

Update on Epanova Phase III STRENGTH trial

13 January 2020 07:00 GMT

Update on Phase III STRENGTH trial for *Epanova* in mixed dyslipidaemia

Independent Data Monitoring Committee has recommended to discontinue the trial as Epanova is unlikely to demonstrate a benefit to patients

Following the recommendation from an independent Data Monitoring Committee, AstraZeneca has decided to close the Phase III STRENGTH trial for *Epanova* (omega-3 carboxylic acids) due to its low likelihood of demonstrating a benefit to patients with mixed dyslipidaemia (MDL) who are at increased risk of cardiovascular (CV) disease.

STRENGTH is a large-scale, global CV outcomes trial designed to evaluate the safety and efficacy of *Epanova* compared to placebo, both in combination with standard-of-care statin medicines.

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: "It was important to assess the potential benefit of *Epanova* in mixed dyslipidaemia. We are disappointed by these results, but we remain committed to addressing the needs of patients in the cardiovascular space where we have an extensive pipeline."

Steven E. Nissen MD, Study Chair for the STRENGTH trial and Chief Academic Officer for the Heart and Vascular Institute, Cleveland Clinic, US, said: "The academic leadership of the STRENGTH trial is obviously disappointed in this result, but we are very proud to have had the opportunity to answer this important scientific question. We are also grateful for the opportunity to conduct the STRENGTH trial as an exemplary collaboration between academic physicians and industry."

This trial will now be closed in an orderly fashion, and full data will be presented at a forthcoming medical meeting.

Financial considerations

A review is being undertaken of the ongoing value of the \$533m *Epanova* intangible asset. Any impairment will be treated as a non-Core item in the fourth quarter of 2019. A write down of up to \$100m relating to inventories is also anticipated to impact the Core earnings in the fourth quarter of 2019.

STRENGTH

STRENGTH is a large-scale CV outcomes trial evaluating the effect of *Epanova* 4g daily compared to placebo (corn oil) on reducing the risk of major adverse cardiovascular events (MACE) in patients on optimal statin therapy with mixed dyslipidaemia and at high risk for CV disease. A total of 13,086 patients were enrolled at 675 sites in 22 countries.

Mixed dyslipidaemia

MDL includes patients with raised triglyceride levels (moderate hypertriglyceridemia) between 175-499mg/dL mg/dL, and low HDL cholesterol. Elevated triglycerides affect a growing number of patients and is often worsened by other factors such as diabetes or obesity. Lifestyle changes and potentially treating the underlying cause is likely to at least partly improve the condition and reduce cardiovascular risk.

Epanova

Epanova is a fish oil-derived mixture of free fatty acids primarily composed of EPA and DHA. It is approved in the US and indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (≥ 500 mg/dL) hypertriglyceridaemia, and this indication is not impacted by the data from the STRENGTH trial.

AstraZeneca in CVRM

Cardiovascular, Renal and Metabolism (CVRM) together forms one of AstraZeneca's three therapy areas and is a key growth driver for the Company. By following the science to understand more clearly the underlying links between the heart, kidneys and pancreas,

AstraZeneca is investing in a portfolio of medicines to protect organs and improve outcomes by slowing disease progression, reducing risks and tackling comorbidities. The Company's ambition is to modify or halt the natural course of CVMR diseases and potentially regenerate organs and restore function, by continuing to deliver transformative science that improves treatment practices and cardiovascular health for millions of patients worldwide.

AstraZeneca

AstraZeneca (LSE/STO/NYSE: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of diseases in three therapy areas - Oncology, Cardiovascular, Renal and Metabolism, and Respiratory. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter [@AstraZeneca](https://twitter.com/AstraZeneca).

Media Relations

Gonzalo Viña		+44 203 749 5916
Rob Skelding	Oncology	+44 203 749 5821
Rebecca Einhorn	Oncology	+1 301 518 4122
Matt Kent	BioPharmaceuticals	+44 203 749 5906
Angela Fiorin	BioPharmaceuticals	+44 1223 344 690
Jennifer Hursit	Other	+44 203 749 5762
Christina Malmberg Hägerstrand	Sweden	+46 8 552 53 106
Michele Meixell	US	+1 302 885 2677

Investor Relations

Thomas Kudsk Larsen		+44 203 749 5712
Henry Wheeler	Oncology	+44 203 749 5797
Christer Gruvis	BioPharmaceuticals (Cardiovascular, Metabolism)	+44 203 749 5711
Nick Stone	BioPharmaceuticals (Renal) Environmental, Social and Governance	+44 203 749 5716
Josie Afolabi	BioPharmaceuticals (Respiratory) Other medicines	+44 203 749 5631
Craig Marks	Finance Fixed income	+44 7881 615 764
Jennifer Kretzmann	Corporate access Retail investors	+44 203 749 5824
US toll-free		+1 866 381 72 77

Adrian Kemp

Company Secretary

AstraZeneca PLC

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact rns@seg.com or visit www.rns.com.