

Acasti Pharma Inc

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Acasti Pharma looking forward to the unblinding of its TRILOGY 2 trial data around end of this month

Acasti Pharma Inc (NASDAQ:ACST) (CVE:ACST) has provided an update on its progress towards a possible new drug application (NDA) for its flagship drug CaPre aimed at treating hypertriglyceridemia and said it expects topline results from its second Phase 3 trial around the end of this month, and posted its first-quarter results.

The group already revealed on July 31 that it submitted its Statistical Analysis Plan (SAP) for the TRILOGY 2 Phase 3 trial to the US Food & Drug Administration (FDA), the data of which it remains blinded to.

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

"With the TRILOGY 2 SAP finalized and now submitted to the FDA, we continue to advance the process towards unblinding of our TRILOGY 2 clinical data," said Jan D'Alvise, CEO of Acasti in a statement on Thursday.

"We believe if TRILOGY 2 can achieve statistical significance, and if the pooled efficacy results with TRILOGY 1 using the Intent to Treat population also reaches significance, we can proceed with our Pre-NDA meeting where we intend to discuss with the FDA the use of this data to support an NDA filing.

"We look forward to the unblinding of TRILOGY 2 data and reporting our findings, concurrent with a conference call update on or about August 31, 2020," he added.

The process is all a result of the fact that topline results from the first study - TRILOGY 1 - of Capre did not reach statistical significance due to an unusually large placebo effect, which prompted a 'rigorous' review of data from that trial.

That review 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 has called a "Pre-randomization Triglyceride (TG) Normalization".

Acasti provided all of the TRILOGY 1 background information and accompanying data to the US Food and Drug Administration (FDA) in a Type C briefing package, which was filed on April 29, 2020.

The FDA then confirmed that pivotal efficacy analyses for TRILOGY 2 will be performed on the full Intent to Treat (ITT) population, as contemplated in the original Statistical Analysis Plan (SAP).

On Thursday, Acasti also reported its first-quarter results to end June, which showed a loss from operations of C\$4.1 million, down from a loss of C\$8 million for the same period last year. The decrease was due mainly to a reduction in research contract expenses, it said.

Cash and cash equivalents at period end came in at C\$12.1 million, compared to C\$16.0 million at June 30, 2019.

1 Year Share Price Graph



January 2020 July 2020 January 2021

Share Information

Code: ACST
Listing: TSX-V
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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Acasti said it believes that its current cash will fully fund operations through the first calendar quarter of 2021.

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