CONGENIA

Congenia Announces Enrollment of First Healthy Volunteer in Phase 1 Clinical Trial of GNX-5086

Milan, August 27th 2013 - Congenia, a clinical stage biopharmaceutical company focused on developing inhibitors of the mitochondrial permeability transition pore (mPTP), announces that on August 15th 2013 it initiated enrollment of healthy volunteers in a Phase 1 clinical trial evaluating the safety and tolerability of GNX-5086. GNX-5086 is a potent small molecule inhibitor of the mPTP, a novel target involved in modulating stress induced cell death. GNX-5086 is being developed to treat cardiac reperfusion injury (RI) that contributes significantly to the morbidity and mortality subsequent to myocardial infarction (MI). There are currently no therapies approved for myocardial RI.

The randomized, double-blind, placebo-controlled Phase 1 study in healthy subjects is designed to evaluate the safety, tolerability and pharmacokinetics of single ascending doses of GNX-5086. The study is expected to enroll 33 healthy volunteers. GNX-5086 is being developed for intravenous administration to infarcted patients just prior to percutaneous coronary intervention (PCI).

The clinical trial application (CTA) to initiate the Phase 1 study of GNX-5086 was filed on July 4th 2013 in the Netherlands and received approval by the local regulatory authorities on July 24th.

About cardiac reperfusion injury and GNX-5086

Myocardial infarction (MI) results from the partial interruption of blood supply to a part of the heart muscle. The resulting ischemia and ensuing oxygen shortage, if left untreated can cause damage or death of heart muscle tissue. As a result, the patient's heart will be permanently damaged. Acute MI is a major cause of death and disability worldwide. In patients with AMI, the treatment of choice for limiting infarction size is timely and effective myocardial reperfusion using either thrombolytic therapy or primary percutaneous coronary intervention (PCI). However, the process of reperfusion can itself induce cardiomyocyte death, known as myocardial reperfusion injury (RI), that can be responsible for one-third or more of cell death and for which there is still no effective therapy. Inhibition of the mPTP is proposed as a cardioprotective strategy for the limitation of infarct size in patients undergoing PCI. GNX-5086 is Congenia's most advanced compound and was selected as lead compound through a longstanding preclinical collaboration with the Drug Discovery Program of the European Institute of Oncology (DDP-IEO). GNX-5086 is a potent mPTP inhibitor able to increase the capacity of isolated mitochondria to retain calcium and thus protect the mitochondria from calcium overload in stress situations. In vivo studies using a rabbit model of acute myocardial infarction clearly demonstrate the effectiveness of GNX-5086 in attenuating RI and reducing infarct size when administered just prior to heart reperfusion.

About Congenia

Congenia S.r.l. is a biopharmaceutical company based in Milan (Italy) fully owned by Genextra SpA and is one of the first companies focused on targeting specifically the mitochondrial permeability transition pore (mPTP). Originally spinned out from the University of Milan and the European Institute of Oncology was then acquired by Genextra SpA. Congenia's main focus is on inhibiting the opening of the mPTP, a protein channel with multiple macromolecular components associated with oxidative stress-induced cell death. Mitochondrial permeability transition is an increase in the permeability of the mitochondrial membranes to molecules of less than 1500 Daltons in molecular weight and results as a consequence of the opening of the mPTPs. Oxidative damage and calcium dysregulation are common features of many "age-related" diseases and therefore opening of the mPTP in response to these phenomena has been suggested to be involved in the pathogenesis of several diseases, including myocardial infarction, stroke, neurodegenerative, cardiovascular, and metabolic diseases. Congenia aims at clinically validating its mPTPis in RI as well as other indications.

For further information, please visit the Company's website *www.congenia.it or www.genextra.it*