

## **Phase II Results of COL-144 Presented at European Headache and Migraine Trust International Congress 2008**

*Results Demonstrate Safety and Efficacy of First-in-Class Neurally Acting Anti-Migraine Agent (NAAMA) for the Treatment of Acute Migraine*

**LONDON, SEPT. 6, 2008** - CoLucid Pharmaceuticals, Inc., an innovative biotechnology company focusing on therapies for central nervous system disorders, announced Phase II results of its lead compound COL-144 in the treatment of acute migraine. Results demonstrated that COL-144 was safe and effective in relieving migraine headaches. COL-144 is a first-in-class Neurally Acting Anti-Migraine Agent (NAAMA), which unlike triptans, exhibits anti-migraine activity without causing vasoconstriction. COL-144 is a highly potent and selective 5HT<sub>1F</sub> receptor agonist. The studies were presented in poster presentations at the European Headache and Migraine Trust International Congress 2008 in London, Sept. 4-7, 2008.

"In the Phase II study, the majority of patients experienced migraine relief 20 to 40 minutes after dosing and COL-144 was generally well-tolerated," Alison Pilgrim, BM, BCh, DPhil, chief medical officer at CoLucid, said. "The study indicates that COL-144 may be a treatment option for all patients including those who don't respond to or are contraindicated for the current standard of care."

The randomized, double-blind study evaluated 130 migraine patients. Patients were not on prophylaxis and received 2.5 to 45 mg of COL-144 or placebo as an intravenous infusion over 20 minutes as first-line treatment of an acute migraine attack. The primary end-point parameter was headache response, defined as a reduction in headache severity from moderate to severe at baseline to mild or no headache at two hours after initiation of infusion of study drug.

A higher proportion of patients showed a headache response at two hours post dose in the 10 mg, 20 mg, 30 mg and 45 mg groups compared to placebo (54.2 to 75% vs. 45.2%) with a statistically significant linear association between response rates and dose levels ( $p=0.0126$ ). The adaptive study design used could identify doses giving a headache response in 50–75% of patients. It did not explore the maximum possible efficacy of the drug.

COL-144 was generally well-tolerated with no serious adverse events or withdrawals due to non-serious adverse events. The most common adverse event was paresthesia, which was usually mild and transient, resolving rapidly after cessation of the infusion. No patient reported triptan-like chest symptoms in relation to the COL-144 infusion. No clinically significant changes were seen in vital signs or ECG parameters.

"We identified doses of 20 mg and higher as doses of interest for further evaluation in future studies, and we plan to continue the clinical development of COL-144, using an oral formulation," added Dr. Pilgrim.

### **About CoLucid Pharmaceuticals, Inc.**

CoLucid Pharmaceuticals was founded in December 2005 by Pappas Ventures to advance innovative drug candidates with the potential to provide safe and effective treatment for central nervous system (CNS) disorders. The company's pipeline includes COL-144, a novel treatment for migraine headache, and a conjugated stigmine platform that has generated a series of preclinical candidates for the treatment of sleep/wake disorders, chronic pain,

Alzheimer's disease and psychiatric disorders. For more information, please visit CoLucid at [www.colucid.com](http://www.colucid.com).

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