

Acasti Pharma Inc

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Acasti Pharma considering FDA's comments after receiving response to its CaPre TRILOGY trials briefing package

Acasti Pharma Inc (NASDAQ:ACST) (CVE:ACST) revealed Friday that it has received a written response from the US Food and Drug Administration (FDA) having submitted a New Drug Application (NDA) briefing package concerning its flagship drug candidate, CaPre to the regulator in April after the TRILOGY trials.

"Acasti and its expert advisors are carefully considering the FDA's comments on the TRILOGY 1 data and will conduct further post-hoc analysis based on their feedback," the biotech said in a statement.

Acasti Pharma hopeful of path towards New Drug Application for CaPre as it submits TRILOGY 1 package

Topline results from the TRILOGY 1 trial, as reported in January, did not reach statistical significance due to an unusually large placebo effect.

The firm filed its FDA meeting request at the end of March, and the briefing package was intended to provide the regulator with a review of the relevant TRILOGY 1 data and audit findings, in a bid to "gain alignment on the interpretation of the TRILOGY 1 results and implications for TRILOGY 2".

Both were Phase 3 studies on the drug, which is krill-oil derived and aimed at treating hypertriglyceridemia, or high levels of triglycerides in the blood, which is known to contribute to heart disease.

"The FDA confirmed that it will require pivotal efficacy analyses for TRILOGY 2 to be performed on the full Intent to Treat (ITT) population as contemplated in the original Statistical Analysis Plan (SAP), and they supported the conduct of post-hoc analyses in TRILOGY 1 for exploratory purposes," the firm said.

"Consistent with the company's prior disclosures, and depending on the outcome of TRILOGY 2, an additional clinical study may still be needed prior to an NDA submission," it added.

Acasti said it will host a conference call on Monday, June 29, 2020, at 1pm EST to discuss its financial results for the year ended March 31, 2020, as well as an update on the TRILOGY 1 and TRILOGY 2 Phase 3 trials of CaPre.

Shares in Acasti slipped around 14% on Friday in Toronto to C\$1.03 each.

---Updates for share price---

Contact the author at giles@proactiveinvestors.com

Price: 0.385

Market Cap: \$37.3 m

1 Year Share Price Graph



December 2019 June 2020 December 20

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.

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