businesswire
A BERKSHIRE HATHAWAY COMPANY

OtiTopic Moves towards Its Clinical Phase with Dry Powder Inhalation of Aspirin to Reduce the Risk of Vascular Mortality in Patients with Suspected Acute Myocardial Infarction (MI)

New England Journal of Medicine Study Reports Harmful Side Effects of Daily Aspirin

March 25, 2019 06:33 PM Eastern Daylight Time

LOS ANGELES--(BUSINESS WIRE)--Extensive studies on the effects of Aspirin on human health have been conducted over the past 100 years. Cardiovascular diseases are one of the top causes of death in America among older adults. For the past couple of decades, daily low dose aspirin has been a primary agent used to manage and prevent cardiovascular disease. It was recommended that patients (men over 50, women over 60) should take a low aspirin dose daily to prevent heart attacks.

However, recently the New England Journal of Medicine published a finalized study https://www.nejm.org/doi/full/10.1056/NEJMoa1805819 which shows daily low dose aspirin provides no significant health benefits and may cause serious harm. The study conducted was a randomized, double blind, placebo-controlled trial that recruited over 19,000 individuals with a median age of 74. Half of the population was given aspirin and the other half received placebos. That study concluded that “The use of low-dose aspirin as a primary prevention strategy in older adults resulted in a significantly higher risk of major hemorrhage and did not result in a significantly lower risk of cardiovascular disease than placebo. (Funded by the National Institute on Aging and others; ASPREE ClinicalTrials.gov number, NCT01038583.)”

Also, CNN reported on March 18, 2019: “Daily aspirin to prevent heart attacks no longer recommended for older adults” https://www.cnn.com/2019/03/17/health/aspirin-heart-disease-guidelines/index.html.

With the side effects of daily dose aspirin outweighing the benefits, OtiTopic is an industry leader in clinical trial stages innovating a new method for emergency delivery of aspirin to patients at high risk of Myocardial infarction (MI). OtiTopic will be conducting a clinical trial to test whether aspirin delivered by inhalation could be more advantageous in providing more rapid absorption and a quicker onset of action than Aspirin delivered orally. As time is an important factor in acute MI outcome (“Time is Muscle”), the desired route of administration is one which has the potential to offer faster delivery to the circulation. A method for efficient emergency delivery of Aspirin at the onset of MI symptoms makes the chronic administration of low dose aspirin unnecessary.

The combination of the Asprihale portable single-use device and patented aspirin inhalation formula allows for faster absorption compared to the oral administration of Aspirin. In the upcoming clinical trials, the Pharmacodynamics (PD) and pharmacokinetics (PK) of oral inhalation of aspirin will be tested. The results will be used to support a Phase II clinical trial To Reduce the Risk of Vascular Mortality in Patients with Suspected Acute Myocardial Infarction.

OtiTopic has finalized its toxicology study in animals and is now in the clinical stages of product testing. Kambiz Yadidi, CEO and president of OtiTopic, states, “With the findings on the side effects pertaining to daily aspirin dosing, I think it is important to look at new ways to innovate this product. This new method of delivery will allow patients to receive the

benefits of aspirin without the side effects. Patients will benefit from having a rescue drug device that is easy to carry and use at the time of MI symptoms. High-risk patients can rapidly inhale Asprihale, and benefit from having quicker access to the drug. This new product can save countless lives."

About OTITOPIC™

OTITOPIC™ (http://otitopic.com/) is an early stage pharmaceutical, privately funded drug development company 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).

Contacts

Kambiz Yadidi
Info@OtiTopic.com
877-443-8710

Tweets by @OtiTopic

OtiTopic
@OtiTopic

ahajournals.org/doi/10.1161/CI…

First In-Human Experience With Inhaled Acetylsalicylic Acid for Imm…
ahajournals.org

Oct 7, 2020

OtiTopic
@OtiTopic

ahajournals.org/doi/10.1161/CI…

First In-Human Experience With Inhaled Acetylsalicylic Acid for Imm…
ahajournals.org

Oct 6, 2020

OtiTopic
@OtiTopic

ahajournals.org/doi/10.1161/CI…

First In-Human Experience With Inhaled Acetylsalicylic Acid for Imm…
ahajournals.org

Oct 6, 2020