

First-in-class cholesterol-lowering treatment NILEMDO®* (bempedoic acid) tablet and its combination with ezetimibe NUSTENDI®* (bempedoic acid and ezetimibe) tablet approved in Switzerland

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- NILEMDO® (bempedoic acid) is the first oral, once-daily treatment approved in almost two decades to lower low-density lipoprotein cholesterol (LDL-C) for indicated patients -
- Bempedoic acid and its fixed combination drug product with ezetimibe both deliver significant reductions in LDL-C when added to a statin or other lipid-lowering therapies^{1,2} -
- Two-thirds of patients in Switzerland with very high cardiovascular risk do not achieve LDL-C target values set out by the European Society of Cardiology,³ indicating a need for additional treatment options -

MUNICH, Germany, and ANN ARBOR, Mich., Dec. 16, 2020 (GLOBE NEWSWIRE) -- Daiichi Sankyo Europe GmbH (hereafter, 'Daiichi Sankyo') and Esperion Therapeutics (NASDAQ: ESPR) announced today Swissmedic approval for NILEMDO®* (bempedoic acid) tablet and NUSTENDI®* (bempedoic acid and ezetimibe) tablet, offering new treatment options for people with high low-density lipoprotein cholesterol (LDL-C) in Switzerland.

Bempedoic acid is the first oral, once-daily treatment option approved in the last two decades for patients who have difficulty reaching their cholesterol-lowering goals. In a recent observational study, two-thirds of patients in Switzerland with very high cardiovascular risk did not achieve LDL-C target values set out by the European Society of Cardiology.³ Patients who do not reach their LDL-C lowering goals are at increased risk for heart attack and stroke.⁴ Diagnosis of high cholesterol has increased among older adults in Switzerland in the past 20 years.⁵

"Cardiovascular disease remains a leading cause of death in Switzerland. In 2017 it accounted for over 30% of deaths across the country, highlighting a critical need for new treatment options for the many people who are having difficulty reaching their LDL-C goals with existing lipid-lowering therapies," said Dr. Lucas Schalch, Country Manager at Daiichi Sankyo Switzerland. "Today's approval of NILEMDO® and NUSTENDI® is a pivotal milestone for patients in secondary prevention, offering them new, convenient treatment options and demonstrating another step forward in our commitment to reduce the risk of atherosclerotic cardiovascular disease."

"Bempedoic acid is a first-in-class adenosine triphosphate-citrate lyase (ACL) inhibitor that lowers LDL-C by inhibiting cholesterol synthesis in the liver. This unique mechanism of action allows it to work alongside existing treatments," said Ashley Hall, Chief Development Officer of Esperion. "Our focus is finding convenient, affordable ways for appropriate patients to manage LDL-C. That is why we also developed a single-tablet combination of bempedoic acid and ezetimibe, to help reduce pill burden."

Bempedoic acid and its fixed combination drug product with ezetimibe were approved in the European Union and the United States earlier this year with different labels and indications.^{1,6,7,8} In Europe, the products are marketed as NILEMDO® and NUSTENDI®, and in the U.S. as NEXLETOL® and NEXLIZET® (respectively).^{1,6,7,8} The Esperion team discovered and developed bempedoic acid, drawing on its deep expertise in developing cholesterol-lowering medicines. With strong commercial capabilities, particularly in cardiovascular medicine, Daiichi Sankyo has licensed exclusive commercialization rights to bempedoic acid and the fixed combination drug product of bempedoic acid and ezetimibe in the European Economic Area, Turkey and Switzerland from Esperion. Marketing Authorization for both products in Switzerland will be transferred to Daiichi Sankyo.

Swissmedic approved bempedoic acid for the treatment of adults with clinically manifesting atherosclerotic cardiovascular disease (ASCVD) or heterozygous familial hypercholesterolaemia (HeFH) who need additional LDL-C lowering, as an adjunct to diet and in combination with the maximum tolerated dose of a statin with or without other lipid-lowering therapies.⁹ The fixed combination drug product of bempedoic acid and ezetimibe is indicated as an adjunct to diet in adults with clinically manifesting ASCVD or HeFH for patients unable to reach LDL-C goals with the maximum tolerated dose of a statin combined with ezetimibe or bempedoic acid, or patients already being treated with the combination of bempedoic acid and ezetimibe as separate tablets.¹⁰ Both approvals were supported by data from the CLEAR trial program, which included more than 3,600 high- and very-high-risk patients.^{9,10} The effect of bempedoic acid on cardiovascular morbidity and mortality is currently being investigated in 14,014 patients across 32 countries as part of the CLEAR Outcomes study.¹¹

Bempedoic acid was generally well-tolerated in clinical studies. The most commonly reported adverse reactions with bempedoic acid during pivotal trials were hyperuricaemia, pain in extremity and anaemia. The majority of adverse reactions reported with bempedoic acid were mild to moderate in severity and balanced in occurrence with adverse events in patients receiving placebo.^{1,6-10}

Daiichi Sankyo

Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical therapies to improve standards of care and address diversified, unmet medical needs of people globally by leveraging our world-class science and technology. With more than 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 15,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for cardiovascular diseases, under the Group's 2025 Vision to become a "Global Pharma Innovator with Competitive Advantage in Oncology," Daiichi Sankyo is primarily focused on providing novel therapies in oncology, as well as other research areas centred around rare diseases and immune disorders. For more information, please visit: www.daiichisankyo.com.

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.

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 Esperion's commercialization plans for bempedoic acid tablet, its expectations for the market for medicines to lower LDL-C and the impact of bempedoic acid tablet in such market, including the commercial launch and the market adoption of bempedoic acid tablet in the United States and European Union. 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 clinical development and commercialization plans, or approval of expanded indications, that existing cash resources may be used more quickly than anticipated, the impact of COVID-19 on our business, clinical activities and commercial development plans, 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.

References

* This medicinal product is subject to additional monitoring in the European Union

(1) European Medicines Agency. NILEMDO[®] Summary of Product Characteristics. 27 Nov 2020: https://www.ema.europa.eu/en/documents/product-information/nilemdo-epar-product-information_en.pdf.

(2) Pinkosky SL, et al. Liver- specific ATP-citrate lyase inhibition by bempedoic acid decreases LDL-C and attenuates atherosclerosis. *Nature Communications*. 2016; 7:13457. DOI:10.1038/ncomms13457.

(3) Rachamin Yael, et al. "Statin treatment and LDL target value achievement in Swiss general practice – a retrospective observational study," 27 May 2020. *Swiss Med Wkly*. 2020;150:w20244: <https://smw.ch/article/doi/smw.2020.20244>

(4) WHO. Cardiovascular diseases (CVDs) Factsheet. 2017. Available online at: [https://www.who.int/en/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](https://www.who.int/en/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds)). Last accessed December 2020.

(5) Swiss Federation Federal Statistical Office report, Gesundheitsstatistik 2019, 29 Oct 2019: <https://www.bfs.admin.ch/bfsstatic/dam/assets/10227275/master>.

(6) European Medicines Agency. NUSTENDI[®] Summary of Product Characteristics. 27 Nov 2020: https://www.ema.europa.eu/en/documents/product-information/nustendi-epar-product-information_en.pdf.

(7) U.S. Food and Drug Administration. NEXLETOL[®] Prescribing Information. 27 Nov 2020: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211616s000lbl.pdf.

(8) U.S. Food and Drug Administration. NEXLIZET[®] Prescribing Information. 27 Nov 2020: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/211617s000lbl.pdf.

(9) Swissmedic. NILEMDO[®] (bempedoic acid) Product Information for Human Medicinal Products. December 2020.

(10) Swissmedic. NUSTENDI[®] (bempedoic acid and ezetimibe) Product Information for Human Medicinal Products. December 2020.

(11) Stephen J Nicholls et al, Rationale and design of the CLEAR-outcomes trial: Evaluating the effect of Bempedoic acid on cardiovascular events in patients with statin intolerance, *American Heart Journal* (2020), <https://doi.org/10.1016/j.ahj.2020.10.060>

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