# Cephalon Exercises its Option to Acquire Ception Therapeutics

## **Ception Delivers Positive Results from a Phase II Study of CINQUIL in Adult Eosinophilic Asthma**

**Press Release** Source: Cephalon, Inc.; Ception Therapeutics, Inc. On Tuesday February 23, 2010, 8:00 am

FRAZER, Pa. and MALVERN, Pa., Feb. 23 /PRNewswire-FirstCall/ -- Cephalon, Inc. (Nasdaq: CEPH - News) announced today that it has exercised its option to acquire Ception Therapeutics, Inc., following receipt of positive data from a clinical study in adults with eosinophilic asthma. A Phase II clinical trial of Ception's lead compound, CINQUIL<sup>TM</sup> (reslizumab), in 106 patients demonstrated improved asthma control in adult patients with moderate to severe asthma and eosinophilic airway inflammation, as measured by the primary study endpoint, a change in Asthma-Control -Questionnaire or ACQ score (p=0.054). In addition, an analysis of the FEV1, a measure of lung function, showed a statistically significant improvement with CINQUIL compared to placebo (p=0.002).

"This study showed a strong treatment signal and compelling internal consistency on the effect of CINQUIL on measurements of asthma and lung function," said Dr. Lesley Russell, Chief Medical Officer at Cephalon. "These data provide confidence that CINQUIL shows a meaningful treatment effect in this patient population. We look forward to advancing CINQUIL into Phase three clinical trials."

Based on these Phase II results, Cephalon exercised its option to acquire Ception on February 22, 2010. Following the exercise of its option, Cephalon's obligation to enter into a merger agreement relating to the acquisition is subject to Cephalon's rights under, and Ception's satisfaction of certain conditions set forth in, the option agreement. The merger agreement is subject to customary closing conditions, including expiration of applicable antitrust waiting periods. Upon the closing of the

merger, Cephalon would purchase all of the outstanding capital stock of Ception for \$250 million, subject to adjustment for any third party debt held by Ception. Ception shareholders could receive additional payments related to clinical and regulatory milestones.

"The acquisition of Ception is consistent with our strategy to diversify into biologics and provides us with an important Phase three asset for further development," said Frank Baldino, Jr., Ph.D., Chairman and CEO of Cephalon.

"Today marks an important milestone for Ception, as well as the asthma community," said Stephen Tullman, President and CEO, Ception Therapeutics. "These encouraging results will allow the advancement of this novel therapeutic for the many people suffering from this severe, poorly controlled form of asthma. The Ception team has done an excellent job, and I am extremely thankful for the support provided by Cephalon and our investors."

#### **About the Study**

The four-month, double-blind, placebo-controlled Phase II clinical trial assessed the efficacy and safety of CINQUIL in the treatment of patients with poorly controlled eosinophilic asthma. In this study, 106 adults patients received CINQUIL (3mg/kg) or placebo administered intravenously once every 28 days for four cycles. Patients entering the study were required to have persistent asthma symptoms, despite high doses of inhaled corticosteroids, and elevated eosinophils in their sputum. The primary study endpoint was improvement in asthma control as assessed by the change in Asthma-Control-Questionnaire (ACQ) score at week 15. Patients on CINQUIL showed an improvement on the ACQ compared to placebo (p=0.054). In this clinical study, CINQUIL was generally well tolerated with an adverse event profile comparable to placebo. The most commonly observed side effect associated with CINQUIL versus placebo was nasopharyngitis.

Secondary endpoints and analysis of a subgroup of patients in the study showed the following:

 A significant reduction in sputum eosinophil counts for CINQUIL compared to placebo (p=0.006)

- A significant improvement in FEV1 and FVC for CINQUIL compared to placebo (p=0.002 and 0.004 respectively). FEV1 and FVC are indices for assessing airway obstruction, bronchoconstriction or bronchodilation
- In a subset of patients with both asthma and nasal polyps (n= 38), patients on CINQUIL compared to placebo showed a significant mean improvement in ACQ (p=0.011) and FEV1 (p=0.046)
- Fewer patients on CINQUIL compared to placebo experienced clinical asthma exacerbations. Clinical asthma exacerbations were defined as a 20 percent decrease in FEV1 from baseline, emergency treatment or hospital admission and treatment for three or more days of oral corticosteroids

Cephalon will further evaluate the study data and work with the FDA to determine the necessary and appropriate steps to move clinical development of CINQUIL forward to Phase III.

#### **About CINQUIL**

CINQUIL is an investigational humanized monoclonal antibody (mAb) against interleukin-5 (IL-5). IL-5 has been shown to play a crucial role in the maturation, growth and chemotaxis (movement) of eosinophils, which are inflammatory white blood cells implicated in a number of allergic diseases including asthma. This investigational agent is currently administered as an intravenous injection; a subcutaneous formulation is being developed.

### **About Eosinophilic Asthma**

Eosinophilic asthma is a type of severe asthma with persistent inflammation of the airways associated with increased levels of eosinophils (a type of white blood cell). There is an increasing body of evidence that asthma is a heterogeneous disease, with eosinophilic airway inflammation a common feature among phenotypes. Many patients with asthma respond well to inhaled corticosteroids. However, there is a subgroup of patients with severe asthma in whom eosinophilic airway inflammation persists despite therapy with high doses of inhaled corticosteroids. Patients with eosinophilic asthma may experience changes in their airways,

impaired lung function, more frequent asthma exacerbations, and near-fatal asthma attacks. Such patients are in need of additional anti-inflammatory therapies to address persistent high levels of eosinophils and associated poor prognosis.

#### About Cephalon, Inc.

Cephalon is an international biopharmaceutical company dedicated to discovering, developing and bringing to market medications for difficult to treat and rare conditions. Since its inception in 1987, Cephalon has brought first-in-class and best-in-class medicines to patients around the world in several therapeutic areas. Cephalon has the distinction of being one of the world's fastest-growing biopharmaceutical companies, now among the Fortune 1000 and a member of the S&P 500 Index, employing approximately 3,000 people worldwide.

Cephalon has a growing presence in Europe, the Middle East and Africa. The Cephalon European headquarters and pre-clinical development center are located in Maisons-Alfort, France, just outside of Paris. Operational subsidiaries are located in the United Kingdom, France, Germany, Italy, Spain, the Netherlands (which covers the entire Benelux region), and Poland (which covers Eastern Europe and Scandinavia). Cephalon Europe markets more than 30 products in 50 countries in four therapeutic areas: central nervous system, pain, primary care and oncology.

The company's proprietary products in the United States include: NUVIGIL® (armodafinil) Tablets [C-IV], TREANDA® (bendamustine hydrochloride) for Injection, AMRIX® (cyclobenzaprine hydrochloride extended-release capsules), FENTORA® (fentanyl buccal tablet) [C-II], TRISENOX® (arsenic trioxide) injection, GABITRIL® (tiagabine hydrochloride), PROVIGIL® (modafinil) Tablets [C-IV] and ACTIQ® (oral transmucosal fentanyl citrate) [C-II]. The company also markets numerous products internationally. Full prescribing information on its U.S. products is available at <a href="http://www.cephalon.com">http://www.cephalon.com</a> or by calling 1-800-896-5855.

#### **About Ception Therapeutics, Inc.**

Ception Therapeutics, Inc., is a privately held biopharmaceutical company focused on the discovery and development of novel products to address areas of unmet

medical need. The company's pipeline includes CINQUIL in clinical development for certain eosinophil-mediated conditions and an established program to discover small molecule, orally-active, anti-TNF (tumor necrosis factor) receptor agents. For further information, visit <a href="https://www.ceptiontx.com">www.ceptiontx.com</a>.

In addition to historical facts or statements of current condition, this press release may contain forward-looking statements. Forward-looking statements provide Cephalon's current expectations or forecasts of future events. These may include statements regarding whether Cephalon will complete the acquisition of Ception, anticipated scientific progress on its research programs, development of, and prospects for, potential pharmaceutical products such as CINQUIL, interpretation of clinical results, prospects for regulatory approval, manufacturing development and capabilities, market prospects for its products, sales and earnings guidance, and other statements regarding matters that are not historical facts. You may identify some of these forward-looking statements by the use of words in the statements such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe" or other words and terms of similar meaning. Cephalon's performance and financial results could differ materially from those reflected in these forwardlooking statements due to general financial, economic, regulatory and political conditions affecting the biotechnology and pharmaceutical industries as well as more specific risks and uncertainties facing Cephalon such as those set forth in its reports on Form 8-K, 10-Q and 10-K filed with the U.S. Securities and Exchange Commission. Given these risks and uncertainties, any or all of these forwardlooking statements may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Furthermore, Cephalon does not intend to update publicly any forward-looking statement, except as required by law. The Private Securities Litigation Reform Act of 1995 permits this discussion.

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