

Acasti Pharma Inc

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Acasti Pharma edging closer to commercializing CaPre as it eyes topline clinical data for Christmas

- Seeking to commercialize CaPre, a prescription drug to treat heart disease
- First topline data from Phase 3 trials expected before Christmas
- Huge potential market in the US and beyond, which is expected to grow

What Acasti Pharma does:

Acasti Pharma Inc (NASDAQ:ACST) (CVE:ACST) is developing a krill-oil derived prescription drug called CaPre to treat hypertriglyceridemia (high levels of triglycerides in the blood), which is known to contribute to heart disease.

In Phase 2 trials, CaPre has also shown that it not only effectively reduces triglycerides, but also has the potential to lower LDL or 'bad' cholesterol levels, raise HDL or 'good' cholesterol levels, and lower hemoglobin A1c (HbA1c) - an important biomarker of long term glucose control in diabetic patients.

In addition, Acasti says CaPre is unique from other Omega-3 drugs in that it also contains phospholipids derived from krill oil. These phospholipids not only significantly enhance the bioavailability and absorption of CaPre, but they are also the reason for the reduction in LDL cholesterol and HbA1c in diabetic patients that was reported in the phase 2 studies.

The phospholipids in CaPre act to block the synthesis and absorption of LDL cholesterol, and they also appear to improve the metabolism of glucose in patients with diabetes.

The company says none of the competitive Omega-3 therapeutic products on the market or in development can deliver all these important clinical benefits.

How is it doing:

The last phase of clinical development of CaPre in patients with severe hypertriglyceridemia prior to potential commercialization of the drug is underway, with two Phase 3 studies and 500 patients involved.

The first trial - Trilogy One - is exclusively in the US, while Trilogy Two is in sites in the US, Mexico and Canada. Data from Trilogy One is expected before Christmas, while in mid to end January, results are set to be released from the Trilogy Two trial.

This month, Acasti announced a major milestone in the journey towards a commercial launch, as it revealed it would partner with Norwegian group Aker BioMarine for a two-year supply of krill oil, the main ingredient to make CaPre.

Notably, the agreement includes a fixed-price, securing an adequate supply to Acasti of raw krill oil through to at least

Price: 0.285

Market Cap: \$27.61 m

1 Year Share Price Graph



September 2019 March 2020 September 2020

Share Information

Code: ACST

Listing: TSX-V

| | | |
|----------------|-------------|-------------|
| 52 week | High | Low |
| | 4.05 | 0.22 |

Sector: Pharma & Biotech

Website: www.acastipharma.com

Company Synopsis:

Acasti is a biopharmaceutical innovator focused on the research, development and commercialization of prescription drugs using omega-3 fatty acids derived from krill oil. Omega-3 fatty acids have extensive clinical evidence of safety and efficacy in lowering triglycerides in patients with hypertriglyceridemia.

action@proactiveinvestors.com

mid-2021.

If Acasti gets FDA approval for CaPre, it will be the only drug company using such an amount of the oil to make a drug, so it's a big tie-up for both firms.

"We are pleased to partner with Acasti to support commercialization of the first-ever, krill oil-based, prescription drug product, which we believe has the potential to become the best-in-class omega-3 therapeutic for the management of cardiometabolic disorders," said Tim de Haas, Aker EVP of human health & nutrition.

Discussions are ongoing with multiple potential strategic partners around the world for licensing and commercialization rights and Acasti is well-funded beyond the completion of Phase 3. It had cash and equivalents of C\$25.4 million as at June 30 this year.

Acasti says the initial market potential for CaPre is compelling since there are between 3 million and 4 million patients in the US alone with severe hypertriglyceridemia.

What analysts say:

In July this year, research firm Aegis Capital initiated coverage on Acasti Pharma with a 'Buy' rating and a US\$3 price target, not long after Mackie Research rated the shares as a 'Speculative Buy' with a C\$8.70 price target.

HC Wainwright & Co labelled Acasti a 'Buy' and set a US\$6 target at the end of June.

"If approved, CaPre would represent the only prescription omega-3 offering triglyceride reduction benefits of DHA, without raising Low-density lipoprotein (LDL) cholesterol," Wainwright's analysts noted.

Meanwhile, Aegis' analysts highlighted the growing prescription omega-3 market as a "compelling" category, noting pharmaceutical giants Amarin and AstraZeneca's successful trials of similar drugs.

Mackie repeated its 'Speculative Buy' stance on Acasti in August in the wake of news that main competitor Amarin had received a setback on approval for its Vascepa heart drug, with the all-powerful US Food & Drug Administration (FDA) scheduling an advisory committee meeting - which Amarin had thought they would not need - on the drug for November 14 this year.

The broker reckons the Trilogy results are very important as they could ultimately validate CaPre is the best-in-class OMG3 product by showing better blood lipid management than Amarin's Vascepa and pharma giants GlaxoSmithKline's Lovaza and AstraZeneca's Epanova.

What the boss says:

Speaking to Proactive on November 5, Acasti's chief operations and scientific officer Pierre Lemieux said: "We'll be announcing top-line data before Christmas," referring to the results of the Trilogy One trial.

"In a second phase of information we'll have more what we call the secondary endpoint and the exploratory endpoint presented later on, probably in January and we are planning to present all this data all together in a scientific meeting at the end of March. We'll be very public about this data," he added.

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