# Esperion Aligns with U.S. Food and Drug Administration to Initiate Phase 3 Clinical Trials of Bempedoic Acid in Pediatric Heterozygous and Homozygous Familial Hypercholesterolemia

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*– Confirms Sufficient Data to Complete Phase 2 Clinical Study Enrollment and Advance to Phase 3 Studies in Both Heterozygous and Homozygous Familial Hypercholesterolemia –*

*– Establishes Pediatric Path Forward to Start and Complete Phase 3 Trial and Secure Additional Six-Month Patent Extension Through June 2031 –*

ANN ARBOR, Mich., March 20, 2025 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced that following meetings with the U.S. Food and Drug Administration (FDA), it has gained alignment on a regulatory path forward for initiating Phase 3 studies of bempedoic acid alone and in combination with ezetimibe in pediatric patients with heterozygous and homozygous familial hypercholesterolemia (HeFH and HoFH, respectively). Based on these discussions with the FDA, the Company plans to initiate Phase 3 clinical studies this year. The FDA previously granted orphan drug designation for bempedoic acid in HoFH indication.

“We are delighted to further advance the development of bempedoic acid for children with familial hypercholesterolemia (FH) and are pleased the FDA has indicated that we have adequate data to proceed into Phase 3 clinical trials,” stated Sheldon Koenig, President and CEO of Esperion. “In addition, this alignment supports our commitment to broaden the reach of our bempedoic acid products as part of our lifecycle management plan, providing the opportunity to extend our patent protection for an additional six months for these important therapies,” added Sheldon Koenig.

**About CLEAR Path 2 and CLEAR Path 3 Studies**
CLEAR Path 2 (in children with HeFH) and CLEAR Path 3 (in children with HoFH) are Phase 3, randomized double-blind, placebo-controlled, multicenter studies to evaluate the efficacy and safety of bempedoic acid with and without concurrent ezetimibe in children with HeFH or HoFH and LDL-C ≥130 mg/dL (3.4 mmol/L) while on protocol defined optimum dose of a statin. Each study is a 52-week design where patients will be randomized 2:1 to treatment or control for 24 weeks, followed by 28 weeks of an open-label extension period.

**About Heterozygous Familial Hypercholesterolemia (HeFH) and Homozygous FH (HoFH)**
HeFH and HoFH are the two types of FH, a genetic condition that causes high cholesterol from birth and if untreated leads to early, aggressive atherosclerotic cardiovascular disease. HeFH is the more common form occurring in 1 in 250 births and results from inheriting a gene that causes FH from one parent. If left untreated, cardiovascular disease can develop during middle adulthood. HoFH is the rarer form of the disease, an orphan indication, occurring in 1 in 300,000 births and results from inheriting a FH gene from both parents. HoFH results in higher cholesterol levels, which are often more difficult to treat as cardiovascular disease can begin as early as in childhood if untreated. In both HeFH and HoFH, the processing of LDL-C is disrupted due to these gene mutations, which leads to dangerously high levels of LDL-C. Both HeFH and HoFH are underdiagnosed and undertreated but with early detection and continued development of LDL-C therapies for patients starting at an early age, there is hope that patients with FH can control their LDL cholesterol and reduce their risk of cardiovascular disease.

**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 marketing strategy and commercialization plans, current and planned operational expenses, future operations, commercial products, clinical development, including the timing, designs and plans for the CLEAR Outcomes study and its results, plans for potential future product candidates, financial condition and outlook, including expected cash runway, 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.

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