



## **OCTOPLUS ANNOUNCES POSITIVE PHASE IIA EFFICACY AND TOLERABILITY RESULTS FOR LOCTERON IN HEPATITIS C**

**Leiden, the Netherlands, 12 October 2007** – OctoPlus N.V. (Euronext: OCTO), the drug delivery and development company, announces today the successful completion of the Phase IIA clinical study with its lead product Locteron™, a controlled release interferon alfa product for the treatment of chronic hepatitis C (HCV).

Results from this study confirm Locteron's potential to substantially improve patient care in HCV. Safety data from the study show a substantially improved tolerability profile for Locteron compared to other interferon products on the market or in development. Efficacy data from the study indicate Locteron's strong antiviral effect, with 100% of the patients achieving early virologic response in the two highest dose groups. In addition, Locteron is a more convenient therapy than existing treatments due to its controlled-release profile, allowing for once every two weeks drug administration versus the current once a week regimen. OctoPlus is co-developing Locteron with its partner Biorex Therapeutics.

Joost Holthuis, CEO of OctoPlus, says: *"We are excited that the results of this study demonstrate Locteron's potential for a convenient, safe and efficacious hepatitis C therapy with less side effects than its competing products. In addition, we believe that the emergence of new oral antiviral products, which are associated with additional side effects, will further add to the opportunity for Locteron to be the interferon of choice for future combination therapy as a result of its potential for improved tolerability. We are on schedule to proceed with the development plan for Locteron and are preparing to commence a Phase IIb clinical study in the first half of 2008."*

### **Top-line results from the complete study confirm Locteron's strong antiviral effect:**

- The dose response in antiviral effect that was observed in the first three dose cohorts continued in the final cohort: average viral reduction after 12 weeks of treatment was greater than 4 logs for the 320 microgram (ug), 480 ug and 640 ug dose cohorts, and 1.8 logs for the 160 ug dose.
- The early virologic response (EVR, defined as at least a two-log reduction in hepatitis C virus after 12 weeks of treatment) that was observed in the first three dose cohorts, also continued in the final cohort: the percentage of patients who achieved this was 38% for the 160 ug dose, 88% for the 320 ug dose, and 100% for both the 480 and 640 ug doses. These results compare favorably with results for the currently marketed pegylated interferon alfa products and for Albuferon™ for which EVR rates ranging from approximately 74% to 90% in clinical trials have been reported.

### **Top-line results from the complete study confirm substantial tolerability improvement:**

- Locteron was well tolerated at all doses
- Approximately 90% of adverse events that were experienced were rated as mild
- There were no serious adverse events in the 160 ug, 320 ug, and 480 ug dose cohorts
- There was one serious adverse event in the 640 ug cohort. This was a case of inflammation of the ear, which completely resolved.

Complete and final results of the study, including viral kinetics and pharmacokinetic results, will be presented at the Annual meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston, USA, on November 6.

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**Notes to editors:**

**About Locteron**

Locteron is designed to be a best-in-class therapeutic for patients with chronic hepatitis C, with the potential to induce less side effects, improve patient compliance and provide a more convenient once every two week dosing schedule compared with current therapies.

Locteron combines OctoPlus' proprietary PolyActive™ drug delivery technology with BLX-883, a recombinant interferon alfa produced by OctoPlus' co-development partner Biolex Therapeutics in its patented LEX System<sup>SM</sup>. Locteron is produced in OctoPlus' cGMP manufacturing facilities in Leiden, the Netherlands.

**About hepatitis C**

More than three million people in the United States, and more than 180 million people worldwide, are currently infected with hepatitis C. The standard treatment for patients with chronic hepatitis C is pegylated interferon alfa administered in combination with the antiviral drug ribavirin. The currently available pegylated interferon alfa products require administration once per week for up to 48 weeks and are associated with substantial side effects, particularly during the period following each administration. Independent market research predicts that modified interferons will continue to be a key component of combination therapy for hepatitis C patients and is expected to be complementary with new agents under development. These sources estimate that total interferon sales for the treatment of hepatitis C will exceed \$5 billion by 2014.

**About OctoPlus**

OctoPlus N.V. is a product-oriented biopharmaceutical company committed to the creation of improved pharmaceutical products that are based on OctoPlus' proprietary drug delivery technologies and have fewer side effects, improved patient convenience and a better efficacy/safety balance than existing therapies. Rather than seeking to discover novel drug candidates through early stage research activities, OctoPlus focuses on the development of long-acting, controlled release versions of known protein therapeutics, other drugs, and vaccines.

Our pipeline consists of 5 products in preclinical and clinical development. Our lead product is Locteron, a sustained-release formulation of interferon alfa for the treatment of chronic hepatitis C, which we are co-developing with Biolex Therapeutics. Locteron has completed Phase IIa clinical development. Furthermore, our pipeline comprises a product candidate for the treatment of chronic middle ear infection, which is in Phase II development, a pre-clinical GLP-1 product candidate for the treatment of diabetes and two preclinical-stage single-shot vaccines.

In addition, OctoPlus is a leading provider of advanced drug formulation and clinical scale manufacturing services to the pharmaceutical and biotechnology industries, with a focus on difficult to formulate active pharmaceutical ingredients in injectable formulations. The earnings and expertise that we derive from rendering formulation and manufacturing services help to support our own drug development programs.

OctoPlus is listed on Euronext Amsterdam under the symbol OCTO. For more information about OctoPlus, please visit our website [www.octoplus.nl](http://www.octoplus.nl).

*This document may contain certain forward-looking statements relating to the business, financial performance and results of OctoPlus N.V. and the industry in which it operates. These statements are based*

*on OctoPlus N.V.'s current plans, estimates and projections, as well as its expectations of external conditions and events. In particular the words "expect", "anticipate", "predict", "estimate", "project", "plan", "may", "should", "would", "will", "intend", "believe" and similar expressions are intended to identify forward-looking statements. We caution investors that a number of important factors, and the inherent risks and uncertainties that such statements involve, could cause actual results or outcomes to differ materially from those expressed in any forward-looking statements. In the event of any inconsistency between an English version and a Dutch version of this document, the English version will prevail over the Dutch version.*