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Acasti Announces Positive Phase II Open Label Clinical Trial Results

LAVAL, Quebec, Aug. 13, 2013 (GLOBE NEWSWIRE) -- Acasti Pharma ("Acasti" or the "Corporation") (Nasdaq:ACST) (TSX-V:APO), a Neptune Technologies & Bioressources Inc.'s ("Neptune") subsidiary, announces positive results for its Phase II "randomized, open-label, dose-ranging, multi-center trial" designed to assess the safety and efficacy of its investigational new drug candidate CaPre® in the treatment of mild to severe hypertriglyceridemia.

CaPre® was found to be safe and effective with significant mean triglyceride reductions above 20% after 8 weeks of treatment with both daily doses of 4g and 2g.

Trial Highlights

- Primary objective was met: CaPre was shown to be safe and effective
- Statistically significant reduction in triglycerides: achieved greater than 20% reductions
- Efficacy of CaPre® increases from 4 to 8 weeks
- CaPre® efficacy at all doses facilitates dose adjustment for better patient management, providing potential advantage over other competitive omega-3 drugs
- Statistically significant HDL increase
- Reductions in LDL and non-HDL

The primary objective of the study was to evaluate the safety and efficacy of CaPre® at different doses over a 4-week treatment period in patients with mild to severe hypertriglyceridemia as compared to Standard of Care alone. Standard of Care could be any treatment physicians considered appropriate in a real-life clinical setting and included lifestyle modifications as well as lipid modifying agents, such as statins, ezetimibe and fibrates. Demographics and baseline characteristics of the patient population were balanced in terms of age, race and gender. Over 230 patients completed the 8 weeks treatment, which exceeded the targeted number of evaluable patients. From this patient population, 88% had mild to moderate baseline triglycerides between 200 and 500mg/dL (2.28 to 5.7 mmol/L).

The study met its primary objective showing CaPre® to be safe and effective in reducing triglycerides in patients with mild to severe hypertriglyceridemia. After only a 4-week treatment, CaPre® achieved a statistically significant triglyceride reduction as compared to Standard of Care. Patients treated with 4g of CaPre® a day over 4 weeks reached a mean triglyceride decrease of 15.5% from baseline and an absolute mean improvement of 18.1% as compared to Standard of Care.

Results also showed increased benefits after 8 weeks of treatment, with patients on a daily dose of 4g of CaPre®, registering a mean triglyceride decrease of 21.6% and an absolute mean improvement of 14.3% as compared to Standard of Care, in which, due to lipid

lowering medication adjustment, a significant improvement in triglyceride levels was observed during the trial between 4 weeks and 8 weeks.

No serious adverse events were reported, indicating that CaPre® is safe and tolerable at all doses tested. Furthermore, data revealed a positive risk/benefit ratio for CaPre®, with patients on CaPre® showing a lower incidence of adverse events compared to the Standard of Care group.

In addition, after doubling the daily dosage of CaPre® from 4 to 8 weeks, the results indicate a dose response relationship revealing a maintained and improved efficacy of CaPre® after an 8-week period. The efficacy of CaPre® at all doses and increased effect with dose escalation suggests that CaPre® may be titratable, allowing physicians to adjust dosage in order to better manage patients' medical needs.

After 8 weeks of treatment, patients under a daily dose of 4g of CaPre® had a mean LDL decrease of 8.3% and non-HDL decrease of 14.3%, while lower doses did not show deleterious effect on LDL or non-HDL. Moreover there was, after a 4 week treatment, a statistically significant HDL increase of 11.1% between the Standard of Care and the 4.0g CaPre® treatment groups.

"Our investigational new drug CaPre® is showing significant statistical and clinical benefits in treating mild to moderate hypertriglyceridemia patients. This harder-to-treat population represents over 40 million people in the U.S.A, for which no Omega-3 prescription drug has yet been approved by the U.S. Food and Drug Administration (FDA). These results can also indicate that CaPre® could be as efficient, if not even more successful, in treating patients with baseline triglycerides above 500mg/dL," highlighted Dr. Harlan W. Waksal, M.D., Executive Vice President, Business and Scientific Affairs at Acasti. "We also foresee that CaPre® could become a multi-faceted drug, whereby medical practitioners would tailor the dosage levels to a patient's need and use it separately or in combination with statin therapy," added Dr. Waksal.

About Acasti Pharma Inc.

Acasti is developing a product portfolio of proprietary novel long-chain omega-3 phospholipids. Phospholipids are the major component of cell membranes and are essential for all vital cell processes. They are one of the principal constituents of High Density Lipoprotein (good cholesterol) and, as such, play an important role in modulating cholesterol efflux. Acasti's proprietary novel phospholipids carry and functionalize the polyunsaturated omega-3 fatty acids EPA and DHA, which have been shown to have substantial health benefits and which are stabilized by potent antioxidants. Acasti is focusing initially on treatments for chronic cardiovascular and cardiometabolic conditions within the medical food and prescription drug markets.

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