CoLucid Pharmaceuticals Receives Clearance for Investigational New Drug (IND) Application for Lasmiditan for the Treatment of Acute Migraine

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DURHAM, N.C., Aug. 18, 2011 /PRNewswire-iReach/ [1] -- Durham, NC, August 18, 2011 /PRNewswire/ -- CoLucid Pharmaceuticals, Inc., a privately held biopharmaceutical company, announced today that it has received clearance to proceed with clinical studies of lasmiditan (formerly known as COL-144) under IND 103,420 from the Food and Drug Administration (FDA).

Lasmiditan is a first-in-class oral tablet formulation of a Neurally Acting Anti-Migraine Agent (NAAMA) designed to deliver efficacy in migraine without the vasoconstrictor activity associated with previous generations of migraine therapies. Lasmiditan is a member of a novel chemical class called "ditans", and, unlike triptans, which target vasoconstrictor 5-HT1B receptors, lasmiditan penetrates the central nervous system (CNS) and selectively targets 5-HT1F receptors expressed in the trigeminal nerve pathway.

Five clinical studies have been successfully completed outside of the U.S., including a Phase 2b double blind placebo controlled dose ranging study treating a single migraine attack which was completed in 2010. In the Phase 2b study, lasmiditan achieved its primary endpoint of reducing a moderate or severe headache at baseline to mild or none 2 hours after dosing ($p<0.0001$) in 391 patients. Differentiation of individual doses from placebo was seen as early as 30 minutes after dosing. Lasmiditan also achieved numerous secondary endpoints per other migraine symptoms such as nausea, photophobia and phonophobia. Importantly, lasmiditan's side effect profile is highly differentiated from triptans and ergotamines, and there was no evidence of drug-related cardiovascular effects or chest symptoms in the previous five clinical studies.

"The migraine market, estimated at 30 million sufferers in the US, is an under-served market. No new class of therapies has been introduced for the treatment of acute migraine since
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