CLEAR OUTCOMES

USE OF BEMPEDOIC ACID IN PATIENTS WITH, OR AT HIGH RISK FOR, CARDIOVASCULAR DISEASE

INDICATION¹

Bempedoic acid (NEXLETOL®) is indicated:

- To reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) and with:
 - o established cardiovascular disease (CVD), or
 - o at high risk for a CVD event but without established CVD.
- As an adjunct to diet, in combination with other LDL-C lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including HeFH.

Please see accompanying full Prescribing Information.

Study Design & Methodology^{2,3}

13,970 patients aged 18-85 years and LDL-C levels ≥ 100 mg/dL, with, or at high risk for, CVD, not receiving recommended statin therapy

Randomized 1:1

Double-blind

Bempedoic acid 180mg QD (n = 6992)

Enrollment: December 2016—August 2019 Median Follow-Up: 40.6 months³

Placebo QD (n = 6978)

Patients without established CVD were considered at high risk for CVD based on meeting at least one of the following criteria:

- Type 1 or 2 diabetes in women >65 or men >60 years of age
- Reynolds Risk score >30% **OR** SCORE risk >7.5% over 10 years
- Any previous Coronary artery calcium score of > 400 AU

Patients **with established CVD** had documented history of at least one of the following:

- coronary artery disease
- symptomatic peripheral arterial disease
- cerebrovascular atherosclerotic disease

Select Baseline Demographics³



LDL-C 139 mg/dL



48% Women



30% Primary
Prevention
(at high risk for CVD)



70% Secondary
Prevention
(with CVD)

*Numbers presented represent patients enrolled in both bempedoic acid and placebo groups

Summary of Safety¹

NEXLETOL is contraindicated in patients with a prior serious hypersensitivity reaction to bempedoic acid or any of the excipients. Serious hypersensitivity reactions, such as angioedema, have occurred.

Hyperuricemia: 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: NEXLETOL is associated with an increased risk of tendon rupture or injury. Tendon rupture may occur more frequently in patients with previous tendon rupture, fluoroquinolone use, corticosteroid use, and over 60 years of age. Discontinue 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 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.

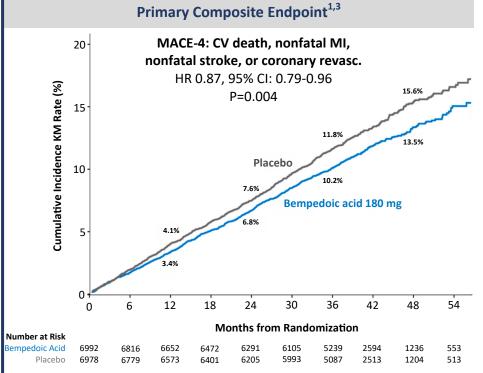
References: 1. NEXLETOL® (bempedoic acid) US Full Prescribing Information. Esperion Therapeutics, Inc. 2. Nicholls SJ, et al. Am Heart J. 2021;235:104-112. 3. Nissen SE, et al. N Engl J Med. 2023;388(15):1353-1364.

Abbreviations: Abbreviations: AE= adverse event; ASCVD= atherosclerotic cardiovascular disease; AU= Agatston units; CVD cardiovascular disease;; LDL-C= low density lipoprotein; HCP= health care provider; PCSK9= proprotein convertase subtilisin/kexin type 9; QD= daily

Esperion Therapeutics, Inc. MED-US-BA-2400012 Last revision: 15 MAR 2024

Results³

At 6 months, LDL-C was reduced by -20% (95% CI: -21%, -19%) with bempedoic acid compared to placebo.



Note: This Kaplan Meier (KM) Curve presents the time to first occurrence for each of the components of MACE-4.

MACE-3 and Components of Primary Composite Endpoint³ MACE-3 HR 0.85 (95% CI: 0.76 - 0.96) 575 8.2% Non-fatal MI HR 0.73 (95% CI: 0.62 - 0.87) 236 3.4% Coronary revascularization 7.6% HR 0.81 (95% CI: 0.72 - 0.92) 6.2% Non-fatal stroke HR 0.82 (95% CI: 0.64 - 1.05) Placebo Bempedoic Acid Cardiovascular death HR 1.04 (95% CI: 0.88 - 1.24) 269 0.0% 2.0% 4.0% 8.0% 10.0% 6.0%

Summary of Safety¹

The most common adverse reactions in the cardiovascular outcomes trial for 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.

Concomitant use of NEXLETOL with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided due to the potential for increased risk of simvastatin- or pravastatin-related myopathy.

Discontinue 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 NEXLETOL.

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



Nicholls SJ, et al. Rationale & Design



Nissen SE, et al. CLEAR Outcomes



NEXLETOL®
Prescribing Information



Contact Us: EsperionMedical.com

Abbreviations: MACE= major adverse cardiovascular event; MACE-4= CV death, nonfatal MI, nonfatal stroke, coronary revascularization; MACE-3= CV death, nonfatal MI, nonfatal stroke; MI= myocardial infarction