

Acasti Pharma Inc

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Acasti Pharma submits Statistical Analysis Plan to FDA for TRILOGY 2 Phase 3 trial of flagship drug CaPre

Acasti Pharma Inc (NASDAQ:ACST) (CVE:ACST) announced Friday it has completed revisions to the pre-specified Statistical Analysis Plan (SAP) for the TRILOGY 2 Phase 3 trial of flagship drug CaPre and has filed it with the US Food and Drug Administration (FDA).

The krill oil-derived drug is aimed at treating hypertriglyceridemia, or high levels of triglycerides in the blood, which is known to contribute to heart disease.

As reported in January, topline results from the TRILOGY 1 trial of the drug candidate did not reach statistical significance due to an unusually large placebo effect.

READ: Acasti Pharma eyeing TRILOGY 2 data as it reveals phenomenon of 'triglyceride normalization' could have played part in first trial

But the company said that further analysis of the TRILOGY 1 data revealed a rapid, significant and sustained reduction in TG levels between screening (during qualification) and the time of patient randomization (prior to patients starting on either drug or placebo), which Acasti refers to as "Pre-randomization Triglyceride (TG) Normalization."

"This artefactual phenomenon affected both treatment groups, but was much greater in the placebo group, resulting in the large placebo effect and significant underestimation of the post-randomization treatment effect of the active drug, CaPre," the company said in a statement.

In April, the TRILOGY 1 data were provided to the FDA in a Type C briefing package. The FDA provided Acasti with a written response to its Type C Meeting request and briefing package, and confirmed that it will require pivotal efficacy analyses for TRILOGY 2. Based on the FDA's feedback and input from key experts, Acasti finalized the SAP for TRILOGY 2 and has submitted it to the FDA.

TRILOGY 2 data release

The Quebec-based company said it remains blinded to the TRILOGY 2 data, and remains on track to report topline TG data on or about August 31.

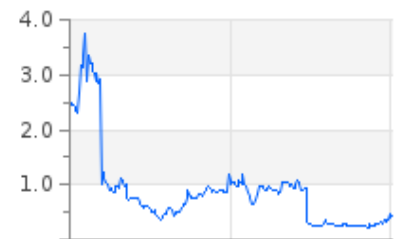
It added that the key secondary and exploratory endpoints from both TRILOGY 1 and TRILOGY 2 trials, and pooled results from both studies, are still expected within several weeks following the unblinding of the TRILOGY 2 results.

Acasti also announced that it plans to host a conference call on or about August 31 to discuss the TRILOGY 2 topline results, as well as to provide an update on the timing for the reporting of the secondary and exploratory endpoints, and the pooled results from both TRILOGY studies.

Price: 0.39

Market Cap: \$37.79 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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For this reason, the company said it does not plan to host its usual quarterly conference call to discuss the financial results for the first fiscal quarter ended June 30, but expects to report and file its first fiscal quarter 2021 financial results on August 13.

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