Esperion Provides Lipid Management Franchise Updates; Reports Fourth Quarter and Full Year 2019 Financial Results

February 27, 2020

ANN ARBOR, Mich., Feb. 27, 2020 (GLOBE NEWSWIRE) -- Esperion (NASDAQ:ESPR) today provided lipid management franchise updates and financial results for the fourth quarter and year ended December 31, 2019.

“2019 was a precedent setting year for our Lipid Management Team highlighted by the January E.U. commercial collaboration with Daiichi-Sankyo Europe (DSE), our February submissions for marketing approvals of bempedoic acid and the bempedoic acid / ezetimibe combination tablet in both the U.S. and E.U., publications and presentations in top-tier journals and medical meetings throughout the year, and fully enrolling our CLEAR Outcomes Trial in August,” said Tim M. Mayleben, president and chief executive officer of Esperion. “2020 has already been transformative for Esperion, with the recent NEXLETOL™ (bempedoic acid) tablet and NEXLIZET™ (bempedoic acid and ezetimibe combination) tablet approvals in the U.S., as well as positive CHMP opinions in the E.U.”

Recent Highlights

November 2019:

- A presentation of pooled analyses from the Phase 3 LDL-cholesterol lowering development program of NEXLETOL™ was presented at the American Heart Association 2019 Scientific Sessions.
- Publication of NEXLETOL™ Study 2 (1002-047) results in *The Journal of American Medical Association (JAMA)*.

January 2020:

- Positive opinions from the Committee for Medicinal Products (CHMP) for Human Use of the European Medicines Agency (EMA) for the marketing authorisation applications (MAAs) for both bempedoic acid and the bempedoic acid / ezetimibe fixed dose combination tablets, recommending approval for the treatment of hypercholesterolemia and mixed dyslipidemia.

February 2020:

- Approvals by the Food Drug Administration (FDA) for NEXLETOL™ and NEXLIZET™.

Upcoming Milestones

March:

- Three data presentations from the LDL-cholesterol lowering development program of NEXLETOL™ and NEXLIZET™ to be presented at American College of Cardiology 2020 Scientific Sessions.
- U.S. commercial launch of NEXLETOL™ on March 30, 2020.

Second Quarter:

- European Commission decisions anticipated for both bempedoic acid and the bempedoic acid / ezetimibe combination tablets Marketing Authorisation Applications (MAAs).
- Potential Rest-of-World (ROW) development and commercial collaboration agreement(s) in April.

Third Quarter:

- U.S. commercial launch of NEXLIZET™ in July.
- $150 million milestone payment from Daiichi Sankyo Europe.

2020 Financial Outlook

Esperion expects $175 million in cash proceeds from the Daiichi Sankyo Europe and Oberland Capital agreements, $150 million and $25 million, respectively. This amount does not include U.S. product sales, for which Esperion will not provide revenue guidance in 2020, E.U. royalties or upfront and/or milestone payment(s) from a potential ROW agreement.

Research and development expenses for the full year 2020 are expected to be $145 million to $155 million. Selling, general and administrative expenses for the full year 2020 are expected to be $225 million to $235 million. These amounts do not include $30 million in non-cash stock-based compensation. The increase in expected operating expenses are primarily related to the anticipated commercialization activities for NEXLETOL™ and NEXLIZET™.

Esperion expects that current cash resources, coupled with expected milestone payments under the Daiichi Sankyo Europe licensing agreement and

the Oberland Capital revenue-based funding agreement, and NEXLETOL™ and NEXLIZET™ commercial net product sales are sufficient to fund operations through profitability.

2019 Fourth Quarter and Full-Year Financial Results

As of December 31, 2019, cash, cash equivalents, restricted cash and investment securities available-for-sale totaled $201.7 million compared with $136.3 million at December 31, 2018.

Revenue was $1.0 million for the fourth quarter of 2019 and $148.4 million for the year ended December 31, 2019, compared to $0.0 million for the comparable periods in 2018. Revenue was primarily attributable to the initial recognition of the upfront payment from the Daiichi Sankyo Europe collaboration agreement.

Research and development expenses were $38.2 million for the fourth quarter of 2019 and $175.6 million for the year ended December 31, 2019, compared to $49.5 million and $171.5 million for the comparable periods in 2018. The increase was primarily attributable to clinical development costs for bempedoic acid, including costs to support the ongoing CLEAR Outcomes Trial, commercial product manufacturing supply, regulatory submission activities and increases in our headcount.

General and administrative expenses were $21.7 million for the fourth quarter of 2019 and $65.9 million for the year ended December 31, 2019, compared to $11.2 million and $33.1 million for the comparable periods in 2018. The increase was primarily attributable to costs to support pre-commercialization activities, support public company operations, further increases in our headcount and stock-based compensation expense, and other costs to support our growth.

Esperion had a net loss of $61.9 million for the fourth quarter of 2019 and a net loss of $97.2 million for the year ended December 31, 2019, compared to a net loss of $60.0 million and a net loss of $201.8 million for the comparable periods in 2018. Esperion had a net loss per share of $2.26 for the fourth quarter of 2019 and $3.59 for the year ended December 31, 2019, compared to $2.24 and $7.54 for the comparable periods in 2018.

Esperion had approximately 27.5 million shares of common stock outstanding, with another 4.9 million issuable upon exercise of stock options and vesting of restricted stock units, and $132.5 million of the revenue interest liability outstanding as of December 31, 2019.

NEXLETOL™ (bempedoic acid) Tablet

NEXLETOL is a first-in-class ATP Citrate Lyase (ACL) inhibitor that lowers LDL-C by reducing cholesterol biosynthesis and up-regulating the LDL receptors. Completed Phase 3 studies conducted in more than 3,000 patients, with over 2,000 patients treated with NEXLETOL, demonstrated an average 18 percent placebo corrected LDL-C lowering when used in patients on moderate or high-intensity statins. NEXLETOL was approved by the FDA in February 2020.

Indication and Limitation of Use
NEXLETOL is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. The effect of NEXLETOL on cardiovascular morbidity and mortality has not been determined.

Important Safety Information

• Warnings and Precautions:

- Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate. The risk for gout events with NEXLETOL™ (bempedoic acid) tablet was higher in patients with a prior history of gout although gout also occurred more frequently than placebo in patients treated with NEXLETOL™ (bempedoic acid) tablet who had no prior gout history.
- Tendon rupture has occurred. Discontinue NEXLETOL™ (bempedoic acid) tablet at the first sign of tendon rupture. Avoid NEXLETOL™ (bempedoic acid) tablet in patients who have a history of tendon disorders or tendon rupture.

• Adverse Reactions:

- The most common (incidence ≥ 2% and greater than placebo) adverse reactions are upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia and elevated liver enzymes.

• Drug Interactions:

- Avoid concomitant use of NEXLETOL with simvastatin greater than 20 mg.
- Avoid concomitant use of NEXLETOL with pravastatin greater than 40 mg.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 or report side effects to Esperion at 833-377-7633 (833 ESPRMED).

Click here to see the full prescribing information for NEXLETOL™ (bempedoic acid) tablet.

NEXLIZET™ (bempedoic acid and ezetimibe) Tablet

NEXLIZET contains bempedoic acid and ezetimibe and lowers elevated LDL-C through complementary mechanisms of action by inhibiting cholesterol synthesis in the liver and absorption in the intestine. Phase 3 data demonstrated NEXLIZET lowered LDL-C by a mean of 38 percent compared to placebo when added on to maximally tolerated statins. NEXLIZET was approved by the FDA in February 2020.

Indication and Limitation of Use
NEXLIZET is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. The effect of NEXLIZET on cardiovascular morbidity and mortality has not been determined.

• Contraindications:

- Known hypersensitivity to ezetimibe tablets.

• Warnings and Precautions:

- Elevations in serum uric acid have occurred. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate. The risk for gout events with NEXLIZET was higher in patients with a prior history of gout although gout also occurred more frequently than placebo in patients treated with NEXLIZET who had no prior gout history.
- Tendon rupture has occurred. Discontinue NEXLIZET at the first sign of tendon rupture. Avoid NEXLIZET in patients who have a history of tendon disorders or tendon rupture.

• Adverse Reactions:

- The most common adverse events reported in the development program were generally reported at similar rates in patients who received placebo (incidence ≥ 2% and greater than placebo) were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, elevated liver enzymes, diarrhea, arthralgia, sinusitis fatigue, influenza.

• Drug Interactions:

- Simvastatin: Avoid concomitant use of NEXLIZET with simvastatin great than 20 mg.
- Pravastatin: Avoid concomitant use of NEXLIZET with pravastatin greater than 40 mg.
- Cyclosporine: Monitor cyclosporine concentrations.
- Fibrates: If cholelithiasis is suspected in a patient receiving NEXLIZET and fenofibrate, consider alternative lipid-lowering therapy.

Please see the full Prescribing Information for NEXLIZET by clicking here.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088 or report side effects to Esperion at 833-377-7633 (833 ESPRMED).

CLEAR Cardiovascular Outcomes Trial

The effect of NEXLETOL or NEXLIZET on cardiovascular morbidity and mortality has not been determined. Esperion initiated a global cardiovascular outcomes trial (CVOT) to assess the effects of bempedoic acid on the occurrence of major cardiovascular events in patients with, or at high risk for, cardiovascular disease (CVD) who are only able to tolerate less than the lowest approved daily starting dose of a statin and are considered "statin averse." The CVOT — known as CLEAR Cardiovascular Outcomes Trial — is an event-driven, global, randomized, double-blind, placebo-controlled study that completed enrollment in August 2019 of 14,032 patients with hypercholesterolemia and high CVD risk at over 1,400 sites in 32 countries.

Esperion Therapeutics

Through scientific and clinical excellence, and a deep understanding of cholesterol biology, the experienced Lipid Management Team at Esperion is committed to developing new LDL-C lowering medicines that will make a substantial impact on reducing global cardiovascular disease, the leading cause of death around the world. For more information, please visit www.esperion.com and follow us on Twitter at www.twitter.com/EsperionInc.

Esperion Therapeutics' Commitment to Patients with Hyperlipidemia

High levels of LDL-C can lead to a build-up of fat and cholesterol in and on artery walls (known as atherosclerosis), potentially leading to cardiovascular events, including heart attack and stroke. In the U.S., 96 million people, or more than 37 percent of the adult population, have elevated LDL-C. There are approximately 18 million people in the U.S. living with elevated levels of LDL-C despite taking maximally tolerated lipid-modifying therapy — including individuals considered statin averse — leaving them at high risk for cardiovascular events1. In the United States, more than 50 percent of atherosclerotic cardiovascular disease (ASCVD) patients and heterozygous familial hypercholesterolemia (HeFH) patients who are not able to reach their guideline recommended LDL-C levels with statins alone need less than a 40 percent reduction to reach their LDL-C threshold goal[2].

Esperion's mission as the Lipid Management Company is to deliver oral, once-daily medicines that complement existing oral drugs to provide the additional LDL-C lowering that these patients need.

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 regulatory approval pathway for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, the therapeutic potential of, and the clinical development plan for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe combination fixed dose tablet, timing for the review and approval of the NDAs and the MAAs, and Esperion's expectations for the market for medicines to lower LDL-C, including the commercial launch and market adoption of bempedoic

acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, if approved. 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, delays or failures in Esperion's studies, that positive results from a clinical study of bempedoic acid may not be sufficient for EMA approval or necessarily be predictive of the results of future or ongoing clinical studies, that notwithstanding the completion of Esperion's Phase 3 clinical development program for LDL-C lowering, the FDA or EMA require additional development in connection with seeking regulatory approval, or approval of an expanded indication, that existing cash resources may be used more quickly than anticipated, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. 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.

References

(1) Esperion market research on file: research project interviewing 350 physicians. Esperion Therapeutics, Inc. Sept-Oct 2018.

(2) Data on file: analysis of NHANES database. Esperion Therapeutics, Inc. 2018.

Esperion Therapeutics, Inc.

Balance Sheet Data
(In thousands)
(Unaudited)

	December 31, 2019	December 31, 2018
Cash and cash equivalents	$ 166,130	$ 36,973
Working capital	145,634	78,299
Investments	34,651	99,293
Restricted cash	928	—
Total assets	214,447	143,451
Revenue interest liability	132,544	—
Common stock	27	27
Accumulated deficit	(695,266)	(598,101)
Total stockholders' equity	19,950	79,118

Esperion Therapeutics, Inc.

Statement of Operations
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2019	2018	2019	2018
Revenues:				
Collaboration revenue	$ 982	$ —	$ 148,364	$ —
Total Revenues	982	—	148,364	—
Operating expenses:				
Research and development	$ 38,234	$ 49,473	$ 175,611	$ 171,488
General and administrative	21,712	11,176	65,854	33,097
Total operating expenses	59,946	60,649	241,465	204,585
Loss from operations	(58,964)	(60,649)	(93,101)	(204,585)
Interest expense	(4,124)	—	(8,120)	(28)
Other income, net	1,142	610	4,056	2,803
Net loss	$ (61,946)	$ (60,039)	$ (97,165)	$ (201,810)
Net loss per common share - basic and dilutive	$ (2.26)	$ (2.24)	$ (3.59)	$ (7.54)

Weighted average shares outstanding – basic and dilutive	27,371,067	26,818,331	27,090,284	26,754,308

Investor Contact:
Alex Schwartz
Esperion
734-249-3386
aschwartz@esperion.com

Media Contact:
Ben Church
Esperion
734-864-6774
bchurch@esperion.com