#### Passion for Innovation. Compassion for Patients.™





### SAVAYSA<sup>™</sup> (edoxaban) U.S. Opportunity

February 17, 2015

Ken Keller President, U.S. Commercial DSI, Inc.

### **Key Discussion Points**



- Daiichi Sankyo, Inc. (DSI) in the U.S.
- SAVAYSA<sup>™</sup> (edoxaban) U.S. Indication
- NOAC Market Opportunity and Dynamics
- SAVAYSA's Unique Benefits
- Key Success Factors
- Expectations

### Daiichi Sankyo, Inc.





**Daiichi Sankyo, Inc.**, headquartered in Parsippany, NJ, is the U.S. subsidiary of Daiichi Sankyo Co., Ltd. Daiichi Sankyo, Inc. is a member of the Daiichi Sankyo Group.

• \$1.7 billion net sales FY 2013 in the U.S.

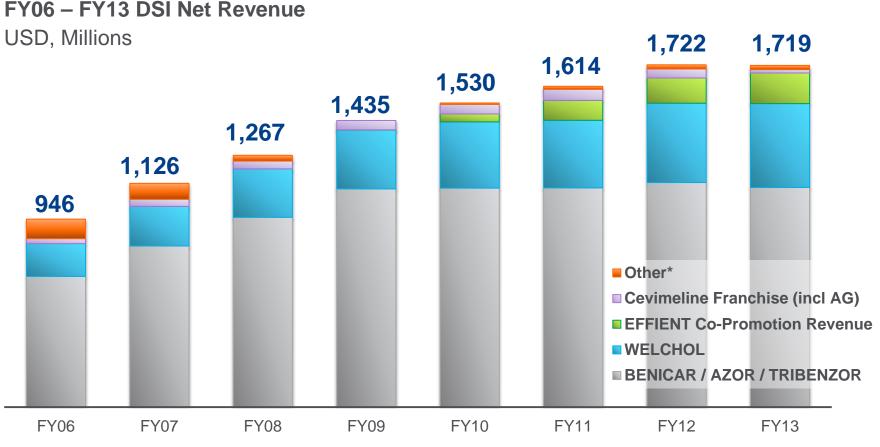
Daiichi Sankyo

• 2,500 total employees in U.S. (approximate)

### **DSI Has Built a Strong Portfolio in the U.S.**



### We Have a History of Competing Intensely and Winning in Highly Competitive Markets



\*Others include revenue from Floxin, Sprix, Partnership Packaging, Zelboraf, and Canada

### Approved in the U.S. on January 8, 2015





Factor Xa Inhibitor 60, 30, 15 mg tablets Once-daily dosing

### **NOW APPROVED FOR:**

#### Nonvalvular Atrial Fibrillation (NVAF)

- Reduction in the risk of stroke and systemic embolism (SE) in patients with NVAF
  - SAVAYSA should not be used in patients with creatinine clearance (CrCL) > 95 mL/min because of increased risk of ischemic stroke compared to warfarin

#### Deep Venous Thrombosis (DVT) & Pulmonary Embolism (PE)

For the treatment of DVT and PE following 5-10 days of initial therapy with a parenteral anticoagulant

\*Please see Important Safety Information (<u>www.savaysa.com</u>)

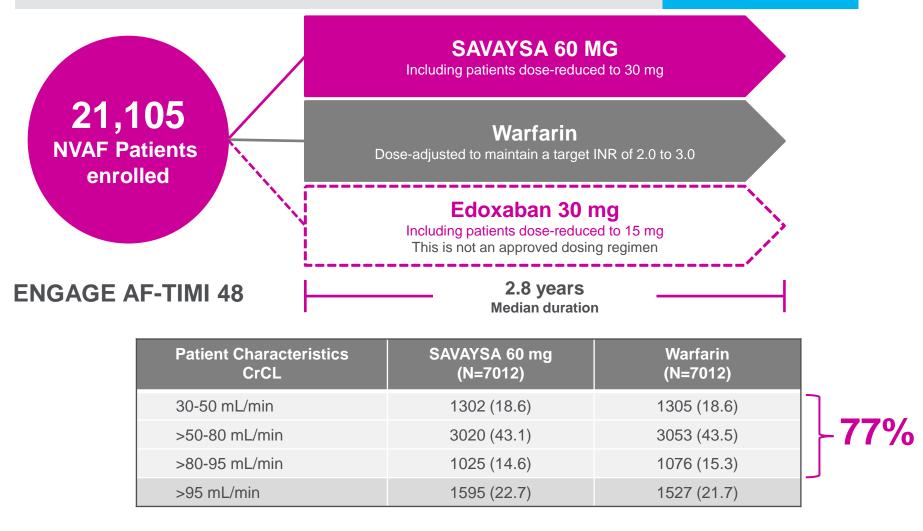
# Atrial Fibrillation Affects 6.1 MM Americans, DVT/PE Close to 1 MM



- NVAF increases the risk of stroke five-fold
- DVT and PE patients are at high risk for recurrence
- For 60 years, a vitamin K antagonist (warfarin) was the only oral anti-coagulant option
  - Highly effective reduces stroke/SE by 60-86%
  - Increases risk of major bleeding versus no treatment
  - High maintenance therapy requires regular blood monitoring tests, food restriction and many drug-to-drug interactions
- Today, three competitor NOAC options exist
  - No need for routine monitoring, fewer drug-to-drug interactions
  - At least as effective and safe as warfarin\*
    - dabigatran: a direct thrombin inhibitor
    - rivaroxaban: a factor Xa inhibitor
    - apixaban: a factor Xa inhibitor

SAVAYSA Demonstrated Significantly Less Major Bleeding and was Non-inferior to Warfarin in Stroke/SEE



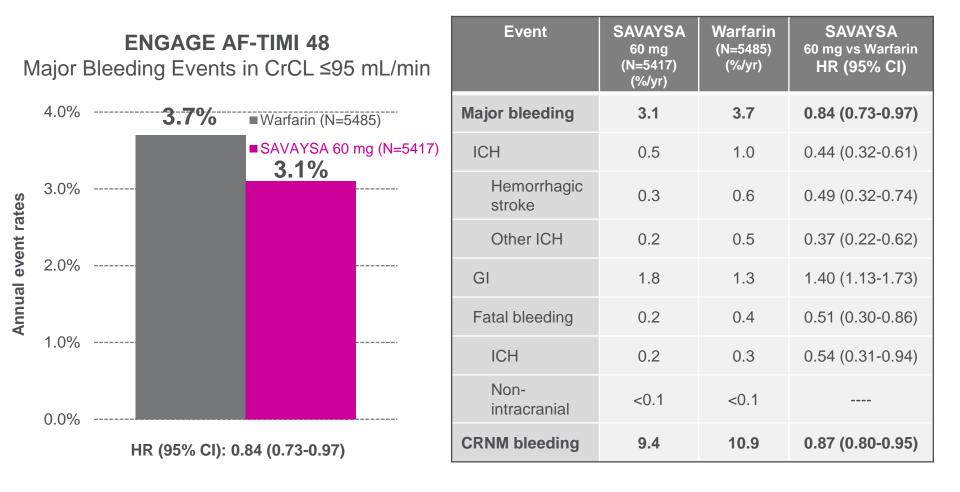


The size and rigor of the ENGAGE AF-TIMI 48 study allowed Daiichi Sankyo to comprehensively characterize the dosing of SAVAYSA by renal function.

## SAVAYSA Safety Profile Compared to Warfarin Maintained in the CrCL ≤95 mL/min Patient Population



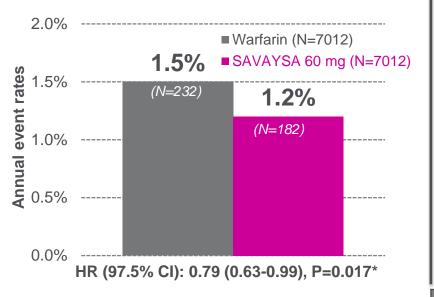
#### SAVAYSA Patients Had Significantly Less Major Bleeding, Similar to Overall Population



# SAVAYSA Reduced Risk of Stroke/SEE in the CrCL ≤95 mL/min Patient Population



**ENGAGE AF-TIMI 48** Non-inferiority for Stroke/SEE in Overall Population



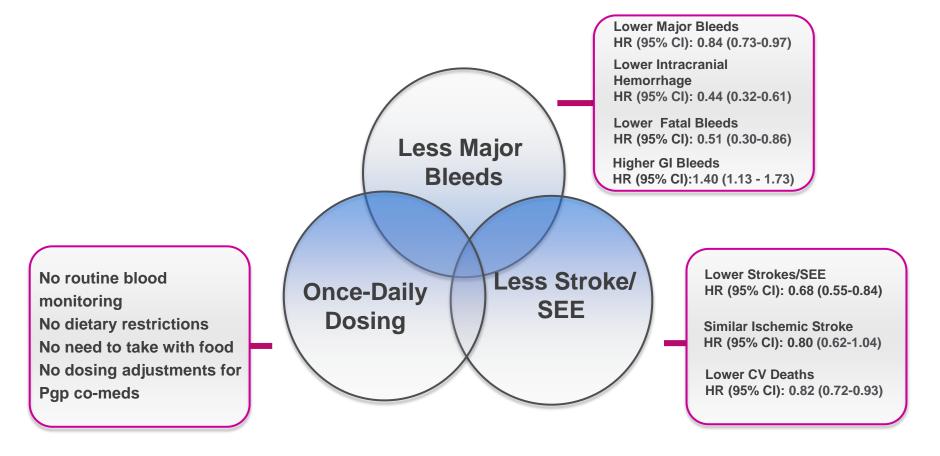
\*Based on the planned superiority analysis (ITT, which required p<0.01 for success), statistical superiority of SAVAYSA compared to warfarin was not established in the total study population, but there was a favorable trend [HR (99% CI): 0.87 (0.71, 1.07)].

**ENGAGE AF-TIMI 48** Stroke/SEE in CrCL ≤95 mL/min 2.0% ----- **1.8%** ---■Warfarin (N=5485) (N=211) ■ SAVAYSA 60 mg (N=5417) Annual event rates 1.5% 1.2% (N=142) 1.0% ------0.5% ------0.0% HR (95% CI): 0.68 (0.55-0.84) HR (95% CI) SAVAYSA Warfarin (N=5485) 60 mg (N=5417) (%/yr) (%/yr) **CV** death 2.95 0.82 (0.72-0.93) 3.59 Ischemic stroke 0.9 1.1 0.80 (0.62-1.04) Hemorrhagic stroke 0.3 0.6 0.50 (0.33-0.75)

### SAVAYSA Approval in the U.S. Supports a Unique, Compelling and Differentiating Profile

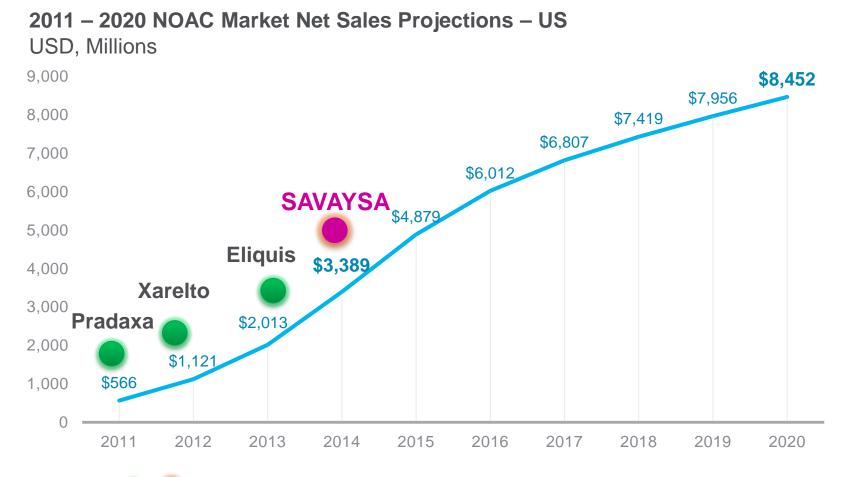


#### For NVAF Patients with CrCL ≤95 mL/min compared to warfarin



### **NOAC Market Large and Accelerating**

#### The Market is Expected to Exceed \$8B in Net Sales by 2020



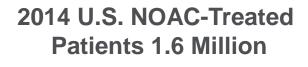
Signifies Product Launch Dates
Source: 2011 - 2014 Symphony Health Solutions PHAST – [Integrated WAC Dollars]; 2015 – 2020 DSI Projections

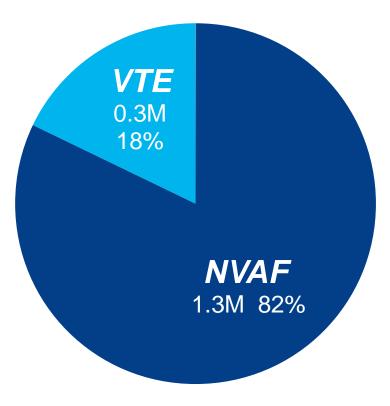
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### **SAVAYSA Opportunity is Driven by NVAF**



#### 82% of NOAC-Treated Patients Have NVAF

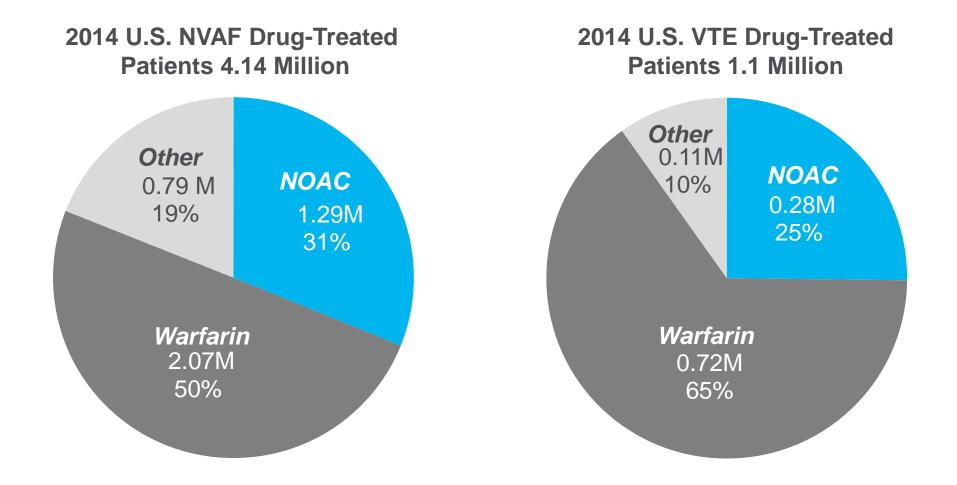




Source: Internal Analysis Based on Decision Resources, Symphony Health Solutions

Nearly a Third of NVAF and a Quarter of VTE Patients are Treated with NOACs, Indicating Significant Opportunity for Expansion



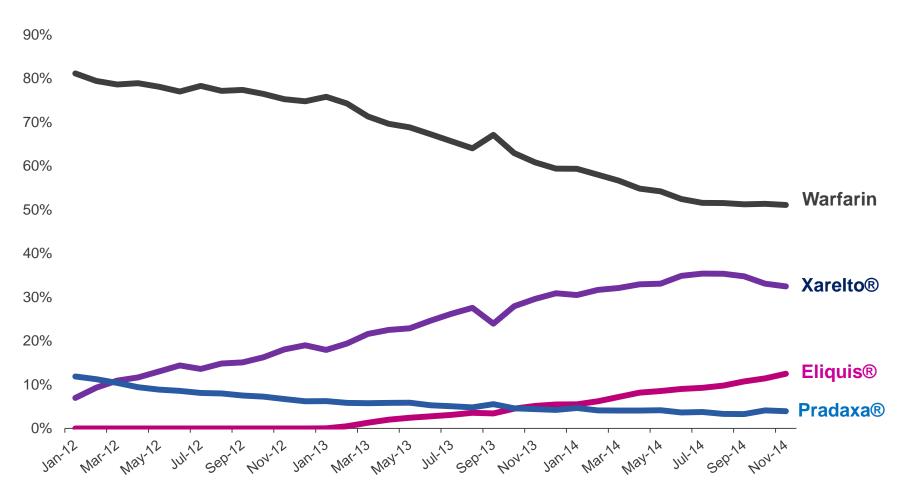


Source: Internal Analysis Based on Decision Resources, Symphony Health Solutions

### **NOACs Remain Significantly Under-Penetrated**

#### New Patient Market Share

%, NBRx



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### Market Research: Physicians Select NOACs Based on a Few Key Benefits



#### **NOAC Use Drivers**



\*Based on modeling exercise; bars represent relative impact of attribute on shares in the NOAC market Source: AF Forecasting Research Nov 2014



### **SAVAYSA Key Market Success Factors**

- Position the unique and compelling clinical profile of SAVAYSA as the drug of choice for appropriate patients
- Establish access and reimbursement
- Compete effectively
- Leverage our existing relationships with prescribers in the cardiovascular space

### **NOAC Pricing**



#### SAVAYSA List Price / Day is 12% Less Than Other NOACs

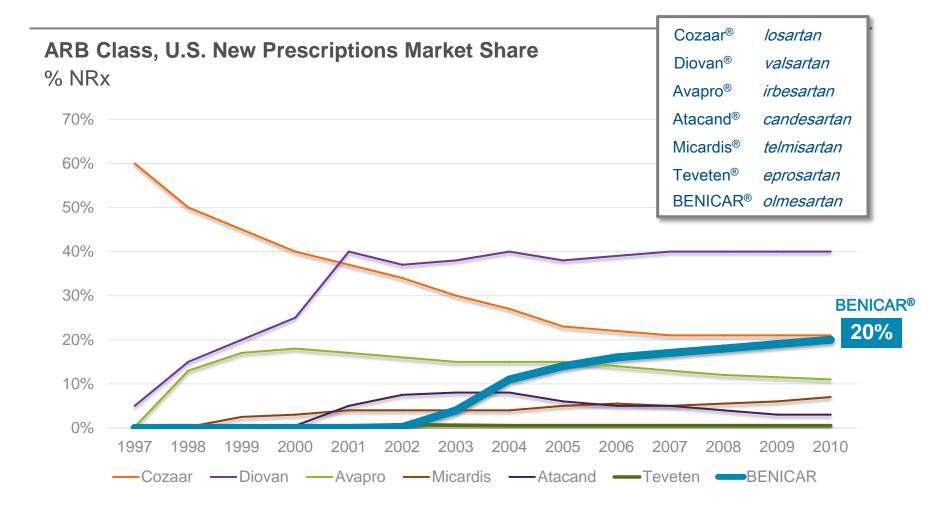


U.S. List Price / Day

Source: First Data Bank (February 2015). List price = WAC (Wholesale Acquisition Cost).

#### DSI Has a History of Success Entering Competitive Markets -Benicar Launched as the 7th Brand in The ARB Class

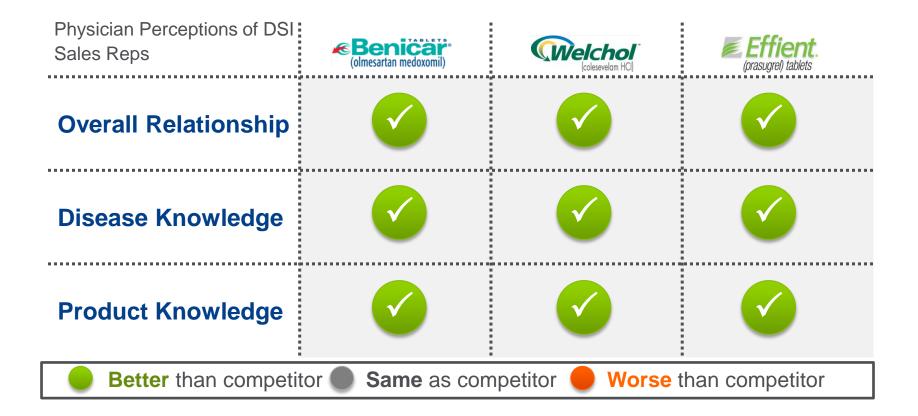




#### The DSI Sales Team is Competitively Tested and Highly Effective



Physicians Consistently Assign High Performance Ratings to Our Sales Team





### SAVAYSA Will Become a Successful and Valuable Drug in the U.S. Market

- 1. Large, growing and under-penetrated market
- 2. We understand the customers
- 3. SAVAYSA unique benefits are motivating
  - Lower major bleeding vs. warfarin
  - Reduced stroke/SEE vs. warfarin
  - Once daily dosing
- 4. Sales organization is competitively tested

#### **Contact address regarding this material**

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