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Otitopic Advances Asprihale® Into Pivotal PK/PD Study

Asprihale® is intended for emergency treatment to reduce the risk of vascular mortality in patients with suspected acute myocardial infarction (MI).

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LOS ANGELES--(BUSINESS WIRE)--Otitopic today announces that it is advancing towards its pivotal PK/PD study following discussions with the FDA. The randomized pivotal study, which is expected to initiate in the fourth quarter of 2020, will compare the pharmacodynamics, pharmacokinetics, safety and tolerability of acetylsalicylic acid inhalation powder with non-enteric coated chewable aspirin, with initial data expected by the end of 2021.

Asprihale® is intended for emergency treatment to reduce the risk of vascular mortality in patients with suspected acute MI. Asprihale® has been developed for self-administration by the patient as emergency supportive therapy; after administration, the patient should seek immediate medical or hospital care. Recent American College of Cardiology and American Heart Association guidelines indicate that chewing aspirin at the onset of MI symptoms is preferable to taking daily preventative aspirin because of increased risk of bleeding associated with daily low-dose aspirin use. In the setting of an emerging MI, it is considered crucial to strongly inhibit platelet function as rapidly as possible after drug administration.

The recent pilot study demonstrated peak plasma concentration in two minutes versus 20 minutes for 162 mg non-enteric coated chewable aspirin. This rapid exposure is unprecedented and has enormous implications for early disruption of an evolving thrombus, where differences in time of restoration of blood flow within minutes with different therapies can be life-altering. The very high levels of serum TxB_2 suppression, and complete inhibition of AA-induced platelet aggregation, both within two minutes, are unprecedented for a non-parenterally administered antiplatelet therapy.

Asprihale®, a novel, proprietary aspirin formulation administered via a dry-powder inhaler (DPI), offers a distinctly more prompt, potent, and predictable PD response than the current standard-of-care. Otitopic will continue working to advance the pivotal study to improve the lives of high- and intermediate-risk MI patients who need a better treatment option at the time of MI. The team is excited and looking forward to starting its pivotal study.

About Otitopic

www.otitopic.com

Otitopic, Inc. is a late-stage clinical company, with a track record of success in pharmaceutical product drug delivery and drug device development. Asprihale® is a novel, proprietary aspirin formulation administered via a DPI, entering the bloodstream faster than oral tablets. Otitopic is on track with Asprihale® to file an NDA in 2021 for a drug device combination product to reduce the risk of vascular mortality in patients with suspected acute MI. Otitopic is pioneering a new class of dry-powder inhalation in the cardiovascular medicine field, based on the company's proprietary drug

delivery platform. This patented technology leverages inhalation as the route of administration, enabling rapid inhibition of platelet aggregation, aimed at providing powerful new therapeutic capabilities. Otitopic is dedicated to making faster-acting antiplatelet treatment, to provide high- and intermediate-risk MI patients with a faster-acting alternative for management of suspected acute MI.

Contacts

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