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Esperion Therapeutics Announces Positive Top-Line Phase 2b Results for ETC-1002, An Investigational Therapy for Patients with Hypercholesterolemia

- ETC-1002-008 study meets primary endpoint -

- LDL-cholesterol lowering significantly greater with ETC-1002 than ezetimibe -

- ETC-1002 appears to be safe and well tolerated -

Conference Call and Webcast on Wednesday, October 1, 2014 at 4:30 p.m. Eastern Time

ANN ARBOR, Mich.--(BUSINESS WIRE)-- Esperion Therapeutics, Inc. (NASDAQ: ESPR), an emerging pharmaceutical company focused on developing and commercializing first-in-class, oral low-density lipoprotein cholesterol (LDL-cholesterol) lowering therapies for the treatment of hypercholesterolemia and other cardiometabolic risk markers, today announced positive top-line results from ETC-1002-008, a Phase 2b study evaluating the efficacy and safety of ETC-1002 monotherapy compared with ezetimibe monotherapy in patients with hypercholesterolemia, with or without statin intolerance.

Top-line results showed the 12-week study met its primary endpoint of greater LDL-cholesterol lowering from baseline with ETC-1002 compared with ezetimibe. In patients who received ETC-1002 as monotherapy, there were 27 and 30 percent reductions in LDL-cholesterol at doses of 120 mg and 180 mg, respectively. These reductions were significantly different from ezetimibe alone ($p=0.0008$ and $p < 0.0001$, respectively). In patients who received the combination of 120 mg of ETC-1002 and 10 mg ezetimibe, substantial LDL-cholesterol reductions of 43 percent were significantly different from ezetimibe alone ($p < 0.0001$). In patients who received the combination of 180 mg of ETC-1002 and 10 mg ezetimibe, substantial LDL-cholesterol reductions of 48 percent were significantly different from ezetimibe ($p < 0.0001$). These reductions occurred within the first two weeks of dosing and continued throughout the treatment period.

ETC-1002 monotherapy and ETC-1002 in combination with ezetimibe demonstrated significantly greater reductions than ezetimibe in high-sensitivity C-reactive protein (hsCRP), an important marker of inflammation in coronary disease.

"Many people with hypercholesterolemia are not able to control their LDL-cholesterol levels with currently available therapies. This is especially true for patients who are statin intolerant because they have limited therapeutic options," said Paul Thompson, M.D., Medical Director of Cardiology and The Athletes' Heart Program, Hartford Hospital. "ETC-1002 has the LDL-cholesterol lowering of a mid-dose statin and is well-tolerated, and could benefit these patients."

ETC-1002 appeared to be safe and well-tolerated. Discontinuation rates due to adverse events (AEs) with ETC-1002 were comparable to those seen with ezetimibe. Rates of adverse events (AEs) and serious adverse events (SAEs) were low and comparable across treatment groups. Elevations in liver enzymes were as expected and comparable to what is typically observed with approved LDL-cholesterol lowering therapies. In patients treated with ETC-1002, including those with statin intolerance, rates of muscle-related AEs were similar to those seen with ezetimibe.

"I am very excited about the positive findings of the 008 study; they are transformational for both ETC-1002 and Esperion," said Tim M. Mayleben, president and chief executive officer of Esperion. "Our ability to show significant differences between ETC-1002 and ezetimibe in both LDL-cholesterol lowering and reductions in hsCRP demonstrate the potential of ETC-1002 as a new oral therapeutic option for patients with hypercholesterolemia, especially those with statin intolerance. The similarity in muscle-related adverse events between ETC-1002 and ezetimibe is especially encouraging."

ETC-1002-008 Design

The randomized, double-blind, active comparator-controlled, parallel group, multicenter Phase 2b study evaluated the efficacy and safety of ETC-1002 monotherapy versus ezetimibe monotherapy in patients with hypercholesterolemia, with or without statin intolerance, treated for 12 weeks. Secondary objectives were to characterize the dose response; assess the effect of ETC-1002 on additional lipid and cardiometabolic biomarkers; characterize the safety, tolerability and rates of muscle-related adverse events and assess lipid-lowering efficacy in combination with ezetimibe versus ezetimibe monotherapy. A total of 348 patients with hypercholesterolemia were washed out of any lipid-regulating therapies prior to a run-in period of five weeks.

Ninety-nine patients were randomized to receive ETC-1002 120 mg; 100 patients were randomized to receive ETC-1002 180 mg; 99 patients were randomized to receive ezetimibe 10 mg; 26 patients were randomized to receive ETC-1002 120 mg + ezetimibe 10 mg; and 24 patients were randomized to receive ETC-1002 180 mg + ezetimibe 10 mg. A total of 177 patients had a history of statin intolerance.

ETC-1002-008 Results

ETC-1002 treated patients achieved LDL-cholesterol lowering of up to 30 percent at 12 weeks compared with 21 percent in the ezetimibe group, and LDL-cholesterol reductions of up to 48 percent when ETC-1002 was added to ezetimibe. Levels of hsCRP were reduced by up to 40 percent with ETC-1002 both as monotherapy and in combination with ezetimibe. The effects of ETC-1002 on atherogenic lipids and lipoproteins were directionally consistent and statistically significant, following the effects on LDL-cholesterol. Consistent with prior clinical studies with ETC-1002, no clinically relevant changes in high-density lipoprotein cholesterol or triglycerides were observed. ETC-1002 appeared to be safe and well tolerated, and was not associated with any dose-limiting side effects. In patients treated with ETC-1002, including those with statin intolerance, rates of muscle-related AEs were similar to those seen with ezetimibe.

LDL-C Percent Change From Baseline to Week 12 Endpoint

Treatment	n	Baseline (mg/dL) Mean (SD)	Week 12 Endpoint (mg/dL) Mean (SD)	Percent Change from Baseline	
				LS Mean (SE)	P Value vs. ezetimibe
ETC-1002 120mg	97	164 (28)	119 (30)	-27% (1.3)	0.0008
ETC-1002 180mg	99	166 (24)	115 (25)	-30% (1.3)	< 0.0001
ezetimibe 10mg	98	165 (25)	129 (20)	-21% (1.3)	-
ETC-1002 120mg + ezetimibe 10mg	24	161 (26)	92 (29)	-43% (2.6)	< 0.0001
ETC-1002 180mg + ezetimibe 10mg	22	164 (27)	86 (21)	-48% (2.8)	< 0.0001

LS = least squares; SD = standard deviation; SE = standard error; mITT population

hsCRP Nonparametric Analysis

Treatment	n	Baseline Level (mg/L)	Percent Change from Baseline	
			Median Change	P Value vs. ezetimibe
ETC-1002 120mg	92	1.60	-30%	≤0.01
ETC-1002 180mg	86	2.50	-40%	≤0.01
ezetimibe 10mg	94	2.60	-11%	NS
ETC-1002 120mg + ezetimibe 10mg	20	1.85	-38%	NS
ETC-1002 180mg + ezetimibe 10mg	21	1.25	-26%	≤0.05

LS = least squares

Conference Call and Webcast Details

The Esperion management team will host a conference call and webcast today at 4:30 p.m. Eastern Time (ET) to discuss these results. The live event will be accessible on the investor relations section of the Esperion website at www.esperion.com, or by calling (877) 831-3840 (domestic) or (253) 237-1184 (international). The access code is 12801596. A replay of the event will be available approximately one hour after completion and will be archived on the Company's website for approximately 90 days following the event.

Esperion's Commitment to Cardiometabolic Disease

Esperion is committed to improving the lives of patients with cardiometabolic diseases. The Esperion team leverages its understanding of, and experience with, key biological pathways to discover and develop innovative therapies for the treatment of patients with hypercholesterolemia who have uncontrolled cholesterol levels despite the use of currently available therapies. Esperion has assembled a portfolio of programs including one product candidate in late-stage clinical evaluation (ETC-1002)

and two pre-clinical product candidates.

About Esperion Therapeutics

Esperion Therapeutics, Inc. is an emerging pharmaceutical company focused on developing and commercializing first-in-class, oral, LDL-cholesterol lowering therapies for the treatment of patients with hypercholesterolemia and other cardiometabolic risk markers. ETC-1002, Esperion's lead product candidate, is a unique, first-in-class, orally available, once-daily small molecule designed to lower LDL-cholesterol levels and avoid the side effects associated with therapies currently available for lowering LDL-cholesterol. ETC-1002 is being developed primarily for patients with hypercholesterolemia and a history of statin intolerance. For more information, please visit www.esperion.com and follow us on Twitter at <https://twitter.com/EsperionInc>.

Forward Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding the therapeutic potential of, and clinical development plan for, ETC-1002. Any express or implied statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause Esperion's actual results to differ significantly from those projected, including, without limitation, the risk that positive results from a clinical study of ETC-1002 may not necessarily be predictive of the results of future clinical studies, particularly in different or larger patient populations, or the risk that other unanticipated developments could interfere with the development (and commercialization) of ETC-1002, as well as other risks detailed in Esperion's filings with the Securities and Exchange Commission, including our Annual Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. You are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this release. Esperion disclaims any obligation or undertaking to update or revise any forward-looking statements contained in this press release, other than to the extent required by law.

Media Contact:

W2O Group

Elliot Fox

212.257.6724

efox@w2ogroup.com

or

Investor Contact:

Esperion Therapeutics, Inc.

Mindy Lowe

734.887.3903

mlowe@esperion.com

Source: Esperion Therapeutics, Inc.

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