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OTITOPIC™ Announces Results of Dose-Finding PK/PD Study for ASPRIHALE® Dry Powder Inhalation of Aspirin for Acute Myocardial Infarction (MI)

Pharmacokinetic (PK) Tmax Response Linked to Inhibition Activity on Platelet Aggregation Observed in Two Minutes

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LOS ANGELES--(BUSINESS WIRE)--OTITOPIC, a leader in the development of pharmaceutical dry powder inhalation of aspirin technology, today announced the results of a dose-finding PK study of its inhalable aspirin. These results identified a dose that completely inhibited platelet aggregation in TWO minutes. The clinical study of ASPRIHALE® demonstrated rapid drug absorption and complete anti-platelet inhibition in two minutes, for use at the time of suspected acute MI through dry powder inhalation compared to 30 minutes for that of chewable aspirin which is currently recommended to be taken at the time of heart attack.

The time to maximum plasma concentration of the drug in the systemic circulation was 10-times faster with ASPRIHALE® than the chewable aspirin (median T_{max} of 2 minutes versus 20 minutes). Sample collection for PK analysis occurred pre-dose and at the following time-points post-dose: 2, 5, 10, 20, 30, and 40 minutes, and 1, 4, and 24 hours. In the setting of an evolving MI, it is considered crucial to strongly inhibit platelet function as rapidly as possible after drug administration. Standard deviation for the inhaled formulation was proportionally less than the chewable formulation.

Dosing with ASPRIHALE® inhaled-aspirin formulation resulted in complete inhibition of arachidonic acid (AA)-induced platelet aggregation at two minutes post dose in comparison to 30 minutes for chewable aspirin. The effect was sustained for 24 hours.

A PK/PD analysis was performed to evaluate the relationship between T_{max} and the time to reach 5% platelet aggregation when induced by AA. A strong linear relationship was found between ASA T_{max} and time to onset of its anti-platelet effect. Earlier attainment of C_{max} (i.e. shorter T_{max}) leads to earlier onset of action with ASPRIHALE®. Once platelets are deactivated, the effect is maintained until new platelets can be synthesized. The results of the dose-finding studies confirmed that ASPRIHALE®, a novel, proprietary formulation of aspirin delivered by dry powder inhalation, offers a viable, attractive and faster alternative option to the currently marketed products.

Kambiz Yadidi, President of Otitopic, said: “We are proud to successfully conclude the clinical studies with ASPRIHALE®, our first-in-class dry powder inhalation of aspirin to treat suspected acute MI. Establishing a PK and PD profile suitable for patients at risk of acute MI is a first important clinical milestone in the development of an innovative drug-device combination product that could represent the next level in treating this serious public health issue along with its ever-looming threat of a new pandemic. These results enable us to select an appropriate dose for advancing to the pivotal stage of clinical development in 2020. We look forward to working with the FDA to bring a new treatment option to reduce the risk of vascular mortality in patients with suspected acute myocardial infarction (MI) sufferers.”

ASA DPI clinical PK/PD results have shown superior results compared to recommended chewable aspirin at the time of MI, having 15-times faster complete inhibition of AA-induced platelet aggregation, 10-times faster suppression of serum thromboxane B_2, and higher ASA plasma concentration post-dose. Also, a reduction in adenosine diphosphate (ADP)-induced platelet aggregation was observed within two minutes for inhaled ASA, whereas a reduction in ADP-induced platelet aggregation with chewable ASA was observed at 30 minutes. A strong correlation was found between PK and the onset of pharmacodynamic (PD) effect. A much more rapid PK/PD profile with ASA inhalation powder resulting in earlier potent platelet inhibition was observed.

About OTITOPIC

www.otitopic.com

Otitopic, Inc. is in clinical stage, with a track record of success in pharmaceutical product drug delivery and drug device development. ASPRIHALE® is a proprietary aspirin formulation delivered via portable dry powder inhaler, 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 emergency management of suspected acute MI. Otitopic is pioneering a new class of dry powder inhalation in the cardiovascular field, based on the company's proprietary drug delivery platform. This patented technology leverages a novel mechanism of action that enables rapid inhibition of platelet aggregation, aimed at providing powerful new therapeutic capabilities. Otitopic is dedicated to making better anti-platelet treatment, to provide high-risk MI patients with a faster-acting alternative for management of suspected acute MI.

Contacts

Kambiz Yadidi, CEO, kamy@gppirx.com