

# Daiichi Sankyo Europe / Esperion – EU Commercialization Agreement

January 2019

## Safe Harbor

#### **Forward-Looking Statements**

These slides and the accompanying oral presentation contain forward-looking statements and information. The use of words such as "may," "might," "will," "should," "expect," "plan," "anticipate," "believe," "estimate," "project," "intend," "future," "potential," or "continue," and other similar expressions are intended to identify forward looking statements. For example, all statements we make regarding the regulatory approval pathway for the bempedoic acid / ezetimibe combination pill and bempedoic acid and the therapeutic potential of, clinical development plan for, the bempedoic acid / ezetimibe combination pill and bempedoic acid, including Esperion's timing, designs, plans and announcement of results regarding its global pivotal Phase 3 clinical development program for bempedoic acid and the bempedoic acid / ezetimibe combination pill, Esperion's timing and plans for submission of NDAs to the FDA and MAAs to the EMA and Esperion's expectations for the market for therapies to lower LDL-C, including the market adoption of bempedoic acid and the bempedoic acid / ezetimibe combination pill, if approved, are forward looking. All forward-looking statements are based on estimates and assumptions by our management that, although we believe to be reasonable, are inherently uncertain. All forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those that we expected. These statements are also subject to a number of material risks and uncertainties, including but not limited to, delays or failures in Esperion's studies, that positive results from a clinical study of bempedoic acid may not be sufficient for FDA or 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 DSE is able to successfully commercialize the bempedoic acid / ezetimibe combination pill and bempedoic acid, if approved, 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. Any forward-looking statement speaks only as of the date on which it was made. Esperion disclaims any obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise, except as required by law.



## Daiichi Sankyo Europe – EU Commercialization Agreement



#### The Esperion and Daiichi Sankyo Europe (DSE) agreement is the **largest EU licensing agreement** in at least the last decade

#### Significant economics to Esperion including;

- \$300 million in upfront and near-term milestones
- \$900 million in total milestones
- Tiered royalties between 15% 25%

#### Daiichi Sankyo Europe is a strong EU commercial partner

- **1000 person cardiovascular sales** organization to support the bempedoic acid launch in the EU
- Fully integrated commercial organization and deep expertise in reimbursement, distribution, and medical affairs
- European-based commercial organization driving multiple synergies with their existing CV portfolio (Lixiana, Efient, Olmesartan)
- Responsible for one of the most successful recent cardiovascular launches in Europe (Lixiana launched in 2015)
- Significant overlap among physicians target for bempedoic acid and those currently prescribing Lixiana

# Esperion retains control of all development with DSE responsible for all European commercial activities



## EU Commercial Collaboration Agreement – What We Wanted

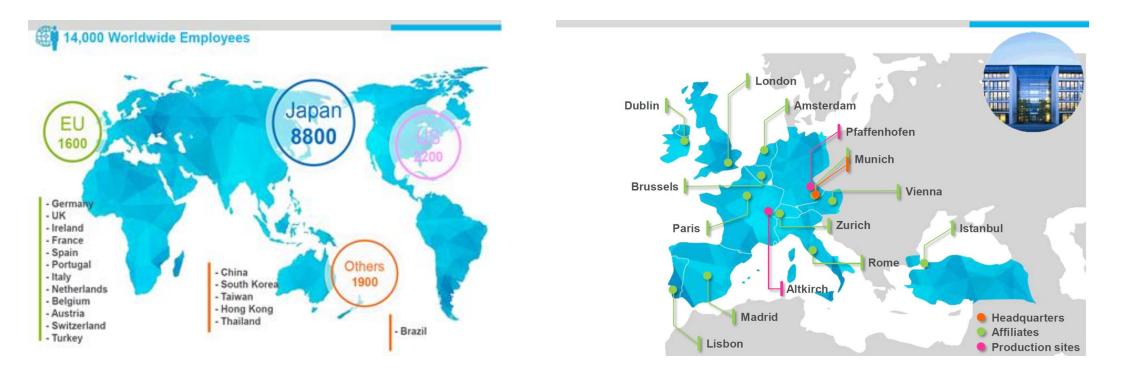
- Global Pharmaceutical Company with significant resources
- Strong history in cardiovascular disease drug development and commercialization
- Recent success and experience in commercializing a cardiovascular drug in the EU
- Strong EU commercial organization with significant personnel and financial resources
- Significant economics to Esperion, reflecting the value of bempedoic acid
- Retain development and regulatory decision making for the bempedoic acid franchise
- Set a precedent for US and ROW commercial partnerships and enhancing the longterm value of Esperion and the bempedoic acid franchise



### Daiichi Sankyo Europe Global Player with a Large, European Cardiovascular Presence



- Top 25 Global Pharmaceutical Company based on revenues
- Daiichi Sankyo Europe brings together a sales organization of more than 1,000 people focusing on the cardiovascular portfolio
- Cardiovascular brands include: Lixiana (NOAC), olmesartan (Hypertension), Efient (Antiplatelet)
- History of cardiovascular innovation: discovered pravastatin





### Daiichi Sankyo Europe Success in the Cardiovascular Market – Out-Performing in this Highly Competitive Therapeutic Area



 Lixiana was launched 4<sup>th</sup> to market in 2015 in the novel oral anticoagulation (NOAC) market competing against the largest global players



• Lixiana sales in Europe: projected to be ~\$400 million during 2018, and achieve ~\$1 billion at peak

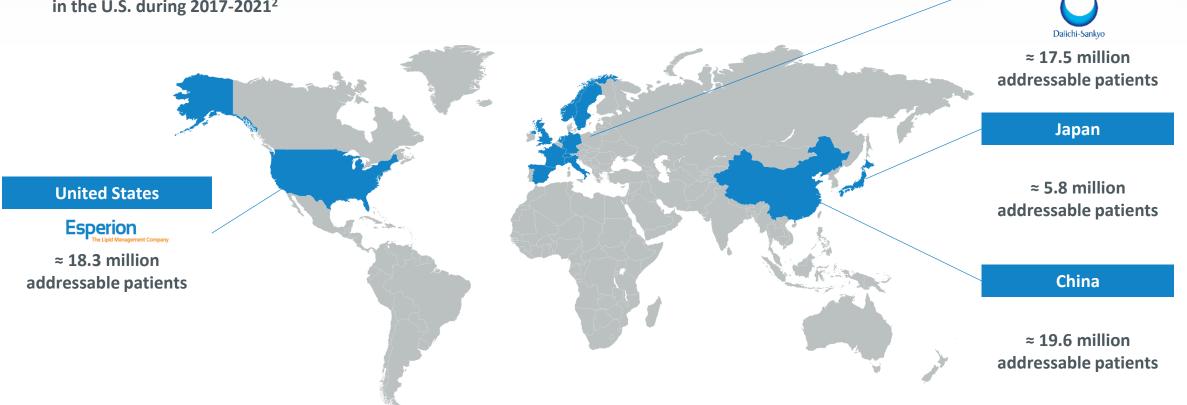


• Daiichi Sankyo Europe has previously achieved commercial success in the highly competitive CV therapeutic area with Olmesartan in Hypertension and Efient in antiplatelet therapies



### The Lipid Management Team: Addressing a Truly Global Problem Cardiovascular Disease Remains the #1 Cause of Death Globally

- CVD accounts for ~1 in 3 deaths in the U.S. and Europe
- >800,000 U.S. CVD deaths annually<sup>1</sup>
- 16.3 million heart attacks, strokes, and related CV events will occur in the U.S. during 2017-2021<sup>2</sup>





Europe

## Two Non-Statin Oral Pills That Lower LDL-C and Reduce hsCRP Complement to Standard of Care LDL-C Lowering Drugs

**Bempedoic Acid / Ezetimibe Combination Pill** 

**Bempedoic Acid** 

#### **Shared Benefits:**

– Oral, once-daily, convenient, cost-effective therapies

- Safe and well-tolerated without increases in muscle-related adverse events

– HbA1c lowering and lower rate of new onset/worsening diabetes

 Efficacy comparable to injectable PCSK9i monotherapy (~50% LDL-C lowering) – plus differentiated hsCRP reduction

- 35% LDL-C lowering on maximally tolerated statins
- 43% LDL-C lowering on no background statins

– 34% hsCRP reduction; a key marker of inflammation

 Consistent and complementary LDL-C lowering – plus differentiated hsCRP reduction

 – 18-20% LDL-C lowering on maximally tolerated statins, including high-intensity statins

- Up to 31% LDL-C lowering on no background statin

– 19-40% hsCRP reduction; a key marker of inflammation



## Bempedoic Acid Commercial Positioning After Standard-of-Care Statins and Before Specialty PCSK9i Medicines

#### Where we fit

BA and BA/EZE FDC are new oral lipid lowering therapies with a unique MOA that delivers significant results alone\* or in combination with other LDL-C therapies, so more patients can finally achieve LDL-C goals

Statins	Bempedoic acid & bempedoic acid / ezetimibe combo pill	PCSK9 Inhibitors
<ul> <li>Standard of first-line care in LDL-C reduction</li> <li>Primary prevention</li> <li>Secondary prevention</li> </ul>	<ul> <li>For patients on maximally tolerated statins who need an additional 20%-43% LDL-C reduction to get to goal</li> <li>Patient types: high risk primary prevention, secondary prevention, diabetes, HeFH</li> <li>Use: add on to statin, alone*, or add on to ezetimibe</li> </ul>	<ul> <li>For patients who need LDL-C reductions of 50% or more</li> <li>Recommended for patients with very complicated, comorbid ASCVD</li> </ul>

\* Post CV outcome trials

#### Who we fit

Patients taking high-intensity statins who are not at LDL-C goal

Patients who need additional LDL-C lowering who are taking low-dose or no statins due to muscle-related issues

Patients with prediabetes or diabetes seeking to avoid HbA1c increases and worsening/new-onset disease

Patients whose health insurance status compromises access to PCSK9 inhibitors

Patients who are unwilling to take injections





# Upcoming Milestones

#### Esperion 2019 Milestones & Key Events What to Watch

#### **Regulatory Submissions**

- BA and BA/EZE combo pill NDA submissions (1Q19)
- BA and BA/EZE combo pill MAA submissions (2Q19)

Data Flow & Study Status

#### DATA

- Study 201 Ph1 BA Sustained Release (1Q19)
- Study 058 Ph2 BA/EZE combo pill in hypercholesterolemia patients with T2D (2H19)

#### **STUDY STATUS**

- CLEAR Outcomes enrollment complete (3Q19)
- Ph3 BA initiation in Patients with T2D (2H19)

Other Events	
ROW licensing / partnership(s)	





## Questions?