



PRESS RELEASE

Addex completes enrollment of first mid-stage clinical GERD trial

Geneva, Switzerland, 28 September 2009 – Addex Pharmaceuticals (SWX:ADXN), the allosteric modulation company, announced the completion of enrollment in the Phase IIb trial of ADX10059 as a monotherapy in patients with gastroesophageal reflux disease (GERD), the cause of heartburn and other symptoms. ADX10059 is a first-in-class reflux inhibitor that works by reducing activation of the metabotropic glutamate receptor 5 (mGluR5) through negative allosteric modulation (NAM). This approach may lead to a new class of drugs that addresses the causes of GERD rather than just the symptoms. ADX10059 also is in clinical trials to treat GERD patients who are partial responders to Proton Pump Inhibitors (PPIs) and separately, as a migraine prophylaxis in patients with frequent migraines.

Chief Medical Officer Charlotte Keywood said: “We are pleased that all three Phase IIb trials of ADX10059 are progressing as planned. We expect to communicate top-line data from study 204 late this year before presenting more detailed data at a scientific conference next year.”

Study ADX10059-204 is a double-blind, placebo-controlled, multi-center European Phase IIb trial in 90 GERD patients known to respond well to proton pump inhibitors (PPIs). There is a two week baseline symptom evaluation period followed by two weeks of administration of ADX10059 120 mg twice daily. ADX10059 is used as a monotherapy so patients in the study do not use PPIs or other acid suppressant therapy during the baseline and study treatment periods. The co-primary endpoints are patient reported symptom control compared to baseline and the effects of ADX10059 on lower esophageal sphincter (LES) function. Objective measures of the effects of ADX10059 on LES function and acid reflux events will be made in a subset of patients using esophageal manometry and pH impedance monitoring. Data are expected to be communicated in late 2009.

Study ADX10059-205 is a double-blind, placebo-controlled, multi-center U.S. and European Phase IIb trial in 280 GERD patients who are partial responders to PPIs. In Study 205 ADX10059 is being used as an add-on therapy to the patients' existing PPI treatment. There will be a baseline symptom evaluation period followed by four weeks of administration of twice-daily ADX10059 (50mg, 100mg or 150mg). The primary endpoint is patient reported symptom control compared to baseline. Enrollment is expected to complete in the fourth quarter and data will be communicated in early 2010 or late 2009.

Study ADX10059-206 is a double-blind, placebo-controlled, dose range finding, multi-center European Phase IIb trial in 240 migraineurs who suffer from three or more migraine attacks per month. Following a one month baseline period, patients will take study medication for 3 months. The primary endpoint will compare migraine frequency and severity in the last month of treatment with the baseline. Data are expected at the end of the first quarter of 2010.

GERD is a chronic condition caused by stomach contents flowing back into the esophagus on a regular basis. The underlying cause of this is an abnormally functioning lower esophageal sphincter (LES) muscle that allows stomach contents to pass too easily back into the esophagus. GERD leads to painful symptoms like heartburn and can also damage the lining of the esophagus. It is a common disorder with prevalence at about 15% in the United States and between 10% and 25% in Marketed GERD products work by reducing the acidity of the stomach contents but do nothing to reduce reflux events, so that in many patients symptoms of GERD persist.

mGluR5 inhibition in GERD, inhibition of mGluR5 aims to restore normal function of the LES muscle thereby preventing reflux and addressing the cause of the disease. Indeed, ADX10059 has been shown by Addex to reduce reflux and reduce esophageal acid exposure in two separate clinical trials(1,2). Research has shown that mGluR5 inhibition improves LES function in animals. Reflux inhibitors are being recognized as potentially the next generation of GERD therapy because they address the cause of the

disease and are complementary to marketed acid suppression therapies. Inhibition of mGluR5 has therapeutic potential in multiple other indications because, as with other glutamate receptors, mGluR5 is involved in a variety of functions in the central and peripheral nervous systems(3). In addition to GERD, mGluR5 inhibitors have achieved clinical proof of concept in separate studies in patients with migraine headache(4), Parkinson's disease levodopa induced dyskinesia (PD-LID) and generalized anxiety disorder (GAD). Inhibition of mGluR5 also has potential in Fragile X syndrome, neuropathic pain and depression.

- (1) Keywood, C., et al., *GUT online* May 20, 2009 (free download: <http://bit.ly/2Rcu0k>)
- (2) Zerbib, F., et al., *Digestive Disease Week (DDW) 2009* (free download: <http://bit.ly/HjehE>)
- (3) Gasparini, F. et al., *Current Opinion in Drug Discovery & Development* 2008 11(5):655-665
- (4) Goadsby, P. et al., *American Academy of Neurology (AAN) 2009* (free download: <http://bit.ly/13aBkw>)

Addex Pharmaceuticals (www.addexpharma.com) discovers and develops allosteric modulators for human health. Allosteric modulators are a different kind of orally available small molecule therapeutic agent, which we believe will offer a competitive advantage over classical drugs. Our lead allosteric modulator product, ADX10059, has achieved clinical proof of concept and is in Phase IIb testing for the treatment of GERD and, separately, migraine headache. ADX10059 is a first-in-class mGluR5 inhibitor, a therapeutic strategy that also is being pursued in multiple indications by large pharma competitors.

Addex products and technology already have proven their value through our relationships with four of the top 10 pharmaceutical companies in the world. Specifically, under an agreement with Ortho-McNeil-Janssen Inc., a Johnson & Johnson company, ADX71149, a positive allosteric modulator (PAM) of mGluR2, is undergoing Phase I clinical testing and has potential for treatment of schizophrenia and anxiety. Under two separate agreements with Merck & Co., Inc., we are developing PAMs of mGluR4 and mGluR5 as drugs to treat Parkinson's disease and schizophrenia, respectively. In addition, GlaxoSmithKline and Roche have made equity investments in Addex.

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