciting time in the diagnosis and treatment of early stage lung cancer. The preliminary results of the National Lung Screening Trial (NLST), combined with the ability that superDimension gives us to access the deep lungs, has changed the game for diagnosis and treatment of early stage lung cancer."

ENB is a minimally invasive procedure, where a catheter is inserted through the throat and uses Global Positioning System (GPS)-like technology to biopsy lung lesions and lymph nodes all in one outpatient procedure. ENB provides a three-dimensional virtual "roadmap" of the lungs that enables a physician to maneuver catheters through multiple branches of the bronchial tree, extending beyond the capabilities of the traditional bronchoscope to distant, previously inaccessible regions of the lungs. If the targeted lesions are determined to be cancerous, the physician can use ENB to place radiosurgical markers in and around lung tumors (lesions) to help radiation oncologists treat patients with external beam radiation. These radiosurgical markers can also be enhanced with dye injected markers that facilitate a minimally invasive surgical procedure. The outpatient procedure typically leaves the patient with no more than a sore throat. ENB has been performed on over 20,000 patients in over 320 hospitals worldwide.

Previously, the "gold standard" to diagnose lung cancer consisted of two invasive surgeries: wedge thoracotomy (open chest partial lung removal) to biopsy the lung and mediastinoscopy (invasive lymph node surgery) to biopsy the lymph nodes. Patients with poor lung function who could not tolerate these more invasive procedures were left with "watchful waiting" as their only option.

### **About Lung Cancer**

According to the Centers for Disease Control (CDC), "Lung cancer is the leading cause of cancer deaths in the United States, causing more deaths than breast cancer, prostate cancer and colon cancer combined. Each year, approximately 200,000 patients are newly diagnosed with lung cancer in the United States and an additional 160,000 patients die from the disease." Over one million patients die worldwide from

lung cancer every year. The World Health Organization estimates that worldwide lung cancer deaths surpassed heart disease in 2010. The company notes, this is in addition to the millions of patients who are currently on watchful waiting with an undiagnosed spot on their lung.

For more information about lung cancer and its diagnosis, please visit [www.spotonyourlung.com](http://www.spotonyourlung.com).

### **About superDimension**

superDimension, Inc. is a Minneapolis-based, privately held company that develops and markets catheter based devices for use in the minimally invasive diagnosis and treatment of early stage lung cancer and other diseases, using the patient's natural airways to avoid surgery. For more information, please visit [www.superdimension.com](http://www.superdimension.com).

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are necessarily estimates reflecting the best judgment of our management and involve a number of risks and uncertainties that could cause actual results to differ materially from those suggested by the forward-looking statements. These forward-looking statements should, therefore, be considered in light of various important factors, including the following: the impact of the global economic recession and tight credit market and related impact on health care spending; recently enacted health care reform legislation in the United States and its implications on hospital spending, reimbursement and fees which will be levied on certain medical device companies; timing and success of product development and market acceptance of developed products; regulatory approvals, clearances and restrictions; guidelines and recommendations in the health care and patient communities; intellectual property positions and litigation; competition in the medical device industry and in the specific markets in which superDimension operates; unanticipated manufacturing disruptions; delays in regulatory approvals of new manufacturing facilities or the inability to meet demand for products; the results of the year end audit and the other factors. Statements concerning forecasts, revenue growth, procedure growth, future financial results, and statements using words such as "estimate", "project", "plan", "intend", "expect", "anticipate", "believe" and similar expressions are intended to identify forward-looking statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release. We undertake no obligation to publicly update or release any revisions to these forward-looking statements to reflect events or circumstances after the date of this press release or to reflect the occurrence of unanticipated events.

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