Nuvilex Updates Shareholders on Recent Activities and Discusses Future Plans for Development of Treatments for Cancer and Diabetes

SILVER SPRING, MD, September 18, 2014 (GLOBE NEWSWIRE) – Nuvilex, Inc. (OTCQB: NVLX), a clinical-stage biotechnology company providing cell and gene therapy solutions for the treatment of diseases, today provides its shareholders with an update on recent activities of Nuvilex and outlines future plans for the development of treatments in the areas of cancer and diabetes.

In commenting on the progress to be made during the balance of the year, Nuvilex's CEO and President, Kenneth L. Waggoner, stated "The progress that Nuvilex has made in the past nine months and we expect to continue to make during the balance of this year is truly impressive. Not only is the development of our pancreatic cancer treatment moving forward on all fronts, but the development of a treatment for type 1 diabetes has finally been launched. Although much remains to be done, we believe that Nuvilex will one day be viewed as an innovator in the treatment of two of the world's most serious diseases - pancreatic cancer and diabetes."

Pancreatic Cancer

Nuvilex holds the exclusive, worldwide rights to use the Cell-in-a-Box® cellulose-based live cell encapsulation technology for the development of a treatment for pancreatic cancer. Nuvilex will use its pancreatic cancer treatment (the combination of the Cell-in-a-Box® technology with low doses of the anticancer prodrug ifosfamide) to combat pancreatic cancer on two fronts. This treatment has been shown to be safe and effective in clinical trials of patients with advanced, inoperable pancreatic cancer.

Effectiveness of the Treatment in Alleviating Symptoms Associated with Pancreatic Cancer

There are two major disease-associated symptoms that are suffered by patients with pancreatic cancer: (i) intractable and virtually untreatable pain; and (ii) the accumulation of fluid (known as ascites) in the abdomen that is extremely uncomfortable for patients with pancreatic cancer as well as other abdominal cancers, such as liver and ovarian. It is also important for oncologists to remove ascites fluid because it often contains cancer cells that can "seed" and form new tumors at sites different from the original tumor. Nuvilex has contracted with Translational Drug Development (TD2), one of the premier Contract Research Organizations (CRO) in the United States that specializes in the development of cancer drugs and treatments, to perform preclinical and clinical studies to determine if Nuvilex's pancreatic cancer treatment will ease these symptoms.

The initial preclinical study being conducted by TD2 concerns the effectiveness of Nuvilex's treatment in slowing the accumulation of ascites fluid. For this work, a mouse model system is being used. Here, mice are implanted with a type of human ovarian cancer cells that grow rapidly and produce significant amounts of ascites fluid relatively quickly. The mice are then given pin-head-sized Cell-in-a-Box® capsules that contain live cells capable of converting ifosfamide into its cancer-killing form. Finally, low doses (compared to normal) of ifosfamide are administered. This study is currently underway. The results from TD2's work should be available relatively soon.

As for Nuvilex's studies into relieving "pain," a clinical trial will be conducted in which the quality of life of patients with advanced pancreatic cancer will be measured to determine if Nuvilex's pancreatic cancer

treatment can reduce the amount of pain medication needed by patients. For this trial, unlike for the preclinical study on ascites, the Cell-in-a-Box® live cell encapsulation process must be done under Current Good Manufacturing Practices (cGMP) conditions. Therefore, this clinical trial cannot begin until construction of Austrianova's cGMP live-cell encapsulation facility has been completed and the facility and the encapsulation process have been validated by regulatory authorities.

The Phase 2b Clinical Trial

Nuvilex is preparing to conduct a Phase 2b clinical trial in patients with advanced, inoperable pancreatic cancer. Nuvilex's pancreatic cancer treatment will be compared "head-to-head" with the current best available treatment for the disease. This treatment is the combination of gemcitabine with Celgene's drug Abraxane® (a nanoparticle albumin formation of the widely used cancer drug paclitaxel). Such a comparison was not done in the previous two clinical trials that were completed in the early 2000s. In those clinical trials, the results obtained with the Cell-in-a-Box® plus ifosfamide combination were compared to historical data for gemcitabine - the only drug approved at that time for use against pancreatic cancer.

Australia's leading CRO, Clinical Network Services (CNS), has been retained by Nuvilex to carry out the Phase 2b clinical trial in Australia. Through its past involvement with the Cell-in-a-Box® technology, CNS is familiar with Nuvilex's pancreatic cancer treatment and has played a major role in the preparation and submission of Nuvilex's application for Orphan Drug Designation for the Cell-in-a-Box® portion of the Company's pancreatic cancer treatment. This Application was recently accepted for consideration by the European Medicines Agency (EMA), the European Union's (EU) equivalent of the FDA in the United States. The "end-points" for the Phase 2b trial will include median survival time and percentage of one-year survivors since they are often determined in pancreatic cancer clinical trials. Like the previous clinical trials, patients' quality-of-life will be assessed as they undergo treatment.

Importantly, noted European gastroenterologist/oncologist Dr. Matthias Löhr of the Karolinska Institute in Stockholm, Sweden, has been retained by Nuvilex as a consultant to assist in all of Nuvilex's activities in the area of pancreatic cancer. Dr. Löhr served as Principal Investigator for the previous Phase 1/2 and Phase 2 clinical trials using the Cell-in-a-Box® technology. This makes him the ideal candidate to oversee all of Nuvilex's efforts associated with this technology.

In order to facilitate the Phase 2b clinical trial in Australia, Nuvilex has established an Australian subsidiary, Nuvilex Australia. By doing so, Nuvilex Australia can take advantage of the Australian Government's Research and Development (R&D) Tax Incentive program. Australia is considered one of the most attractive locations in the world to undertake biotech R&D activities.

The cGMP Live-Cell Encapsulation Facility

Nuvilex has contracted with its partner Austrianova to construct and equip a cGMP-compliant live cell encapsulation facility within the Thai Science Park in Bangkok, Thailand. This facility will be used for the Cell-in-a-Box® live cell encapsulation of the types of cells that will be required for clinical trials of Nuvilex's pancreatic cancer treatment as well as Nuvilex's future diabetes treatment. The construction of the facility continues on schedule. The facility has been constructed and the equipment necessary for the encapsulation of live cells has been ordered and is in the process of being delivered. Once the facility is completed, it will need to be inspected for compliance with cGMP standards by the drug regulatory authorities from various countries before it can be used for its designated purposes.

Application for the Orphan Drug Designation

The orphan drug designation is only given to drugs or treatments that are being developed to treat "rare" diseases. Because pancreatic cancer is considered one such disease by most countries, Nuvilex, with the assistance of Dr. Löhr, Prof. Dr. Walter H. Günzburg, Dr. Brian Salmons and CNS, has submitted an application for to obtain orphan drug designation status to the EMA in Europe. Such a designation has previously been given by the EMEA (the EMA's predecessor) in the mid-2000s to Austrianova's predecessor for the Cell-in-a-Box® portion of what is now Nuvilex's pancreatic cancer treatment. The application has been deemed "valid" for consideration by the EMA. It is believed that a final decision by the EMA will be made near the end of 2014.

If the orphan drug designation is granted by the EMA, the period of marketing exclusivity for Nuvilex's pancreatic cancer treatment can be extended by up to 10 years in the EU. Similar applications are being prepared for submission to the FDA in the United States and the Therapeutic Goods Authority (TGA) in Australia. Granting of the orphan drug designation would confer 7 additional years of marketing exclusivity in the United States and 5 additional years in Australia for Nuvilex's pancreatic cancer treatment in these countries. Nuvilex has established a subsidiary in Ireland, Nuvilex Europe, to comply with guidelines for submissions of the application in the EU.

Diabetes

About 370 million people have been diagnosed with diabetes worldwide. Approximately185 million remain undiagnosed. Because the complications of diabetes (diseases of the eyes, kidneys, nerves of the feet and legs, and cardiovascular system) can be extremely serious and even deadly, it is imperative that effective treatments for the disease be developed. There are two types of diabetes – type 1 and type 2. Type 1 (insulin-dependent or juvenile-onset diabetes) occurs because the insulin-producing beta islet cells of the pancreas have been destroyed by an autoimmune disease. In type 2 (adult-onset) diabetes, insulin is produced by the pancreas, but a phenomenon termed "insulin resistance" occurs whereby the available insulin is no longer of maximal effectiveness. Nuvilex plans to develop a treatment for type 1 diabetes that is unique among available treatments for the disease.

Insulin is a hormone that facilitates the transport of glucose (sugar) from the blood into cells of the human body where it is used as a source of energy. Individuals with type 1 diabetes require daily doses of insulin, must monitor their "blood sugar" levels several times a day and must be careful with their diet. Numerous treatments for diabetes have been developed over the years in an attempt to avoid the necessity for a patient having to take insulin. Many of these have relied on the use of insulin-producing pancreatic islet cells from human cadavers or from animals such as pigs. However, their success has been limited by a variety of problems, including the scarcity of "donor" cells or the need for potent immunosuppressive drugs to avoid rejection of the transplanted islet cells. The constant use of these drugs leaves patients open to a myriad of "opportunistic" infections. In an attempt to preclude the use of immunosuppressive drugs, pancreatic islet cells have been encapsulated before they are transplanted in patients. A variety of encapsulating materials have been tried. The most prevalent of these is agarose – a substance derived from seaweed.

The use of agarose-encapsulated pancreatic islet cells is problematic. For example, the fairly short lifespan of agarose "capsules" in the human body necessitates that agarose-encapsulated cells be replaced on a fairly regular basis. As agarose capsules "break down," they elicit a response from the human body's immune system. In addition, the lifespan of the islet cells within the agarose capsules can be somewhat limited. By contrast, cells of many different types have been successfully encapsulated using the Cell-in-a-Box® technology. Cell-in-a-Box® capsules have a long lifespan (greater than 2 years) in the human body as evidenced by the clinical trials in pancreatic cancer. Likewise, the cells within the capsules stay "alive and well" for extended periods of time and are not subject to attack by a patient's immune system.

In order to avoid the problems discussed above, Nuvilex's strategy is to develop a unique treatment for type 1 diabetes involving the Cell-in-a-Box® encapsulation of human insulin-producing cells - not pancreatic beta islet cells.

Human Insulin-Producing Non-pancreatic Cells

A line of insulin-producing cells has been developed by researchers at a major institution in Australia. These cells which originated from a human liver cancer cell line have been tested and shown to produce insulin in direct proportion to the amount of glucose in their surroundings. Nuvilex's partners at Austrianova have successfully encapsulated these cells using the Cell-in-a-Box® technology. Accordingly, Nuvilex is in the process of negotiating a license agreement with the institution that owns the patent rights to this cell line to obtain the worldwide rights to use these insulin-producing cells for the development of a treatment for type 1 diabetes. The material terms of this license agreement have been agreed upon by Nuvilex and this institution. The license agreement is now undergoing a final legal review before being signed by the parties.

Studies at the University of Veterinary Medicine Vienna

A Collaborative Research Agreement has been entered into between Nuvilex and the University of Veterinary Medicine Vienna (UVMV). It relates to a variety of preclinical studies that will be conducted by the UVMV and are needed for Nuvilex's Diabetes Program to be advanced. These preclinical studies will be conducted under the supervision of Dr. Prof. Walter H. Günzburg, a faculty member at the UVMV and an officer of our partner Austrianova. Initially, scientists at the UVMV will perform tumorigenicity testing of the insulin-producing cell line being licensed by Nuvilex.

Additional Plans

Prominent researchers at a major institution in Germany have developed novel and unique animal (mice and pigs) model systems that mimic type 1 diabetes in humans. A second Collaborative Research Agreement is in the process of being negotiated between Nuvilex and this institution. Once in place, this Collaborative Research Agreement will provide Nuvilex the rights to use these animal model systems for future testing of any diabetes treatment developed by Nuvilex that utilizes the Cell-in-a-Box® encapsulation technology.

Dr. Löhr, who will assist Nuvilex in developing its Cell-in-a-Box® pancreatic cancer treatment, will also be playing a major role as Nuvilex develops its treatment for type 1 diabetes.

About Nuvilex

Nuvilex (OTCQB: NVLX) is a clinical stage biotechnology company focused on developing and preparing to commercialize treatments for cancer and diabetes based upon a proprietary cellulose-based live cell encapsulation technology known as Cell-in-a-Box®. This unique and patented technology will be used as a platform upon which treatments for several types of cancer, including advanced, inoperable pancreatic cancer, and diabetes are being built. Nuvilex's treatment for pancreatic cancer involves the anticancer prodrug ifosfamide, together with encapsulated live cells, which convert ifosfamide into its active or "cancer-killing" form. Nuvilex is also working towards improving the quality of life for patients with advanced pancreatic cancer by treating their symptoms, as well as novel treatments for other abdominal cancers.

Safe Harbor

This press release may contain forward-looking statements regarding Nuvilex and its future events and results that involve inherent risks and uncertainties. The words "anticipate," "believe," "estimate," "expect," "intend," "plan" and similar expressions, as they relate to Nuvilex or its management, are intended to identify forward-looking statements. Important factors, many of which are beyond the control of Nuvilex, could cause actual results to differ materially from those set forth in the forward-looking statements. They include Nuvilex's ability to continue as a going concern, delays or unsuccessful results in clinical trials or flaws or defects regarding its product candidates, changes in relevant legislation or regulatory requirements, uncertainty of protection of Nuvilex's intellectual property and Nuvilex's continued ability to raise capital. Nuvilex does not assume any obligation to update any of these forward-looking statements.

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