



OCTOPLUS' LICENSEE BIOLEX PRESENTS FINAL PHASE IIB RESULTS AT EASL HIGHLIGHTING TOLERABILITY ADVANTAGES OF LOCTERON® IN TREATMENT OF HCV

Presentation highlights strong antiviral activity and SVR rates, significant reductions in flu-like adverse events and reduced rates of depression

Significant tolerability advantages and a 50% reduction in dosing frequency support Locteron's attractiveness for use in new triple- and quad-combination regimens

Leiden, the Netherlands, 31 March 2011 - OctoPlus N.V. ("OctoPlus" or the "Company") (Euronext: OCTO) announces that its licensee Biolex Therapeutics will present today final results from the Locteron® Phase Iib clinical study at the 46th Annual Meeting of the European Association for the Study of the Liver (EASL) in Berlin, Germany. These data highlight important tolerability advantages of Locteron versus current HCV treatments.

Jan Egberts, CEO of OctoPlus, comments: "*These positive final results from the Phase Iib clinical study with Locteron further confirm the long term benefits of Locteron's controlled release mechanism. Our PolyActive technology has enabled the development of an interferon alpha with a significantly improved side effect profile, achieving both a 50% reduction in flu-like adverse events and substantially lower rates of depression compared to conventional interferon treatments. In combination with its reduced injection frequency, these benefits clearly position Locteron as the interferon of choice for future hepatitis C treatments.*"

The following information was taken directly from Biolex' press release (see www.biolex.com).

Biolex announces that final 72-week results from its SELECT-2 Phase 2b trial of Locteron® for the treatment of hepatitis C are being presented today at the 46th Annual Meeting of the European Association for the Study of the Liver (EASL) in Berlin, Germany. Data presented today show that Locteron achieved the SELECT-2 study objectives by demonstrating viral kinetics and response rates that were comparable with or exceeded the PEG-Intron® control while also achieving a statistically significant reduction in flu-like adverse events, reduced rates of depression, lower use of concomitant medications and a reduced rate of discontinuation due to adverse events. Locteron, the only controlled-release interferon alpha, is designed to offer key tolerability and dosing advantages over currently marketed interferons and serve as a core component of new combination therapies as the treatment of hepatitis C evolves to triple- and quad-drug regimens.

Locteron dosing convenience and efficacy

Locteron is administered once every other week and requires half as many injections as the currently marketed interferons, each of which are injected once per week. In SELECT-2, the sustained virologic response rate (SVR) for each of the three Locteron doses studied was comparable with or exceeded the response rate for the PEG-Intron control as outlined in the table below.

SELECT-2 SVR results

	Locteron			PEG-Intron
	(Administered once every two weeks)			(Administered every week)
	<u>640 µg</u>	<u>480 µg</u>	<u>320 µg</u>	
	(n=29)	(n=29)	(n=28)	(n=30)
Patients achieving SVR ¹	41%	34%	36%	33%

Locteron tolerability advantages

A major objective of the SELECT-2 trial was to further demonstrate the ability of Locteron's controlled-release mechanism to improve patient tolerability. In SELECT-2, patients treated with Locteron experienced a significant reduction in the frequency and severity of flu-like adverse events, reduced use of concomitant (analgesic/antipyretic) medications and reduced rates of depression compared to patients treated with the PEG-Intron control.

The SELECT-2 results were presented by the lead author, Eric Lawitz, MD, Medical Director and Principal Investigator, Alamo Medical Research, in a poster titled "SVR for Controlled-Release Interferon Alpha-2b (CR2b) + Ribavirin Compared to Pegylated Interferon Alpha-2b (Peg2b) + Ribavirin in Treatment-Naïve Genotype-1 (G1) Hepatitis C: Final Results from SELECT-2."

In SELECT-2, flu-like adverse events were predefined to include arthralgia, chills, fever, headache, and myalgia and were captured in two ways:

- Traditional weekly adverse event assessments performed by medical personnel at the clinical sites during the entire 48 weeks of treatment.
- Daily electronic patient reported outcome (ePRO) system where patients directly reported their flu-like adverse events each day for the first 12 weeks of the trial.

Locteron substantially reduced flu-like side effects under both measures as shown below:

SELECT-2 final results Reduction in flu-like adverse events compared to PEG-Intron control

	Locteron		
	<u>640 µg</u>	<u>480 µg</u>	<u>320 µg</u>
Weekly clinic reports:	(% reduction versus PEG-Intron)		
Through 12 weeks	53%	55%	59%
	p<0.001 ²	p<0.001 ²	p<0.001 ²
Through 48 weeks	65%	65%	65%
Daily ePRO reports (through 12 weeks):			
Flu-like AEs	41%	39%	56%
Severe flu-like AEs	31%	69%	73%

As the ePRO results were reported in real-time directly by the patients, they provide important insight into the patients' real-world experiences with these side effects and the impact on their daily activities. A comparison of the ePRO and clinic site reporting highlights the fact that flu-like adverse events may be even more important to patients than historically believed. The total flu-like adverse events reported directly by the patients using the ePRO system during the first 12 weeks of SELECT-2 were almost five times greater than the total flu-like adverse events recorded by the clinical sites. Also of importance, patients rated 77% of their flu-like adverse events as moderate or severe in their ePRO reports, compared to the clinical site reporting in which only 16% of flu-like adverse events were rated as moderate or severe. Despite the apparent differences in sensitivity in the two adverse event reporting methods, the results from both the ePRO and weekly clinic visits complement each other and each demonstrates the substantial

¹Percentage of patients who maintained undetectable levels of virus at week 72 of the trial, 24 weeks after completion of 48 weeks of treatment (includes all patients who were dosed at least once in the trial).

² The reductions in flu-like adverse events were tested after four and 12 weeks of treatment and were statistically significant at both time points for all three Locteron doses.

reduction in flu-like adverse events for patients treated with Locteron compared to patients treated with PEG-Intron.

Consistent with the reduction in flu-like adverse events, fewer Locteron patients used concomitant medications (analgesics and antipyretics) compared to PEG-Intron patients during the study period. Furthermore, Locteron patients had reduced rates of discontinuation due to adverse events versus the PEG-Intron patients.

SELECT-2 final results
Patients using analgesics and discontinuations due to adverse events

	Locteron			PEG-Intron
	640 µg	480 µg	320 µg	
	(During 48 weeks of study)			
Patients using analgesics	59%	45%	46%	77%
Patients discontinuing due to adverse events	21%	14%	14%	23%

SELECT-2 depression results

In SELECT-2, depression was measured in both patient-reported and clinic-reported methods and showed an advantage for Locteron for the dose groups encompassing the expected commercial dose range, the 320 and 480 µg doses. These results will be presented at the EASL conference today in a separate presentation titled “Timing and Frequency of Depression During HCV-Treatment with Controlled-Release INFα2b (CR2b) vs. Pegylated INFα2b (PEG2b): Results from SELECT-2, a Randomized Open-Label 72-week Comparison in 116 Treatment-Naïve Patients with Genotype-1 HCV.”

About the SELECT-2 Study

Biolex’s SELECT-2 Phase 2b trial was designed to identify one or more doses of Locteron that demonstrated viral kinetics and response rates comparable to the PEG-Intron control while also achieving at least a 50% reduction in flu-like adverse events. SELECT-2 was conducted in the United States and Europe in 116 treatment-naïve, genotype-1, chronic hepatitis C patients. Patients were randomized into one of four dosing cohorts, the 320, 480 or 640 µg dose of Locteron (administered once every two weeks) or a control arm consisting of PEG-Intron (1.5 µg/kg, administered every week), with all patients receiving weight-based ribavirin. Patients were treated for 48 weeks and were followed for an additional 24 weeks to determine the SVR rate. All results reported include all patients who were dosed at least once in the trial.

Locteron overview

Locteron, controlled-release interferon alpha 2b, is designed to offer key advantages compared to currently approved products, including reduced flu-like symptoms and rates of depression, and cutting in half the number of injections required. In contrast to Locteron, the currently approved products, Pegasys® and PEG-Intron, are immediate-release products that lack a controlled-release mechanism. The two-drug combination of interferon alpha and ribavirin serves as the current standard of care for the treatment of hepatitis C. However, the launch of the first direct-acting anti-viral (DAA) product, projected to occur this year, will transform treatment of genotype-1 patients to a triple-drug therapy (interferon plus ribavirin plus DAA) and substantially raise cure rates. Other recent triple or quad drug combinations with interferon (including interferon plus ribavirin plus two DAA agents) have shown promise in early clinical testing, further solidifying the continued role of interferon in the treatment of hepatitis C. It is estimated that worldwide sales of interferon products for the treatment of hepatitis C will approach \$6 billion by 2016.

Locteron incorporates an advanced controlled-release drug delivery technology that allows dosing once every two weeks. This is considerably more convenient than Pegasys and PEG-Intron, each of which requires dosing every week. More importantly, Locteron’s controlled-release mechanism results in the gradual release of interferon alpha 2b to patients over the duration of two weeks and avoids the early peak plasma levels of the active interferon that characterize the pegylated interferons. This controlled-release mechanism is designed to reduce the frequency

and severity of flu-like symptoms and depression commonly experienced by patients treated with pegylated interferons.

Locteron is an investigational therapeutic candidate and has not been approved for sale by the United States Food and Drug Administration or by any international regulatory agency.

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About OctoPlus

OctoPlus is a drug delivery service 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. OctoPlus focuses on the development of long-acting, controlled release versions of known protein therapeutics, other drugs, and vaccines on behalf of its clients.

The clinically most advanced product incorporating our technology is Biolex Therapeutics' lead product Locteron[®], a controlled release formulation of interferon alpha for the treatment of chronic hepatitis C. OctoPlus licensed Locteron exclusively to Biolex in October 2008. Locteron is being manufactured for Biolex by OctoPlus and has recently completed Phase IIb clinical studies with superior clinical data versus current treatment.

In addition, OctoPlus is a leading European 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.

OctoPlus is listed on Euronext Amsterdam by NYSE Euronext under the symbol OCTO. For more information about OctoPlus, please visit our website www.octoplus.nl.

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