

# NEXLIZET™ (BEMPEDOIC ACID AND EZETIMIBE) TABLETS

## U.S. FDA APPROVAL CONFERENCE CALL

February, 2020

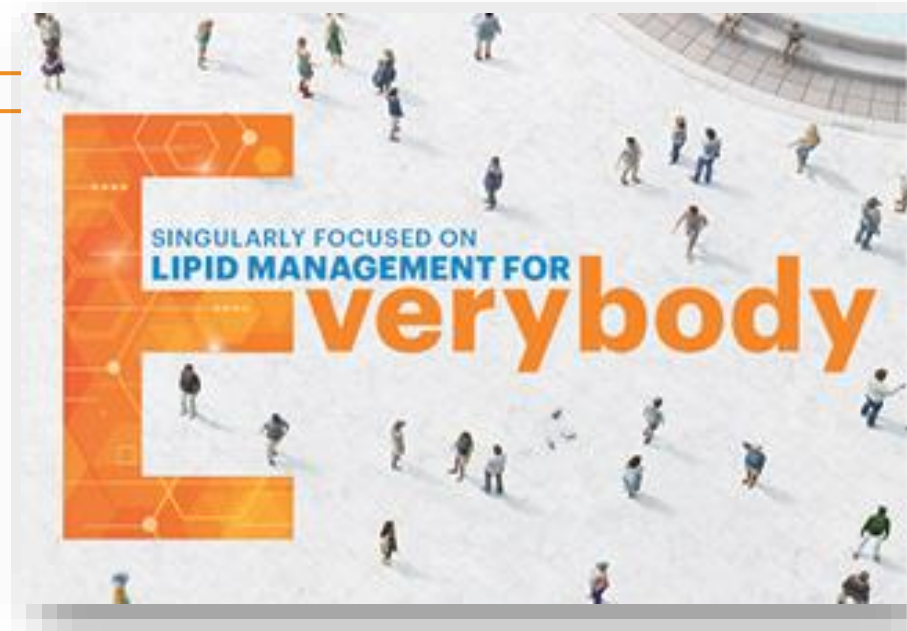
# SAFE HARBOR

## 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 the regulatory approval pathway for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, the therapeutic potential of, and the clinical development plan for bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet, including Esperion's timing, designs, plans for announcement of results regarding its CLEAR Outcomes study and other ongoing clinical studies for bempedoic acid tablet and the bempedoic acid / ezetimibe combination fixed dose tablet, timing for the review and approval of the MAAs, and Esperion's expectations for the market for medicines to lower LDL-C, including the U.S. commercial launch and market adoption of bempedoic acid tablet and the bempedoic acid / ezetimibe fixed dose combination tablet. 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 studies, that positive results from a clinical study of bempedoic acid may not be sufficient for EMA approval or necessarily be predictive of the results of future or ongoing clinical studies, that notwithstanding the completion of Esperion's Phase 3 clinical development program for LDL-C lowering, the FDA or EMA may require additional development in connection with seeking regulatory approval, that existing cash resources may be used more quickly than anticipated, and the risks detailed in Esperion's filings with the Securities and Exchange Commission. 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.

# OUR DECADE-LONG PURSUIT TO ACHIEVE OUR SINGULAR MISSION

Introducing innovative medicines to help appropriate patients reach their LDL-C goals



# AN EXPERIENCED TEAM – THE LIPID EXPERTS



**Tim Mayleben**  
President and  
Chief Executive Officer



**Mark Glickman**  
Chief Commercial  
Officer



**Ashley Hall**  
Chief Development  
Officer



**Rick Bartram**  
Chief Financial Officer



**Regina Cavaliere**  
Chief Ethics and  
Compliance Officer



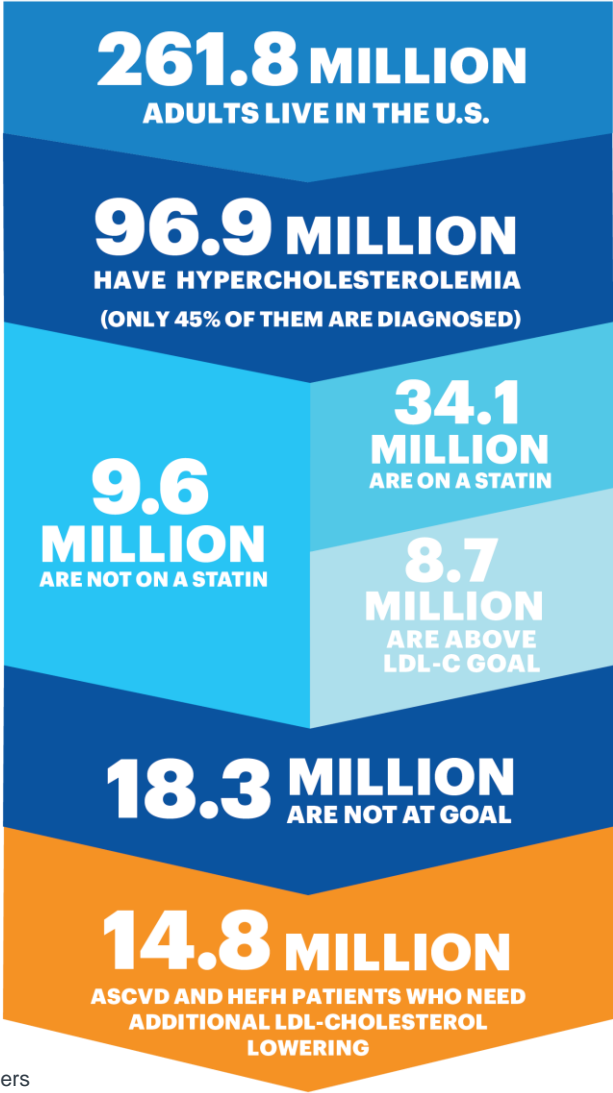
**Ken Fiorelli**  
Chief Technical  
Operations Officer



**Bill Sasiela**  
Sr. VP, Clinical  
Development

# MILLIONS OF PATIENTS REMAIN UNABLE TO ACHIEVE LDL-C GOALS

MORE LOWERING NEEDS TO BE DONE



Source: ZS Associates primary and secondary research, Sep-Oct 2018. Primary research N = 350 healthcare practitioners

# NEXLETOL™ AND NEXLIZET™ FDA APPROVED IN U.S.

## HELPING APPROPRIATE PATIENTS ACHIEVE THEIR LDL-C GOALS

NEXLETOL™ is the first oral, once-daily, non-statin LDL-C lowering medicine approved since 2002 for indicated patients



**NEXLETOL™**  
(bempedoic acid) tablets

**NEXLIZET™**  
(bempedoic acid and ezetimibe) tablets



NEXLIZET™ is the first non-statin, LDL-C lowering combination medicine ever approved

NEXLETOL™ and NEXLIZET™ are available by prescription only.

# ANSWERING HEALTH CARE PROVIDERS' CALL

HELPING TO GET MORE PATIENTS TO LDL-C GOAL



Available March 30, 2020



Available July 2020

NEXLETOL™ and NEXLIZET™ are each indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or established atherosclerotic cardiovascular disease (ASCVD) who require additional lowering of LDL-C.

Limitations of Use: The effect of NEXLETOL™ and NEXLIZET™ on cardiovascular morbidity and mortality has not been determined.



Oral, once-daily, non-statin medicines, with no need to titrate dose



Significant additional LDL-C lowering as an add on to maximally tolerated statin therapy



Both rely on ACL inhibition, a first-in-class mechanism of action complementary to statins



Safety profiles with incidence of most common adverse events generally comparable to placebo



# NEXLIZET™: SIGNIFICANT ADDITIONAL LDL-C LOWERING EFFICACY IN PATIENTS ON MAXIMALLY TOLERATED STATINS

FDA APPROVAL BASED ON ROBUST EVIDENCE FROM PIVOTAL PHASE 3 STUDY IN OVER 300 PATIENTS\*

**NEXLIZET™**  
(bempedoic acid  
and ezetimibe) tablets



- 38% mean LDL-cholesterol lowering compared to placebo on top of maximally tolerated statin therapy
- USPI notes positive effects on other lipid parameters including non-HDL-C, apolipoprotein B (apo B), and total cholesterol (TC)
- Results were consistent across age, gender, and ethnic groups

\*See appendix for additional information on the pivotal Phase 3 Study



# NEXLIZET™ SAFETY PROFILE

## INCIDENCE OF MOST COMMON ADVERSE EVENTS GENERALLY COMPARABLE TO PLACEBO

**Safety profile based on results of NEXLIZET™ (bempedoic acid and ezetimibe) tablets pivotal Phase 3 Study, as well as NEXLETOL™ (bempedoic acid) tablets Phase 3 studies and existing ezetimibe safety profile:**

- A positive benefit / risk profile in appropriate patients
- Contraindicated in patients with a known hypersensitivity to ezetimibe tablets
- Warnings and Precautions statements include increased risk of hyperuricemia and tendon rupture
- Adverse events generally comparable to placebo
- Most common adverse reactions in  $\geq 2\%$  of patients taking NEXLIZET and more frequently than placebo;
  - Upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, elevated liver enzymes, diarrhea, fatigue, influenza, sinusitis, and arthralgia
  - Adverse events reported less frequently but still more often than in placebo included benign prostatic hyperplasia and atrial fibrillation
- Avoid concomitant use with simvastatin ( $>20$  mg/day) or pravastatin ( $>40$  mg/day). Monitor cyclosporine concentrations with cyclosporine. If cholelithiasis is suspected in a patient receiving fenofibrate, consider alternative lipid-lowering therapy.

This summary does not reflect the full safety profile - see [Full Prescribing Information](#)



**NEXLETOL™**  
*(bempedoic acid) tablets*

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**NEXLETOL™**  
Available  
March 30, 2020

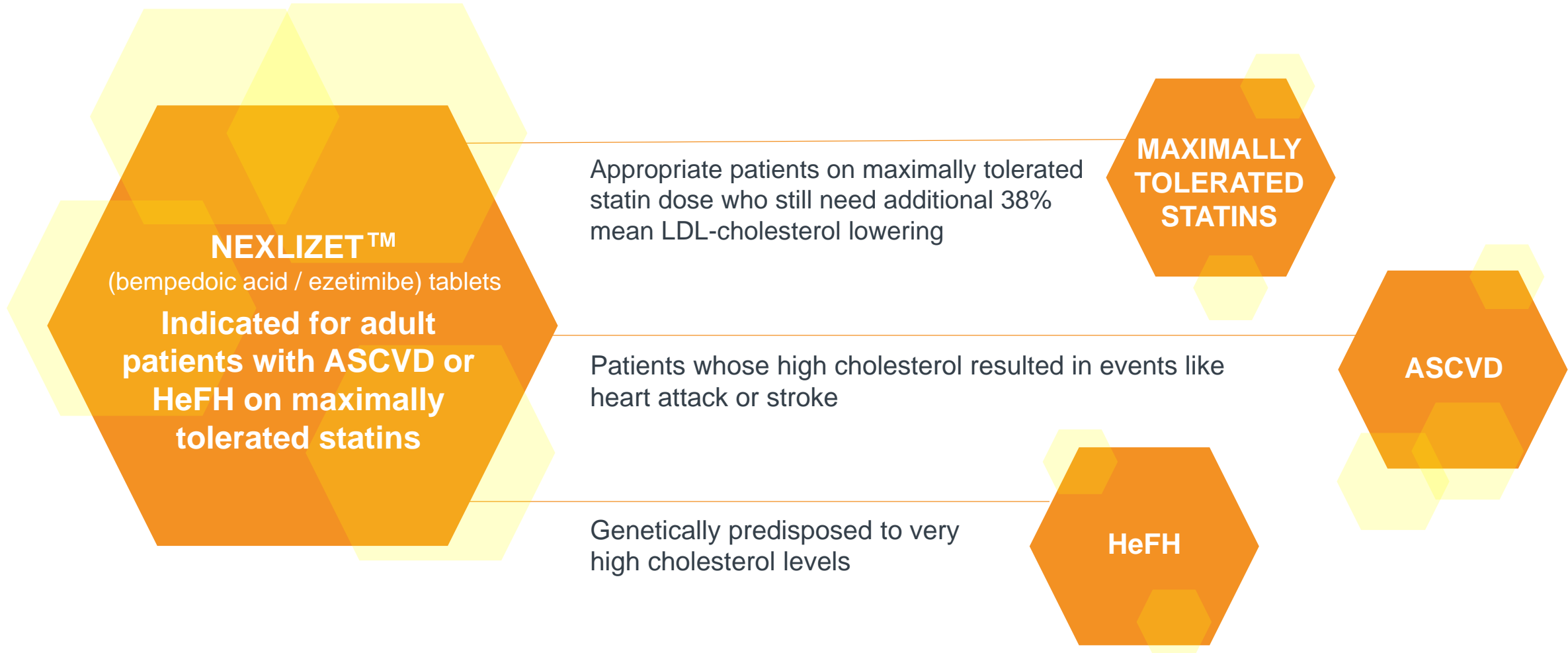
**NEXLIZET™**  
Available  
July 2020



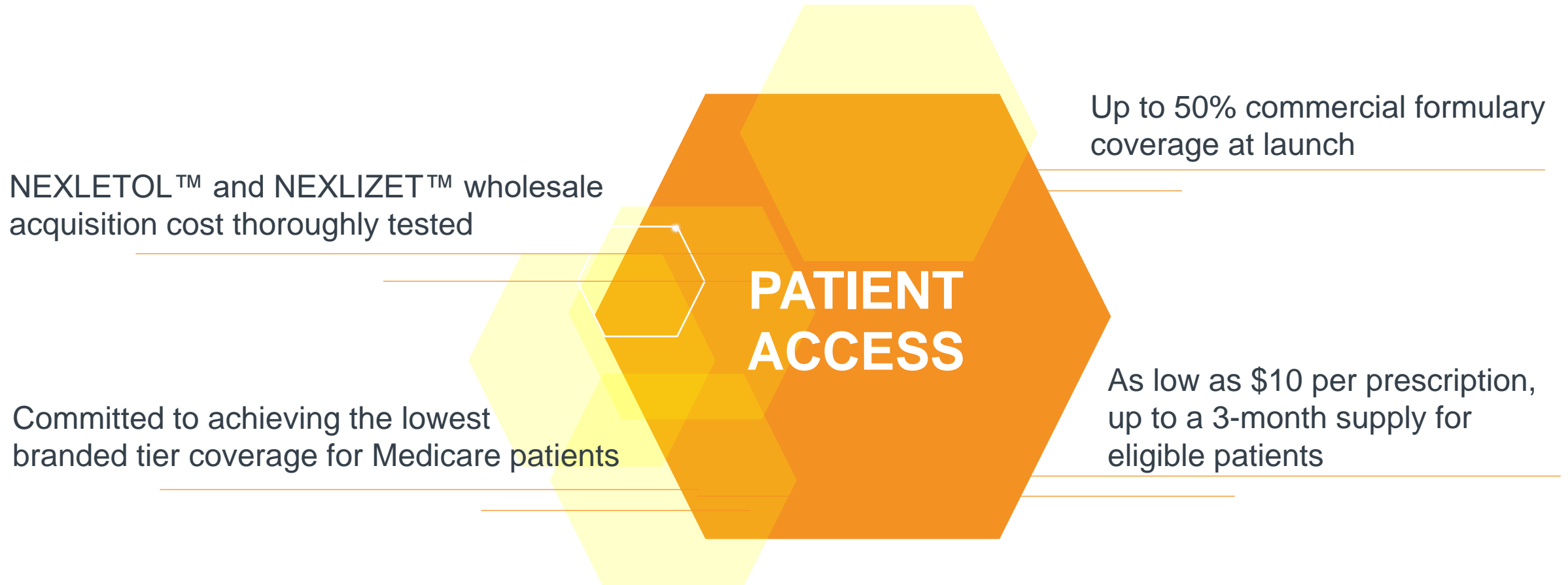
**NEXLIZET™**  
*(bempedoic acid  
and ezetimibe) tablets*

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# FITS INTO LDL-C TREATMENT ARMAMENTARIUM



# COMMITTED TO PATIENT AFFORDABILITY AND ACCESS



# STRATEGICALLY-BUILT, PHYSICIAN-FACING TEAM SET TO DEPLOY FOR A SUCCESSFUL LAUNCH



**QUIPPED** with expertise, experience, and resources to reach target audience

## TARGET AUDIENCE IDENTIFIED

- Over 36,000 healthcare providers who write 40% of all LDL-C lowering medicine prescriptions

## EXPERTS READY TO GO

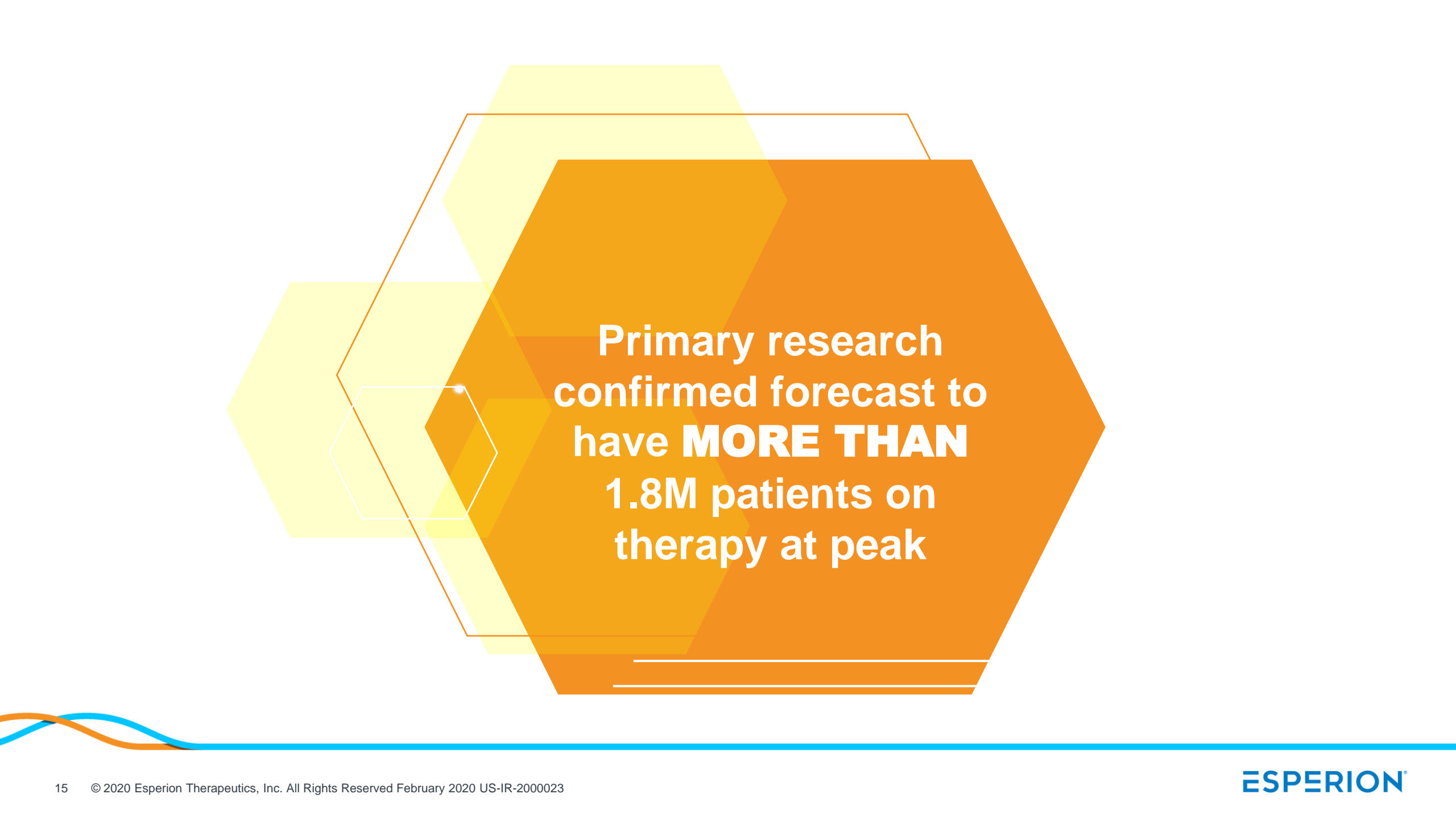
- 290 industry tenured territory managers with an average of 13 years of CV expertise in sales
- 30 regional directors with an average of 15 years of sales leadership experience

## PHASED APPROACH TO LAUNCH, BASED ON REVENUE MILESTONES

- Launch focused on Cardiologists, Lipidologists, Endocrinologists and high CV Rx-writing PCPs
- Additional territory managers will be added as prescription milestones are achieved
- Progress to be transparent through Symphony and IQVIA databases

# MULTICHANNEL APPROACH TO EDUCATE AND SUPPORT SUCCESSFUL INITIATION





Primary research  
confirmed forecast to  
have **MORE THAN**  
1.8M patients on  
therapy at peak



# COMMITMENT FULFILLED

WE'VE PUT IN THE WORK TO WIN FOR ALL STAKEHOLDERS



## HCPs

Delivered a product to help adult patients with HeFH or ASCVD on maximally tolerated statin achieve their LDL-C goals

## Patients

Ensured optimal access to an oral, once-daily, non-statin product with proven LDL-C efficacy, and safety profile that can help patients finally reach their goals

## Payers

Built extensive managed care relationships through productive conversations helping ensure the best patient access

Note: The effect of NEXLIZET™ on cardiovascular morbidity and mortality has not been determined.

# IMPORTANT SAFETY INFORMATION

**Indication:** NEXLIZET is indicated as an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease who require additional lowering of LDL-C. **Limitations of Use:** The effect of NEXLIZET on cardiovascular morbidity and mortality has not been determined.

**Dosage Form and Quantity:** NEXLIZET is available as an oral tablet containing 180 mg of bempedoic acid and 10 mg of ezetimibe, taken once a day with or without food.

**Contraindications:** NEXLIZET is contraindicated in patients with a known hypersensitivity to ezetimibe tablets. Hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria have been reported with ezetimibe.

**Warnings and Precautions:** *Hyperuricemia:* Bempedoic acid, a component of NEXLIZET, may increase blood uric acid levels. Hyperuricemia may occur early in treatment and persist throughout treatment, and may lead to the development of gout, especially in patients with a history of gout.

*Tendon Rupture:* Bempedoic acid, a component of NEXLIZET, is associated with an increased risk of tendon rupture, most commonly involving the biceps tendon, rotator cuff, or Achilles tendon. Tendon rupture occurred within weeks to months of starting bempedoic acid. Tendon rupture may occur more frequently in patients over 60 years of age, patients taking corticosteroid or fluoroquinolone drugs, patients with renal failure and patients with previous tendon disorders.

**Adverse Events:** In the NEXLIZET pivotal trial the most commonly reported adverse events observed with NEXLIZET, but not observed in clinical trials of bempedoic acid or ezetimibe, and occurring more frequently than with placebo were urinary tract infection, nasopharyngitis and constipation.

In clinical trials with bempedoic acid, a component of NEXLIZET, the most commonly reported adverse events were upper respiratory tract infection, muscle spasms, hyperuricemia, back pain, abdominal pain or discomfort, bronchitis, pain in extremity, anemia, and elevated liver enzymes. Events reported less frequently but still more often than in placebo included benign prostatic hyperplasia and atrial fibrillation.

Adverse reactions reported in clinical trials with ezetimibe, a component of NEXLIZET, occurring at an incidence greater than placebo include upper respiratory tract infection, diarrhea, arthralgia, sinusitis, pain in extremity, fatigue and influenza. Other adverse events reported in postmarketing use of ezetimibe include hypersensitivity reactions, including anaphylaxis, angioedema, rash, and urticaria; erythema multiforme; myalgia; elevated creatine phosphokinase; myopathy/rhabdomyolysis; elevations in liver transaminases; hepatitis; abdominal pain; thrombocytopenia; pancreatitis; nausea; dizziness; paresthesia; depression; headache; cholelithiasis; cholecystitis.

**Laboratory Tests:** Treatment with bempedoic acid, a component of NEXLIZET, was associated with persistent changes in laboratory tests within the first four weeks of treatment, including increases in creatinine and blood urea nitrogen, decreases in hemoglobin and leukocytes, increases in platelet counts, increases in liver enzymes (AST and/or ALT), and increases in creatine kinase. Laboratory abnormalities generally did not require medical intervention. Laboratory test values generally returned to baseline following discontinuation of treatment.

**Drug Interactions:** *Simvastatin and Pravastatin:* Concomitant use results in increased concentrations and increased risk of simvastatin or pravastatin-related myopathy. Use with greater than 20 mg of simvastatin or 40 mg of pravastatin should be avoided.

*Cyclosporine:* Caution should be exercised when using NEXLIZET and cyclosporine concomitantly due to increased exposure to both ezetimibe and cyclosporine. Monitor cyclosporine concentrations in patients receiving NEXLIZET and cyclosporine. In patients treated with cyclosporine, the potential effects of the increased exposure to ezetimibe from concomitant use should be carefully weighed against the benefits of alterations in lipid levels provided by NEXLIZET.

*Fibrates:* Co-administration of NEXLIZET with fibrates other than fenofibrate is not recommended. Fenofibrate and ezetimibe, a component of NEXLIZET, may increase cholesterol excretion into the bile, leading to cholelithiasis. If cholelithiasis is suspected in a patient receiving NEXLIZET and fenofibrate, gallbladder studies are indicated and alternative lipid-lowering therapy should be considered.

*Cholestyramine:* Concomitant use of NEXLIZET and cholestyramine decreases ezetimibe concentration. This may result in a reduction of efficacy. Administer NEXLIZET either at least 2 hours before or at least 4 hours after bile acid sequestrants.

**Special Populations:** It is not recommended that NEXLIZET be taken during breastfeeding. A pregnant patient should consult with their healthcare provider about whether to continue treatment with NEXLIZET during the pregnancy. The safety and efficacy of NEXLIZET have not been established in patients under the age of 18 years. Patients over 65 years of age accounted for 50% of patients in the clinical trial. No adjustments in dosing are required for age, or for patients with mild or moderate renal or hepatic impairment. NEXLIZET is available only by prescription.

To report SUSPECTED ADVERSE REACTIONS, contact FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or ESPERION at 1-833-377-7633 (833 ESPRMD).

Please see [Full Prescribing Information](#) at [Esperion.com](http://Esperion.com).

**INVESTORRELATIONS@ESPERION.COM**



# APPENDIX



# ADDITIONAL INFORMATION ON NEXLIZET™ (BEMPEDOIC ACID AND EZETIMIBE) TABLETS PHASE 3 STUDY

Study 1002FDC-053 was a 4-arm, 12-week trial that assessed the efficacy of NEXLIZET™ in 301 adult patients randomized 2:2:2:1 to receive either NEXLIZET™ (n = 86), NEXLETOL™ (n = 88), ezetimibe (n = 86), or placebo (n = 41) once daily as add-on to maximally tolerated statin therapy. The trial included patients aged >30 years that were high-risk patients with ASCVD and/or heterozygous familial hypercholesterolemia or with multiple risk factors for ASCVD being treated with maximally tolerated statins. The primary endpoint was the percent change from baseline to Week 12 in LDL-C. Secondary objectives included assessments of high-sensitivity C-reactive protein (hsCRP), non-HDL-C, total cholesterol (TC), and apolipoprotein B (apoB).