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Esperion Therapeutics Provides Update on the ETC-1002 Development Program Following End-of-Phase 2 Meeting With FDA

Company on Track to Initiate Phase 3 Development Program in 2015 Conference Call and Webcast on Monday, August 17, 2015 at 4:30 p.m. Eastern Time

ANN ARBOR, MI -- (Marketwired) -- 08/17/15 -- Esperion Therapeutics, Inc. (NASDAQ: ESPR), an emerging pharmaceutical company focused on developing and commercializing first-in-class, oral, low-density lipoprotein cholesterol (LDL-C) lowering therapies for the treatment of patients with hypercholesterolemia, provided an update today from the ETC-1002 (bempedoic acid) End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) last week. The FDA confirmed that LDL-C remains an acceptable clinical surrogate endpoint for the approval of an LDL-C lowering therapy such as ETC-1002 in patient populations who have a high unmet medical need, including patients with heterozygous familial hypercholesterolemia (HeFH), or clinical atherosclerotic cardiovascular disease (ASCVD), who are already taking maximally tolerated statins yet require additional LDL-C reduction and where there is a positive benefit/risk ratio. Based on feedback from the FDA, approval of ETC-1002 in the HeFH and ASCVD patient populations will not require the completion of a cardiovascular outcomes trial (CVOT). The Company continues to plan and initiate a CVOT prior to NDA filing to pursue broader label indications related to cardiovascular disease risk reduction.

Esperion remains on track to initiate the ETC-1002 Phase 3 development program by the end of 2015. The program will support a proposed label indication for the use of ETC-1002, an oral, once-daily LDL-C lowering therapy, "as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH), or atherosclerotic cardiovascular disease (ASCVD), who require additional lowering of LDL-C." Approximately nine million patients in the U.S. fall into these two combined categories.

The ETC-1002 Phase 3 development program will include clinical studies in patients with ASCVD and HeFH. The study designs will be finalized once minutes from the FDA meeting are received. The Company plans to continue to evaluate ETC-1002 as an add-on to statins, including at all doses.

In the fourth quarter, Esperion plans to finalize development plans for the fixed-dose combination of ETC-1002 and ezetimibe and will file a separate Investigational New Drug (IND) application with the FDA.

"After an informative and collegial meeting with the FDA, we are pleased that LDL-C remains an accepted clinical surrogate endpoint for the approval of an LDL-C lowering therapy such as ETC-1002 in patients with HeFH and/or patients with ASCVD," said Tim M. Mayleben, president and chief executive officer of Esperion. "We have a clear regulatory path forward for development and approval of ETC-1002, an oral, once-daily treatment option for these patients that require additional LDL-C lowering."

Conference Call and Webcast Information

Esperion's management will host a conference call to discuss these updates. The call can be accessed by dialing (877) 831-3840 (domestic) or (253) 237-1184 (international) five minutes prior to the start of the call and providing access code 15397722. A live, listen-only webcast of the conference call can be accessed on the investor relations section of the Esperion website at investor.esperion.com. A webcast replay of the call will be available approximately two hours after completion of the call and will be archived on the Company's website for two weeks.

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 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), one product candidate entering into clinical evaluation (a fixed-dose combination of ETC-1002 and ezetimibe), as well as two preclinical product candidates.

About Esperion Therapeutics

Esperion Therapeutics, Inc. is an emerging pharmaceutical company focused on developing and commercializing first-in-class, oral, LDL-C lowering therapies for the treatment of patients with hypercholesterolemia. ETC-1002 (bempedoic acid), the Company's lead product candidate, is an inhibitor of ATP Citrate Lyase, a well-characterized enzyme on the cholesterol biosynthesis pathway; the same pathway that includes HMG-CoA reductase, the enzyme target of statins. ETC-1002 and statins have a similar mechanism of action, inhibiting cholesterol biosynthesis, decreasing intracellular cholesterol, up-regulating LDL-receptors, and causing increased LDL-C clearance and reduced plasma levels of LDL-C. 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 and the fixed-dose combination of ETC-1002 and ezetimibe. 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 FDA may require additional studies or data prior to approval that might cause approval to be delayed, that Esperion may need to change the design of its Phase 3 program once final minutes from the FDA meeting are received, that positive results from a clinical study of ETC-1002 and the fixed-dose combination of ETC-1002 and ezetimibe may not necessarily be predictive of the results of future clinical studies, particularly in different or larger patient populations, or in all statin doses, including high doses, or the risk that other unanticipated developments or data could interfere with the scope of development and commercialization of ETC-1002 and the fixed-dose combination of ETC-1002 and ezetimibe, 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. 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.

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