



## **Hydra Biosciences Receives Approval from Health Canada to Begin Phase 1 Trial for HX-100**

**April 14, 2015 – Cambridge, MA – [Hydra Biosciences](#)**, a leader in the field of Transient Receptor Potential (TRP) channel modulation, today announced that Health Canada approved the Company's Clinical Trial Application (CTA) to begin a Phase 1 study of HX-100. This study will provide the safety data necessary for Phase 2 studies in painful diabetic neuropathy (PDN) and allergic asthma that are expected to begin later this year.

"Entering the clinic represents a significant step for HX-100 and our TRP pipeline," said Russell Herndon, President and CEO of Hydra Biosciences. "HX-100 inhibits TRPA1, a novel target for the treatment of painful diabetic neuropathy and allergic asthma. TRPA1 inhibitors show preclinical efficacy in a broad range of pain, pulmonary and dermatological models, indicating a significant therapeutic potential."

TRP channels are membrane-bound proteins that play a role in controlling cellular calcium levels and excitability in response to a variety of stimuli. The 28 members of the TRP family differ from better-known ion channels in that they are not primarily voltage gated and have significant sequence diversity, providing the opportunity to develop truly selective modulators. In addition to their well-documented role in pain and pulmonary disorders, TRPs have been linked to CNS, renal and dermatological diseases.

TRPA1 is a unique member of the TRP family, activated by reactive chemicals, products of aberrant glucose metabolism, tissue injury, and inflammation. Environmental irritants that lead to channel activity include common asthma triggers such as cigarette smoke, ozone and chlorine.

HX-100 is a highly selective, potent inhibitor of TRPA1. Pre-clinical data demonstrate promising safety and efficacy with several potential advantages over currently available treatments for chronic pain and asthma. HX-100 can be taken orally, and it is expected to have robust efficacy without abuse liabilities, given the limited expression of TRPA1 in the brain.

This Phase 1 trial of HX-100 follows a standard single ascending dose and multiple ascending dose design with approximately 90 healthy volunteers.

The Company expects to initiate separate Phase 2 studies in painful diabetic neuropathy and allergic asthma in late 2015 with results from these trials expected before the end of 2016.

### **About Painful Diabetic Neuropathy**

Painful Diabetic Neuropathy (PDN) is a common complication due to chronic diabetes that causes peripheral painful nerve damage. Nerve damage may be due to prolonged elevation of glucose levels, which include increased circulating levels of methylglyoxal. Other contributors may be immune factors that lead to nerve inflammation and reactive oxygen species. Symptoms

include but are not limited to pain, numbness and loss of function of hands and feet. PDN reduces the quality of life and is often accompanied by depression. About seven million people are currently affected by PDN and will likely increase to nine million in the year 2022.

### **About Allergic Asthma**

Allergic asthma is recurrent airflow obstruction and inflammation triggered by an allergic reaction. This reaction causes intermittent wheezing, breathlessness, chest tightness and cough. Allergic asthma is the most common form of asthma and affects about 300 million people worldwide. It is estimated that the number of people with asthma will grow by more than 100 million by 2025. For about 80 percent of children with asthma, allergy is the most relevant risk factor for their disease. It is estimated that asthma accounts for about one in every 250 deaths worldwide.

### **About a Clinical Trial Application (CTA)**

Health Canada, the pharmaceutical regulatory body in Canada, requires that a Clinical Trial Application (CTA) is filed and approved before the start of a clinical trial in Canada. This process is equivalent to the IND-filing process with the U.S. Food and Drug Administration (FDA). Upon approval of the CTA, Health Canada issues a No Objection Letter (NOL) which permits the Company to complete Institutional Review Board (IRB) review and initiate the trial. Data from trials conducted in Canada may be used as the basis for filing an IND with the FDA or CTX with the European Medicines Agency for additional or later-stage trials.

### **About Hydra Biosciences**

Hydra Biosciences is a privately-held biopharmaceutical company based in Cambridge, Mass. that develops drugs to treat pain, inflammation, anxiety and other diseases using its expertise in novel ion channels. Hydra Biosciences' proprietary platforms enable the company to identify and develop drug candidates that address significant unmet medical needs. The Company also has two agreements with Boehringer Ingelheim for research and development of novel TRP compounds. More information about Hydra Biosciences is available at: [www.hydrabiosciences.com](http://www.hydrabiosciences.com).

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