Otsuka Submits New Drug Application in Japan for Bempedoic Acid in the Treatment of Hypercholesterolemia

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ANN ARBOR, Mich., Nov. 26, 2024 (GLOBE NEWSWIRE) -- Esperion (NASDAQ: ESPR) today announced that Otsuka Pharmaceutical Co., Ltd. (Otsuka) has submitted a New Drug Application (NDA) to the Japanese Ministry of Health, Labour and Welfare for the manufacture and sale of bempedoic acid in Japan for the treatment of hypercholesterolemia and familial hypercholesterolemia.

Bempedoic acid has a novel mechanism of action that inhibits a cholesterol synthesis pathway by acting on ATP (adenosine triphosphate) citrate lyase, a citrate-degrading enzyme in the liver. Bempedoic acid is marketed for the treatment of hypercholesterolemia in several regions around the world, including the United States and Europe. In 2020, Otsuka acquired exclusive development and commercialization rights for bempedoic acid in Japan from Esperion and is currently developing it domestically.

The Japanese Phase 3 trial was conducted as a placebo-controlled, randomized, multicenter, double-blind, parallel-group comparative study, in 96 patients with high LDL cholesterol and in whom statins have insufficient effect or cannot be tolerated. Trial participants were administered either 180 mg of bempedoic acid or a placebo, orally, once a day, for 12 weeks to evaluate the efficacy and safety of bempedoic acid. In the preliminary results, the percentage change from baseline in LDL-C at Week 12, the primary endpoint, was -25.25 percent in the group receiving bempedoic acid group and -3.46 percent in the placebo group, demonstrating positive outcomes with statistical significance compared to placebo ($p<0.001$). Furthermore, the safety and tolerability of bempedoic acid were consistent with findings from previous trials, and no serious adverse events were observed.

Some patients with hypercholesterolemia are unable to achieve their target values even when taking statins (insufficient response to statins), or they are unable to continue taking statins due to the occurrence of adverse events associated with statin use (statin intolerance). This drug candidate in Japan is expected to become a new treatment option for hypercholesterolemic patients with insufficient response to statins or statin intolerance.

IMPORTANT SAFETY INFORMATION

NEXLIZET and NEXLETOL are contraindicated in patients with a prior hypersensitivity to bempedoic acid or ezetimibe or any of the excipients. Serious hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported.

Hyperuricemia: Bempedoic acid, a component of NEXLIZET and NEXLETOL, may increase blood uric acid levels, which may lead to gout. Hyperuricemia may occur early in treatment and persist throughout treatment, returning to baseline following discontinuation of treatment. Assess uric acid levels periodically as clinically indicated. Monitor for signs and symptoms of hyperuricemia, and initiate treatment with urate-lowering drugs as appropriate.

Tendon Rupture: Bempedoic acid, a component of NEXLIZET and NEXLETOL, is associated with an increased risk of tendon rupture or injury. Tendon rupture may occur more frequently in patients over 60 years of age, in those taking corticosteroid or fluoroquinolone drugs, in patients with renal failure, and in patients with previous tendon disorders. Discontinue NEXLIZET or NEXLETOL at the first sign of tendon rupture. Consider alternative therapy in patients who have a history of tendon disorders or tendon rupture.

The most common adverse reactions in the primary hyperlipidemia trials of bempedoic acid, a component of NEXLIZET and NEXLETOL, in ≥2% of patients and greater than placebo were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes.

Adverse reactions reported in ≥2% of patients treated with ezetimibe (a component of NEXLIZET) and at an incidence greater than placebo in clinical trials were upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity, fatigue, and influenza.

In the primary hyperlipidemia trials of NEXLIZET, the most commonly reported adverse reactions (incidence ≥3% and greater than placebo) observed with NEXLIZET, but not observed in clinical trials of bempedoic acid or ezetimibe, were urinary tract infection, nasopharyngitis, and constipation.

The most common adverse reactions in the cardiovascular outcomes trial for bempedoic acid, a component of NEXLIZET and NEXLETOL, at an incidence of ≥2% and 0.5% greater than placebo were hyperuricemia, renal impairment, anemia, elevated liver enzymes, muscle spasms, gout, and cholelithiasis.

Discontinue NEXLIZET or NEXLETOL when pregnancy is recognized unless the benefits of therapy outweigh the potential risks to the fetus. Because of the potential for serious adverse reactions in a breast-fed infant, breastfeeding is not recommended during treatment with NEXLIZET or NEXLETOL.

Report pregnancies to Esperion Therapeutics, Inc. Adverse Event reporting line at 1-833-377-7633.

Please see full Prescribing Information for NEXLIZET and NEXLETOL.

Esperion Therapeutics

At Esperion, we discover, develop, and commercialize innovative medicines to help improve outcomes for patients with or at risk for cardiovascular and cardiometabolic diseases. The status quo is not meeting the health needs of millions of people with high cholesterol – that is why our team of passionate industry leaders is breaking through the barriers that prevent patients from reaching their goals. Providers are moving toward reducing LDL-cholesterol levels as low as possible, as soon as possible; we provide the next steps to help get patients there. Because when it comes to high cholesterol, getting to goal is not optional. It is our life's work. For more information, visit esperion.com and esperionscience.com and follow us on X at

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 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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