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NEOMED Receives Approval to Initiate Phase I Clinical Trial for a Medication Intended for Osteoarthritis-Associated Pain

Montreal, January 22, 2015 – NEOMED, a public-private organization developing early stage drug discovery projects up to human proof of concept, announced today that it has received a notice of authorization from the Medicines and Healthcare Products Regulatory Agency (MHRA), the UK regulatory agency, to initiate the first-in-human study of its product candidate NEO6860. The study is expected to commence during the first quarter of 2015 and the top-line safety, pharmacokinetic, and pharmacodynamic data are to be delivered by year-end.

“We are extremely pleased to enter into clinical development for this exciting and unique program,” said Max Fehlmann, President and CEO of NEOMED and the NEOMED Institute. “With the approval of this trial, we have reached a major milestone in our research and development objectives. We have very strong preclinical data supporting the progression of this investigational product and we believe this trial has excellent potential to produce a positive outcome. Our ultimate objective, aligned with NEOMED’s strategy, is to attract co-development partners to conduct the Phase II clinical trial.”

Vanilloid receptor (TrpV1) antagonists were explored about a decade ago by many biopharmaceutical companies. Most trials failed because of two common side effects: dysregulation of body temperature (hyperthermia) and reduced ability to sense high temperatures, which resulted in burn injuries. NEO6860 is a potent, reversible, modality selective, and orally available TrpV1 antagonist. It has a uniquely different pharmacological profile, in that it blocks only the channel’s activation by capsaicin, not heat or pH. All the *in vitro* and *in vivo* efficacy and IND-enabling GLP safety studies support NEO6860 being a safe and effective analgesic. NEO6860 is developed for the treatment of pain associated with osteoarthritis – the most prevalent type of arthritis and a leading cause of disability in Canada. In addition, based on preclinical observations, a safe TrpV1 antagonist would open the way to clinical evaluations in multiple indications, from pain control to respiratory diseases.

Dan Chiche, MD, Vice-President, Clinical Development and Medical Affairs for NEOMED, commented, “The Phase I clinical trial will be a randomized, double-blind, placebo-controlled, dose-escalation study in healthy volunteers. The goal is to assess the safety and tolerability profile, and pharmacokinetic properties, of NEO6860. This study will also provide evidence that the expected properties of the compound are present, namely robust pharmacodynamic effects and lack of safety issues characteristically seen within the class. It will serve to select the range

of optimal safe and efficacious dose levels of NEO6860 to be used in the proof-of-concept trial that we are planning for early 2016.”

ABOUT NEOMED AND THE NEOMED INSTITUTE

NEOMED is a not-for-profit organization whose mission is to foster the development of promising therapeutic approaches emerging from academia and biotechnology companies. NEOMED supports the development of projects up to the stage of human proof of concept. NEOMED is jointly funded by the pharmaceutical industry, the *Ministère de l'Économie, de l'Innovation et des Exportations du Québec*, and the Networks of Centres of Excellence (NCE) of Canada.

NEOMED operates within the NEOMED Institute, a high-tech research and development centre located at Technoparc Montréal's Saint-Laurent Campus. NEOMED Institute acts as an open-access drug discovery hub, housing commercial companies and offering a unique environment to nurture collaboration, innovation, and creativity.

For more information, please visit our website: www.neomed.ca.

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