Acasti Pharma Inc

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Acasti Pharma updates on TRILOGY 1 and TRILOGY 2 Phase 3 trials of lead heart drug CaPre

Acasti Pharma Inc (NASDAQ:ACST) (CVE:ACST) said Monday that a "detailed examination" of the Phase 3 TRILOGY 1 results for lead drug CaPre, which treats severe hypertriglyceridemia, is underway in specific clinical site audits and an audit of the central testing lab.

The active ingredient in Laval, Quebec-based Acasti's lead product CaPre, which lowers triglyceride levels in people at risk of cardiovascular disease, is an extract from krill oil.

The findings of a Phase III trial have been highly anticipated. However, as earlier reported, further analysis is underway after topline results from its TRILOGY 1 trial for CaPre did not reach statistical significance due to the unusually large placebo effect.

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

The company said it noted "a highly unusual placebo" response in its topline triglyceride reduction primary endpoint, far greater than seen in any prior omega-3 triglyceride-lowering trials, with five sites out of the total 54 enrolling sites disproportionately contributing to this placebo response.

"These sites accounted for about 36% of the 242 patients enrolled in the TRILOGY 1 study," said the company.

By comparison, TRILOGY 2 was conducted at 71 sites in Canada, Mexico and the US that enrolled a total of 278 patients. The five sites also participated in TRILOGY 2, however, these sites accounted for only 12% of the total patients, with the majority of these patients coming from only three sites.

The company said it has subsequently identified some "unexpected and inconsistent findings" in the TRILOGY 1 trial that it believes may have negatively contributed to the overall topline results.

The findings are now being further reviewed by an independent team of auditors. To support the effort, the company's independent Clinical Research Organization which conducted the TRILOGY studies, Dr Dariush Mozaffarian, the principal investigator for the study, and other regulatory advisors, are conducting a thorough review of all the data and records from patients taking both CaPre and a placebo. This "assessment is well underway," and the company said a thorough investigation of the data must be reviewed with the FDA, before it can report the findings from TRILOGY 1 and the implications for TRILOGY 2.

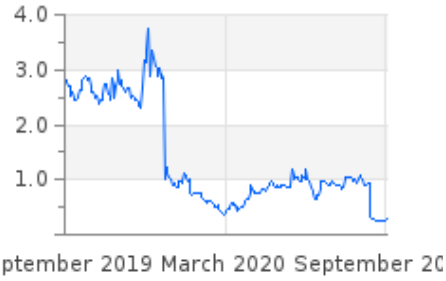
Requesting a meeting with the FDA

Acasti said it will request a meeting with the FDA to discuss the TRILOGY 1 data, and will seek its guidance on how to conduct the analysis of the TRILOGY 2 data prior to unblinding TRILOGY 2.

Once it asks for the meeting with the FDA in the second quarter, the US regulatory agency will have 75 days to review

Price:	0.285
Market Cap:	$27.61 m

1 Year Share Price Graph



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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the findings and provide feedback, noted the company.

Given the need to complete the TRILOGY 1 data audit, and get FDA feedback, the company now expects the unblinding of the topline results for TRILOGY 2 in the third quarter.

Accordingly, key secondary and exploratory endpoints from both TRILOGY 1 and TRILOGY 2 studies, are now expected after the unblinding of TRILOGY 2 results. If the analyses is supported by the FDA, and if TRILOGY 2 achieves statistical significance, Acasti believes it may still have a "viable path forward" to file an NDA for CaPre.

"Taking into account that the audit is still underway, that the data that we are evaluating is still preliminary, and that any findings will be subject to guidance from the FDA, we look forward to concluding the necessary work, which we hope will help us to better understand the unexpected TRILOGY 1 results," said Acasti Pharma CEO Jan D'Alvise in a statement.

"Any learnings we can take from this investigation that may allow us to proactively adjust the SAP for TRILOGY 2, gives us a better chance of accurately reflecting the clinical value that we believe we still see in CaPre. Moreover, we have confirmed that there is established precedent for the FDA accepting post-hoc analyses of study results, assuming the analyses are transparent, well justified and well supported," she added.

Strong cash position

The Acasti Pharma boss said the company was "moving quickly" to gain a greater understanding of the TRILOGY 1 results.

"We project that our current cash position will now last through calendar 2020, giving us the necessary runway to complete our extended analysis of the TRILOGY program," said D'Alvise.

"We remain fully committed to our goal of gaining NDA approval for CaPre and appreciate the tremendous support and patience of our shareholders," she added.

Trial data shows that CaPre lowers triglycerides while also benefiting both good and bad cholesterol.

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