Acasti Pharma Inc

09:55 13 Aug 2020

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

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.

action@proactiveinvestors.com

Acasti said it believes that its current cash will fully fund operations through the first calendar quarter of 2021.

Contact the author at giles@proactiveinvestors.com

Proactive Investors facilitate the largest global investor network across 4 continents in 4 languages. With a team of analysts journalists & professional investors Proactive produce independent coverage on 1000's of companies across every sector for private investors, private client brokers, fund managers and international investor communities.

Contact us +44 (0)207 989 0813 action@proactiveinvestors.com

No investment advice

The Company is a publisher. You understand and agree that no content published on the Site constitutes a recommendation that any particular security, portfolio of securities, transaction, or investment strategy is suitable or advisable for any specific person. You understand that the Content on the Site is provided for information purposes only, and none of the information contained on the Site constitutes an offer, solicitation or recommendation to buy or sell a security. You understand that the Company receives either monetary or securities compensation for our services. We stand to benefit from any volume which any Content on the Site may generate.

You further understand that none of the information providers or their affiliates will advise you personally concerning the nature, potential, advisability, value, suitability or profitability of any particular security, portfolio of securities, transaction, investment, investment strategy, or other matter.

You understand that the Site may contain opinions from time to time with regard to securities mentioned in other products, including Company-related products, and that those opinions may be different from those obtained by using another product related to the Company. You understand and agree that contributors may write about securities in which they or their firms have a position, and that they may trade such securities for their own account. In cases where the position is held at the time of publication and such position is known to the Company, appropriate disclosure is made. However, you understand and agree that at the time of any transaction that you make, one or more contributors may have a position in the securities written about. You understand that price and other data is supplied by sources believed to be reliable, that the calculations herein are made using such data, and that neither such data nor such calculations are guaranteed by these sources, the Company, the information providers or any other person or entity, and may not be complete or accurate.

From time to time, reference may be made in our marketing materials to prior articles and opinions we have published. These references may be selective, may reference only a portion of an article or recommendation, and are likely not to be current. As markets change continuously, previously published information and data may not be current and should not be relied upon.

The Site does not, and is not intended to, provide investment, tax, accounting, legal or insurance advice, and is not and should not be construed as providing any of the foregoing. You should consult an attorney or other relevant professional regarding your specific legal, tax, investment or other needs as tailored to your specific situation.

In exchange for publishing services rendered by the Company on behalf of Acasti Pharma Inc named herein, including the promotion by the Company of Acasti Pharma Inc in any Content on the Site, the Company receives from said issuer annual aggregate cash compensation in the amount up to Twenty Five Thousand dollars ($25,000).