Esperion Reaches Settlement Agreement with Second ANDA Filer Not to Market Generic Version of NEXLETOL® (bempedoic acid) Prior to April 19, 2040

June 2, 2025

ANN ARBOR, Mich., June 02, 2025 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced that it has entered into a settlement agreement with Hetero USA, Inc. and its affiliates Hetero Labs Limited, Hetero Labs Limited Unit-V, and Honour Lab Limited (together, Hetero USA). This agreement resolves the patent litigation brought by Esperion against Hetero USA in response to Hetero USA' s Abbreviated New Drug Application (ANDA) seeking approval to market a generic version of NEXLETOL prior to the expiration of the applicable patents. Pursuant to the agreement, Hetero USA has agreed not to market a generic version of NEXLETOL in the United States prior to April 19, 2040, unless certain limited circumstances customarily included in these types of agreements occur.

The pending patent litigation against the remaining defendants (Accord Healthcare Inc; Alkem Laboratories Ltd.; Aurobindo Pharma Limited (along with an affiliate); Dr. Reddy's Laboratories Inc. (along with an affiliate); MSN Pharmaceuticals Inc. (along with an affiliate); Renata Limited; and Sandoz Inc.) is ongoing, and there can be no assurance whether such ongoing patent litigation will allow a generic version of NEXLETOL and/or NEXLIZET, as applicable, to be marketed in the U.S. prior to April 19, 2040.

About Esperion Therapeutics
Esperion Therapeutics, Inc. is a commercial stage biopharmaceutical company focused on bringing new medicines to market that address unmet needs of patients and healthcare professionals. The Company developed and is commercializing the only U.S. Food and Drug Administration (FDA) approved oral, once-daily, non-statin medicines for patients who are at risk for cardiovascular disease and are struggling with elevated low density lipoprotein cholesterol (LDL-C). These medications are supported by the nearly 14,000 patient CLEAR Cardiovascular Outcomes Trial. Esperion continues to build on its success with its next generation program which is focused on developing ATP citrate lyase inhibitors (ACLYi). New insights into the structure and function of ACLYi fully enables rational drug design and the opportunity to develop highly potent and specific inhibitors with allosteric mechanisms.

Esperion continues to evolve into a leading global biopharmaceutical company through commercial execution, international partnerships and collaborations and advancement of its pre-clinical pipeline. For more information, visit esperion.com and follow Esperion on LinkedIn and X.

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 pending patent litigation and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "suggest," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions. 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 net sales, profitability, and growth of Esperion's commercial products, clinical activities and results, supply chain, commercial development and launch plans, the outcomes and anticipated benefits of legal proceedings and settlements, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. Any forward-looking statements contained in this press release speak only as of the date hereof, and 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.

Esperion Contact Information:
Investors:
Alina Venezia
investorrelations@esperion.com
(734) 887-3903

Media:
Tiffany Aldrich
corporateteam@esperion.com
(616) 443-8438