Acasti Pharma

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CaPre®

Acasti has an exclusive licence from Neptune to develop pharmaceutical products customized to manage cardiovascular disease. CaPre® is currently Acasti's only prescription drug candidate, and is being developed to address the prevention and treatment of cardiometabolic disorders including hypertriglyceridemia, a condition which is characterized by abnormally high levels of triglycerides.

CaPre® is a highly purified omega-3 phospholipid concentrate derived from krill oil. The active ingredient of CaPre® is a mixture of concentrated omega-3 fatty acids purified from krill oil and developed as an oral formulation. CaPre® contains EPA and DHA bound to phospholipids as well as free EPA and DHA for a total concentration of approximately two-thirds phospholipids and approximately 30% EPA and DHA.

Acasti's near-term strategy is to develop and commercialize CaPre® in the United States as a prescription drug with a claim for the treatment of severe hypertriglyceridemia and, as a next step, the treatment of mild to moderate hypertriglyceridemia.

Going forward Acasti hopes, CaPre® can be used as a therapy in conjunction with positive lifestyle changes and administered either alone or with other treatments such as statins (statins are a class of drug used to reduce cholesterol

levels) and potentially for use by statin-intolerant or statin-resistant patients. In addition to targeting the reduction of high to very high triglycerides, Acasti's longer-term objective is to demonstrate that CaPre® can also reduce LDL (bad cholesterol) and raise HDL (good cholesterol). Based on nonclinical and clinical studies to date, Acasti believes CaPre® may provide significant benefits in all three areas. However, further clinical research is required in order to confirm an analogous efficacy in humans. CaPre®'s precursor, NKO®, has demonstrated significant clinical benefits in all three areas.

Acasti initiated two Phase II **clinical trials** designed to evaluate the safety and efficacy of CaPre® for the management of hypertriglyceridemia. These trials are a central part of its US and international regulatory compliance program and are an essential step in securing regulatory approval to distribute and market CaPre® as a prescription drug in the pharmaceutical marketplace. To date, Acasti has successfully completed one Phase II trial, **announcing positive results** in August 2013. Obtaining regulatory approval for CaPre® requires that safety is confirmed and the product is effective for sufficiently reducing triglycerides.

There are competing products in the marketplace to treat hypertriglyceridemia, including products that have been manufactured from omega-3 fish oil, and products that, if approved, would compete with CaPre®. However, to Acasti's knowledge, CaPre® is the only omega-3 phospholipid product being developed with a potential to demonstrate a clear clinical superiority in treating triglycerides, LDL and HDL. To date, no competing product currently on the market has demonstrated efficacy in treating all three indications.

Based on preclinical evaluations and the demonstrated benefits of NKO®, Acasti has reason to expect that the competitive advantages of CaPre® may also include a range of clinical benefits that are superior to products currently being prescribed for the treatment of hypertriglyceridemia, as well as efficacy at lower dosage levels than products now on the market, which is essential for good patient compliance, and no gastrointestinal side-effects.

Market participants have estimated that the total prescription omega-3 market generated over $2 billion in sales worldwide in 2012. Acasti believes that there will be increased growth in the prescription omega-3 market based on the expected introduction, and resulting increased promotion and awareness, of new prescription omega-3 products, as well as the emergence of new clinical data regarding the efficacy of omega-3 in the treatment and prevention of cardiometabolic disorders.