UK: +44 (0)207 989 0813
NA: +1 646 896 3065
AU +61 2 9280 0700
action@proactiveinvestors.com

# Acasti Pharma Inc

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## Acasti Pharma says further analysis underway after TRILOGY 1 topline results show unexpected placebo effect

Acasti Pharma Inc (NASDAQ:ACST) (CVE:ACST) says further analysis is underway after topline results from its TRILOGY 1 trial for lead product CaPre did not reach statistical significance due to the unusually large placebo effect.

The biotech is developing the krill-oil derived drug called CaPre to treat hypertriglyceridemia (high levels of triglycerides in the blood), which is known to contribute to heart disease and the findings of this Phase III trial have been much anticipated.

READ: Acasti Pharma shares on the move, expects to report TRILOGY 1 results of CaPre trial in January
Both the placebo and CaPre study groups saw significant reductions in triglycerides within the first four weeks from baseline, the firm said.

Although the difference at 12 and 26 weeks was in favor of CaPre, due to the unexpectedly large placebo response, TRILOGY 1 did not reach statistical significance, the firm said in a statement.

"While we are encouraged by the magnitude of reduction in triglyceride levels seen among patients receiving CaPre, the large placebo effect was completely unexpected, and was about double what was seen in all other therapeutic OM3 hypertriglyceridemia trials," noted Jan D'Alvise, the president and CEO of Acasti.

Several hypotheses are being investigated now by the group's clinical team, and by our CRO and Dr. Dariush Mozaffarian, the principal investigator for the study, she added.

"These avenues of investigation are being carefully and rigorously pursued, and we are moving as quickly as possible to try to gain understanding and insight into the large and unexpected placebo response seen in TRILOGY 1.

"The company will continue to provide updates on this investigation, as well as topline results for TRILOGY 2 as we get them, to be followed by all secondary and exploratory endpoints for TRILOGY 1 and 2 once the TRILOGY 2 study is completed and fully analyzed."

Acasti told investors that a full audit of enrolling sites, including review of all raw data and records from patients taking both CaPre and placebo, will be conducted to identify a possible root cause of this 'unprecedented' placebo effect.

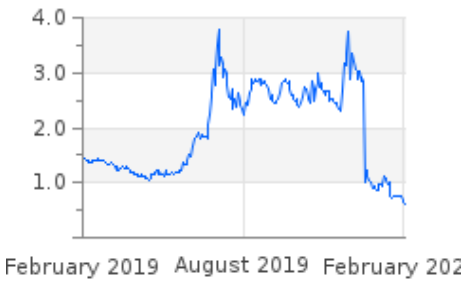
This is likely to take at least several weeks, with an outcome expected by the end of February, it said.

Notably, due to additional resources now going toward TRILOGY 1, there could be a small delay of a couple of weeks in reporting topline results for TRILOGY 2 to mid-February 2020.

**Price:** 0.61

**Market Cap:** $55.03 m

**1 Year Share Price Graph**




### Share Information

| | | |
|---|---|---|
| **Code:** | | ACST |
| **Listing:** | | TSX-V |
| **52 week** | **High** | **Low** |
| | **4.05** | **0.56** |
| **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**

Key secondary and exploratory endpoints
But key secondary and exploratory endpoints from both studies would be expected sometime in the first quarter of 2020, it said.

Acasti also highlighted that assuming the primary endpoint reaches statistical significance in TRILOGY 2, it may still have a path forward to file an NDA (new drug application).

It would seek a meeting with the FDA as soon as possible to discuss all of the TRILOGY data, investigational findings, and obtain its input and guidance on the next steps, it added.

Results showed a 30.5% and 36.7% reduction in triglyceride levels, compared with baseline, among patients receiving CaPre at 12 and 26 weeks respectively.

There was also a 42.2% reduction in triglyceride levels among patients receiving CaPre while on background statin therapy at 12 weeks.

Contact the author at giles@proactiveinvestors.com