



## OTITOPIC™ Pursues Additional New Indication for Dry Powder Inhalation of Aspirin as a Treatment for Non-Small-Cell Lung Cancer (NSCLC)

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LOS ANGELES--(BUSINESS WIRE)--OTITOPIC™ recently announced a new additional indication for treatment of lung cancer for its aspirin inhalation product. Delivering an inhaled Dry Powder formulation of Aspirin directly into the deep sites of the lung is a novel new approach to lung cancer treatment. This new treatment can potentially provide benefits superior to other common therapies greatly improving clinical outcomes for patients being treated for lung cancer.

Lung cancer is one of the leading causes of morbidity and mortality among all malignant tumors worldwide. Small-cell lung cancer (15%–20%) and non-small-cell lung cancer (NSCLC) (80%–85%) are the main types of lung cancer.

Clinical treatments of primary lung cancer mainly include surgery, radiotherapy and chemotherapy. Treatments for lung cancer commonly use at least two chemotherapeutic agents which are administered orally or injected. The most common clinical treatments result in whole-body exposure to toxic chemotherapeutic agents with significant side effects and relatively low local concentrations of chemotherapeutic agents at the lung where the tumor is located.

Aspirin is one of the most studied and most popular products used in the past century. Aspirin has been demonstrated to have extensive pharmacological activities including anti-inflammation, anticancer and pain-relieving activities. Aspirin also inhibits platelets and has blood thinning properties which are beneficial in preventing and treating heart attacks.

Several epidemiological studies have correlated regular aspirin use with decreased lung cancer risk. These epidemiological findings suggest a potential inhibitory effect of Aspirin on the growth and development of lung cancer cells and disease progression. Also, a recent study using cancer-like cultured cells as a model system for lung cancer found that incubation of these cells under hypoxic conditions with aspirin inhibited cell proliferation and arrested the cell cycle at the G2/M stage, preventing cell division. The conversion of cells to a less differentiated stem-like state characteristic of malignant cancer cells was also inhibited as well as the release of exosomes which increase cancer malignancy. Another study in nude mice inoculated with cancer cell lines found that the amount of cancer tissue metastasized to the lung was reduced in mice administered aspirin orally for six weeks after inoculation with the cancer cell lines relative to controls. Additionally, since the Inhibition of COX-2 by aspirin is well established, studies provided evidence that the COX-2 enzyme is upregulated in metastatic cancer cells and that Aspirin prevents tumor progression by inhibiting the COX-2 enzyme. Unfortunately, excessive bleeding and gastric side effects limit the oral aspirin tablet doses which can be administered for cancer therapy, making it difficult to achieve the high concentrations of aspirin required in the lung for optimal cancer therapy using oral aspirin.

OTITOPIC™'s main asset is ASPRIHALE™ (Dry Powder Inhalation of Aspirin drug/Device combination product), which delivers aspirin directly to the lung by oral inhalation, achieving high local concentrations of aspirin in lung tissue upon inhalation. By delivering high local concentrations of aspirin directly to the lung tissue upon inhalation, our clinical plans are:

- 1- Inhibit cell proliferation and arrest the cell cycle at the G2/M stage
- 2- preventing cell division
- 3- Inhibit growth and development of lung cancer cells and disease progression
- 4- Prevent tumor progression by inhibiting the COX-2 enzyme.

Our successful TOX studies have shown local delivery of aspirin directly to the lung by dry powder inhalation is safe. Lung cancer therapy is a potential new indication for ASPRIHALE™ which may be a superior and safer treatment than oral aspirin tablets.

#### About OTITOPIC™

OTITOPIC™ (<http://otitopic.com/>) is a privately funded drug development company in clinical stage with a track record of success in Pharmaceutical product drug delivery and drug device development. ASPRIHALE™ is a proprietary Dry Powder Inhalation of aspirin formulation delivered via portable dry powder inhaler (DPI) that is expected to enter the bloodstream faster than oral tablets at the time of MI. OTITOPIC™ is on track with ASPRIHALE™ to file an NDA for a novel drug-device combination product in rescue management of suspected acute myocardial infarction (MI). OTITOPIC™ is committed to providing high-risk MI patients with a faster alternative for management of suspected myocardial infarction (MI). Additionally, OTITOPIC™ is actively exploring new additional indication for treatment of lung cancer for its aspirin inhalation product, such as delivering inhaled dry powder formulation of Aspirin directly into the deep sites of the lung for treatment of lung cancer.

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