

**A Rare Opportunity
in Transplant.**



Forward Looking Statements

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Veloxis at a Glance

Company

Specialized transplant focused sales force

Commercial stage with efficient infrastructure enables 100% market coverage with 20 reps

Product

ENVARUSUS XR[®] once-daily extended release tacrolimus formulation for transplantation

Clinically differentiated PK achieves target exposure with a lower peak

Based on proprietary MeltDose[™] drug delivery technology

Market

Multiple factors driving growth in # of kidney transplants

Broad payer reimbursement

Strong rate of conversion from immediate release formulations

IP

Broad intellectual property franchise

15 orange book listed patents with expiries through 2028

Orphan drug exclusivity through 2022

\$

9 months 2018 product revenue +101% versus same period last year

~\$30.6M cash at September 30

Broad Opportunities for Growth in the Hospital



Continue to capture share from existing, growing tacrolimus market



Potential label expansion to include de novo kidney transplant patients



Explore new transplant initiatives (Currently indicated for liver transplant in Europe)



Leverage MeltDose™ drug delivery technology to expand pipeline or pursue collaborations



Acquire additional assets to further leverage hospital-based commercial infrastructure

Current Kidney Transplant Treatment Regimen

- Kidney transplant patients typically leave the hospital taking 12-15 new medications, most of which are taken for life
- For >90% of patients, this complex medication regimen includes *lifelong* triple immunosuppression therapy consisting of:
 - Tacrolimus
 - Mycophenolate
 - Corticosteroids
- Tacrolimus is a narrow therapeutic index drug that, unlike other medications, requires lifelong monitoring of blood levels to ensure safe and efficacious use
- Target Tacrolimus trough concentrations are patient-specific and dependent on many factors, including physician practices and institutional protocols
- Target Tacrolimus trough concentrations are gradually reduced after the period of highest risk has passed



Unmet Needs in Immunosuppression for Organ Transplantation



Tacrolimus, a widely used maintenance immunosuppressive agent for organ transplant, has a narrow therapeutic index

Achieving the appropriate balance between over and under immunosuppression is an important goal in transplantation.



Suboptimal compliance

50% of graft loss is currently tied to compliance. Ideal formulation would drive more accurate and timely dosing and reduce missed doses.



Better control of rapid metabolizers

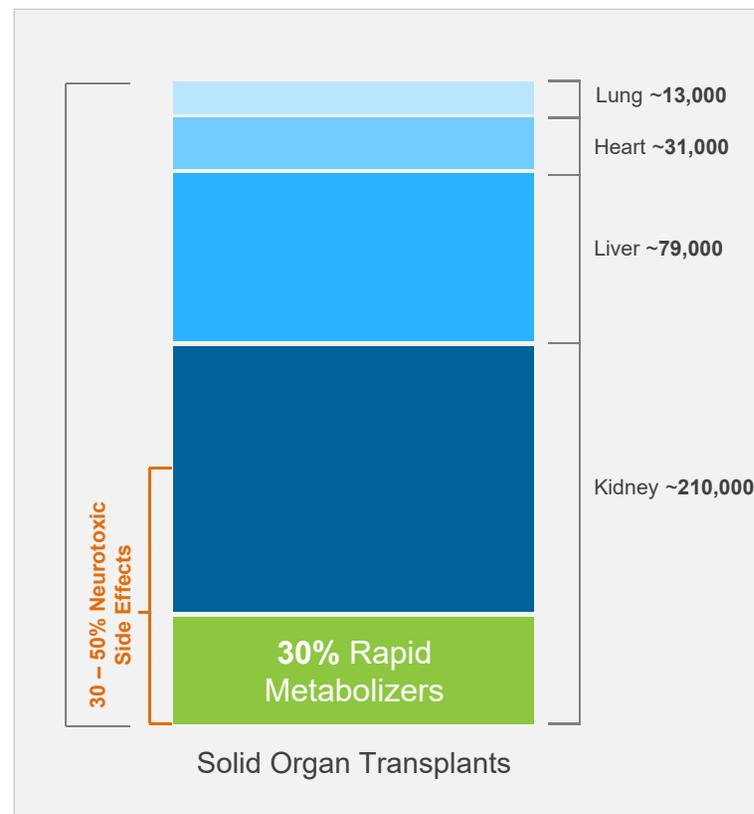
Require 1.5x-2.0x higher doses to achieve the same trough levels

- Run greater risk of under-immunosuppression → poor outcomes
- 210,000 patients who have undergone kidney transplant and there are an additional ~20,000 new patients each year, of which 30% are rapid metabolizers of tacrolimus



Neurotoxicity

30-50% of patients experience severe side effects

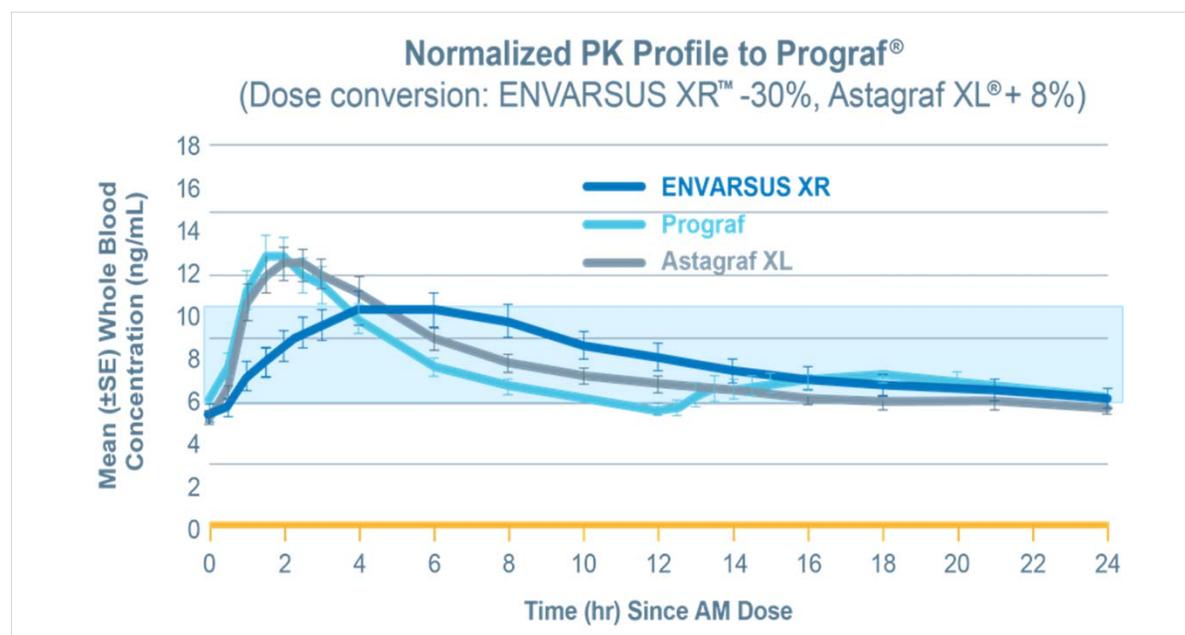


PK Differentiation Versus Current Treatment Options

High peak blood concentration of tacrolimus may be associated with side effects

ENVARSUS XR demonstrates an optimal pharmacokinetic profile compared with standard of care (Prograf®) or generic IR-TAC

ENVARSUS XR does not exhibit the high peak associated with Prograf



Both Astagraf XL and Prograf exhibited similar PK profiles with higher peak concentration, shorter time to T_{max} , and higher peak-trough ratio compared with ENVARSUS XR

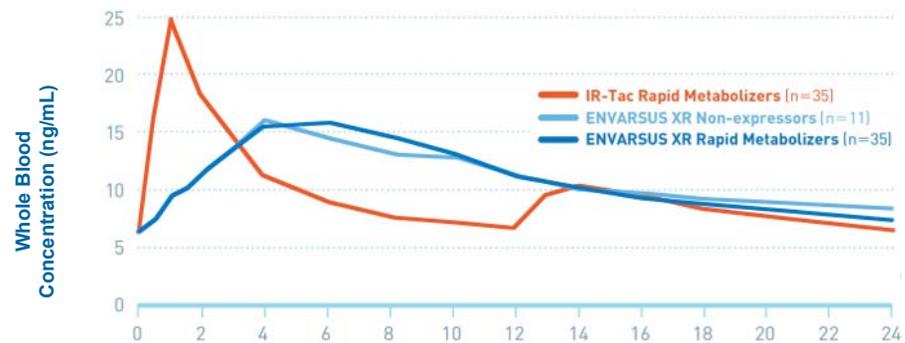
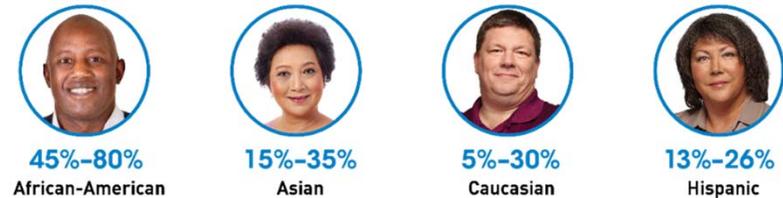
Tremblay S et al. Am J Transplant. 2017; 17: 432-442. Prograf is a registered trademark of Astellas Pharma, Inc.

1 in 3 Patients are Rapid Metabolizers of tacrolimus at High Risk of Rejection and Treatment Failure

Carriers of the CYP3A5*1 gene are “Rapid Metabolizers” of tacrolimus

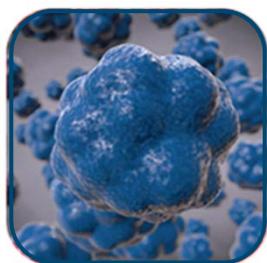
- 01** Require higher tacrolimus doses to achieve therapeutic tacrolimus trough concentrations
- 02** At risk of underimmunosuppression
- 03** Even in Rapid Metabolizers, ENVARSUS XR delivers with lower peak concentrations

30% of patients are rapid metabolizers



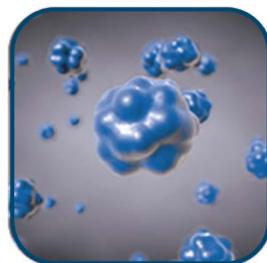
MeltDose Technology

Increases absorption by reducing particle size to a single molecule



Conventional Drug

10 μm



Nanocrystal Technology

0.1-1 μm

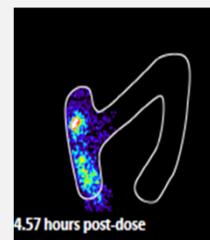


MeltDose[®] Technology

Single Molecules

- MeltDose technology enhances the oral bioavailability of poorly water-soluble drugs
- Particle size reduction to single molecules is achieved by heating the active drug to create a “melt” solution
- Smaller particle size enhances better absorption through increased surface area

24-Hour Scintiscan



4.57 hours post-dose



11.23 hours post-dose



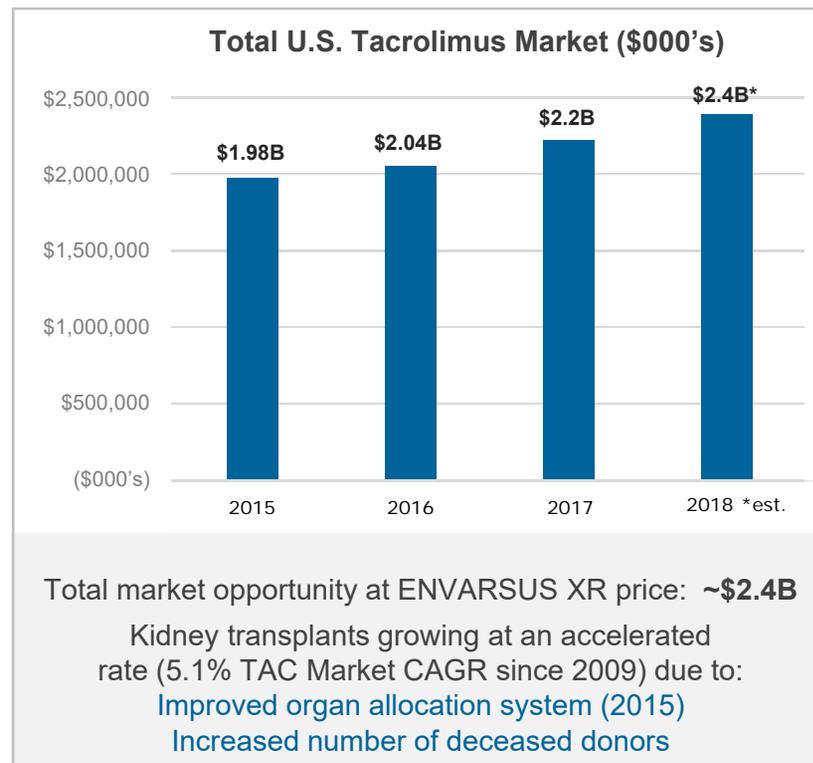
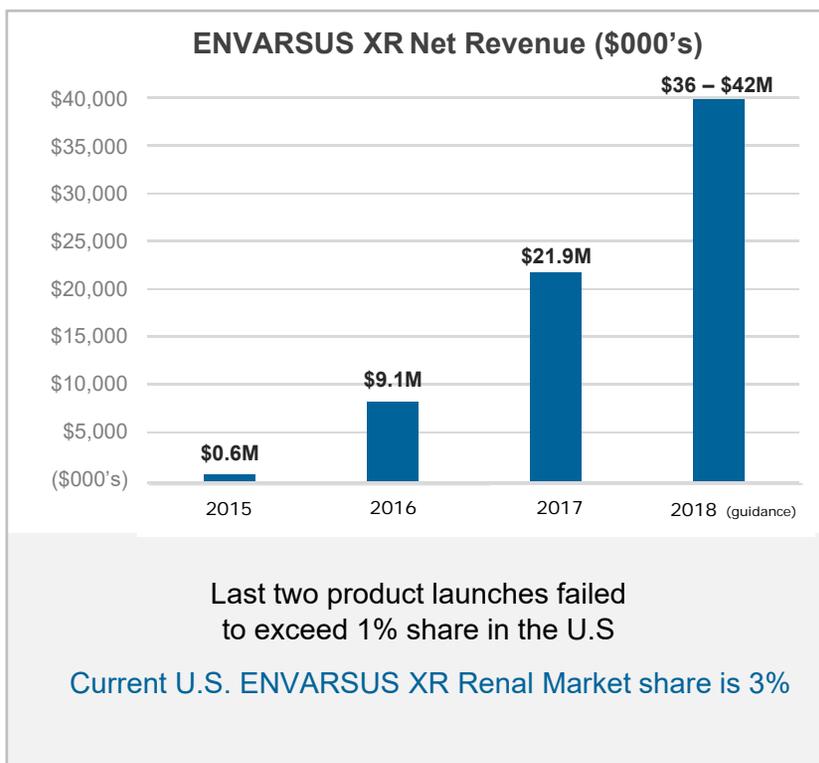
23.32 hours post-dose

Proof of Concept

MeltDose demonstrates dissolution and absorption throughout the GI tract

ENVARSUS XR Has Grown Rapidly Since December 2015 Launch

The Fastest Growing Product in the \$2.4 Billion Tacrolimus Market (\$1.5B Kidney Only)



Targeted Specialty Sales Force



Efficient sales organization

Can achieve coverage of 100% of U.S. transplant centers with ~20 reps

Commercial & medical affairs team optimally deployed within the hospital

Account-oriented operations to drive future growth



Unique expertise

Unique expertise achieving favorable positions on hospital formularies and protocols

Reps average 10+ years in hospital, rare disease and transplant

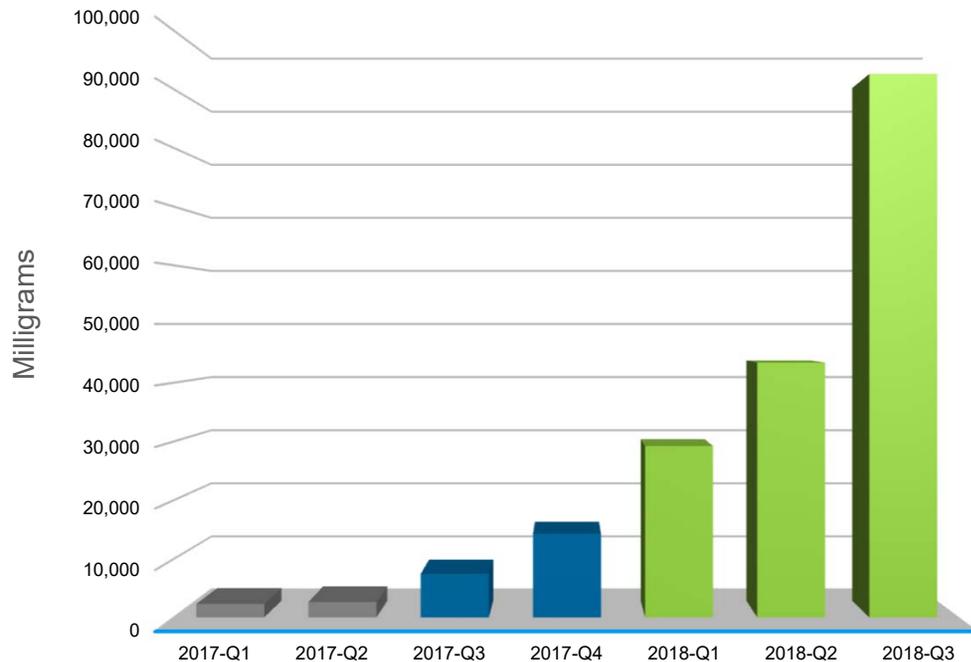
Best-in class patient services



Leverage existing commercial infrastructure

Ability to further leverage existing commercial infrastructure through incremental hospital-based products

Tier-1 Hospital with ENVARSUS XR on Conversion Protocol



Favorable hospital formulary and protocol positioning is key to ENVARSUS XR's growth

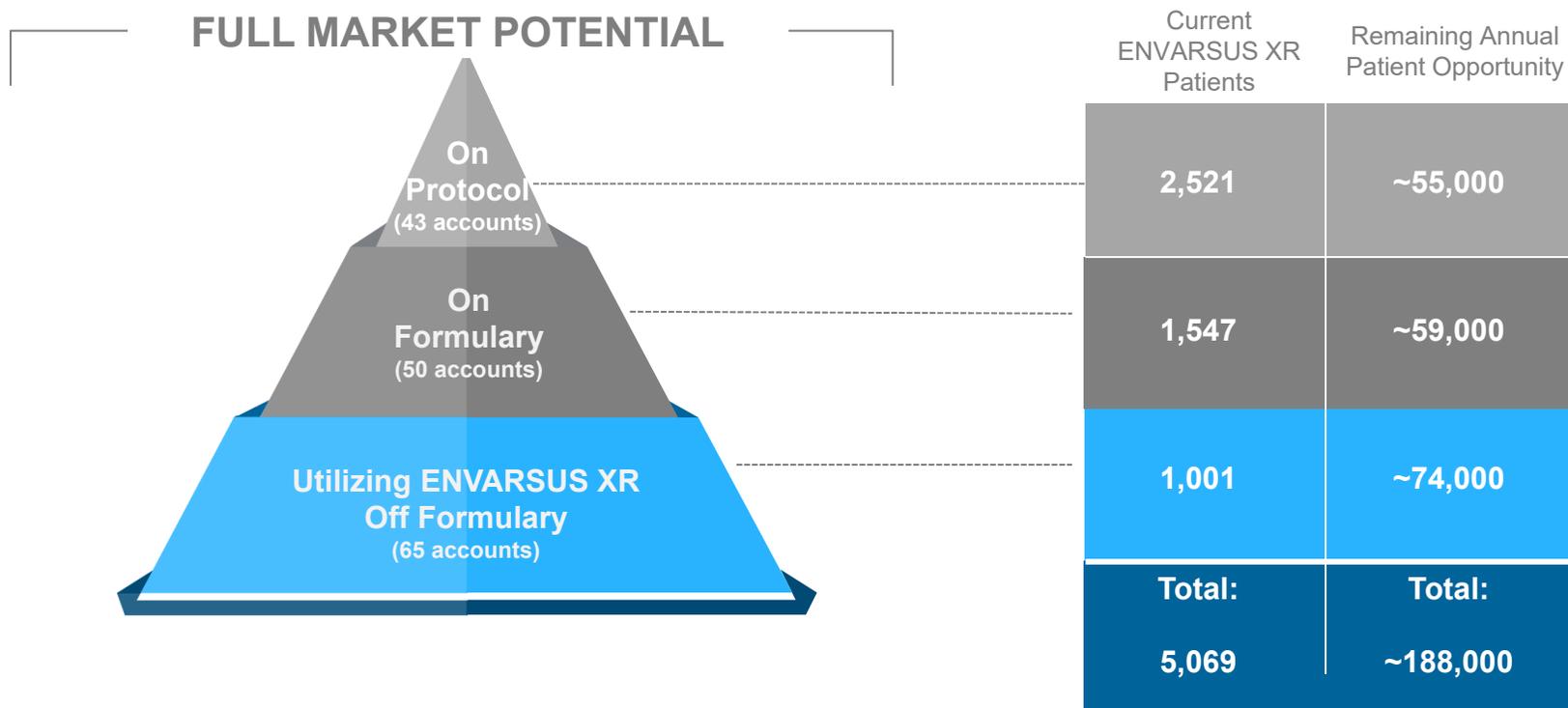
Formulary

A predetermined list of medications that clinicians can prescribe to their patients. *Usually only 1 or 2 drugs in a given therapeutic class are available to clinicians*

Protocol

Comprehensive treatment guidelines unique to each institution. Transplant protocols ensure that patients receive the best possible care and consistent, treatment regimen

Opportunity for ENVARSUS XR to Move Toward Full Potential



Data utilized in this analysis do not capture the entire tacrolimus market (e.g. non-reporting pharmacies, other organs)

As a Transplant Immunosuppressant for Patients with End Stage Renal Disease (ESRD), ENVARSUS XR Benefits from Mandatory Medicare Coverage



Payer Access*

79% of patients have access to ENVARSUS XR

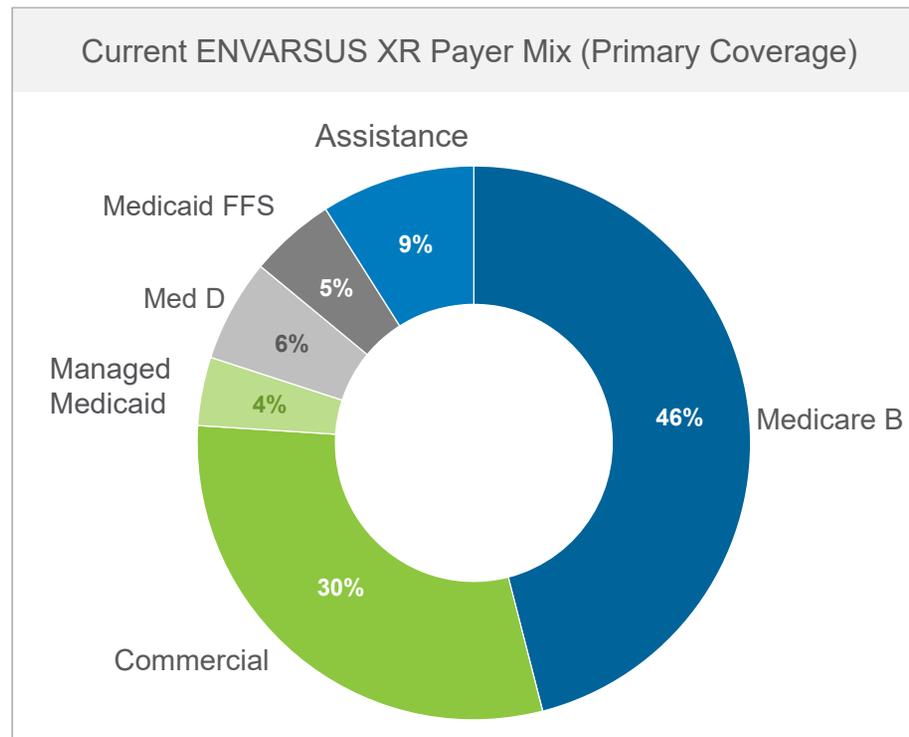
J7503 Unique HCPCS J Code



Q3 2018 ENVARSUS XR Prescription Approval Rates

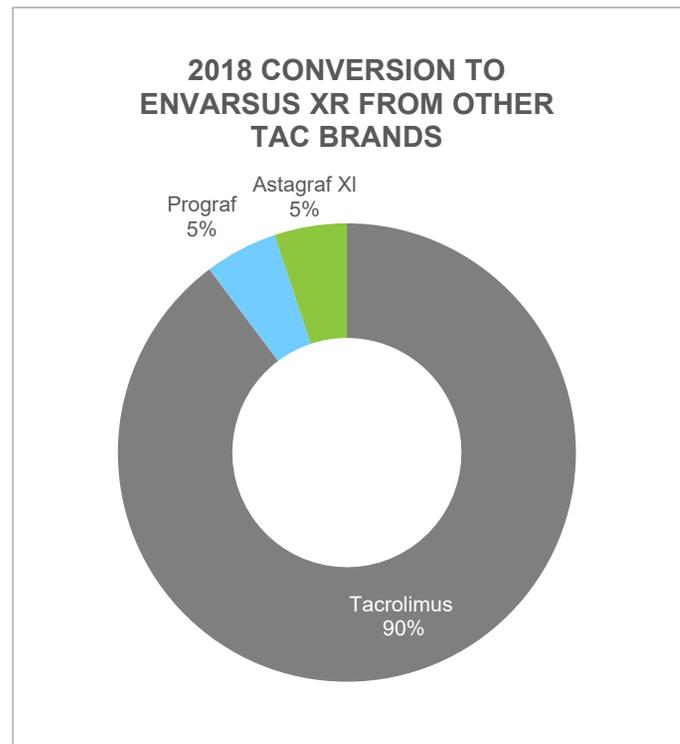
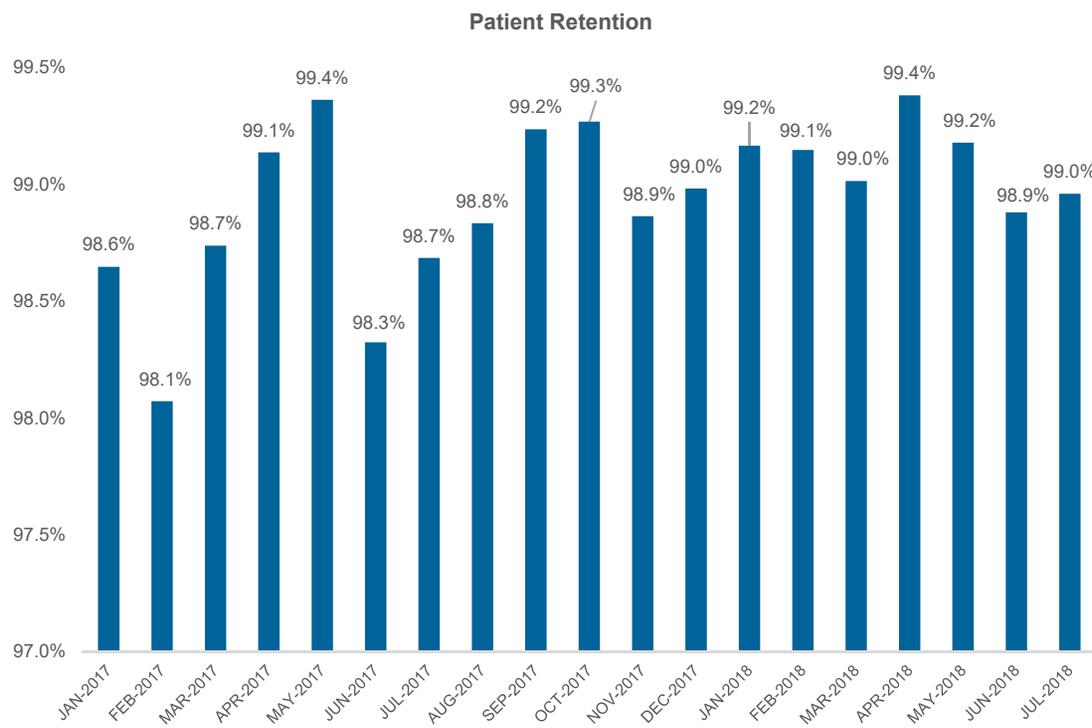
New TRx 78%

Refill TRx 96%



*Excluding Med B where there is 100% coverage of ENVARSUS XR

Patient Retention on ENVARSUS XR is 99% with the Majority of Conversions to ENVARSUS XR from Generic Tacrolimus



De Novo Immunosuppression: A New Indication for ENVARSUS XR

December 19, 2018: Now Approved for De Novo Patients

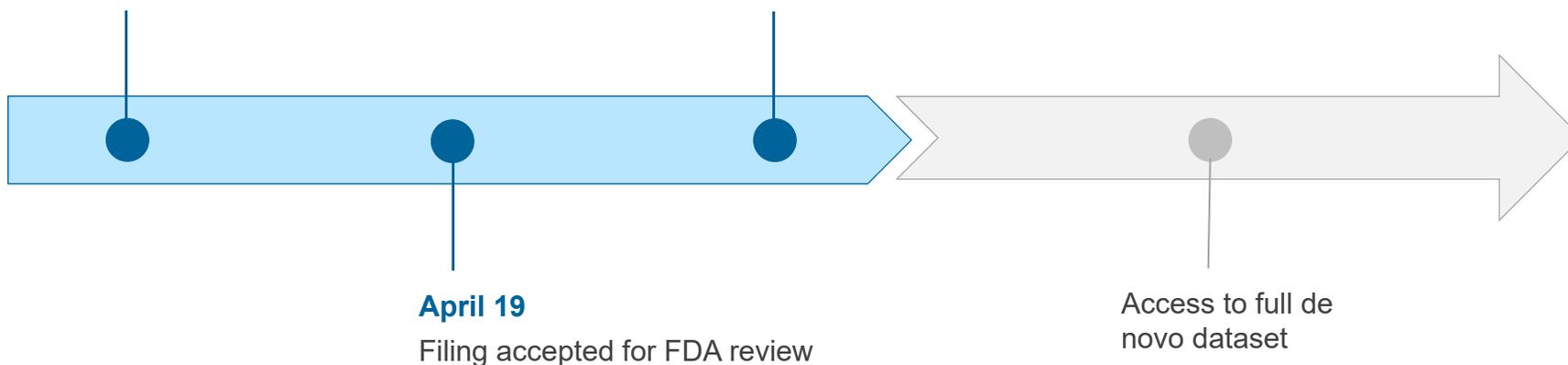


March 7

Submission for label expansion to include **de novo** immunosuppression

December 19

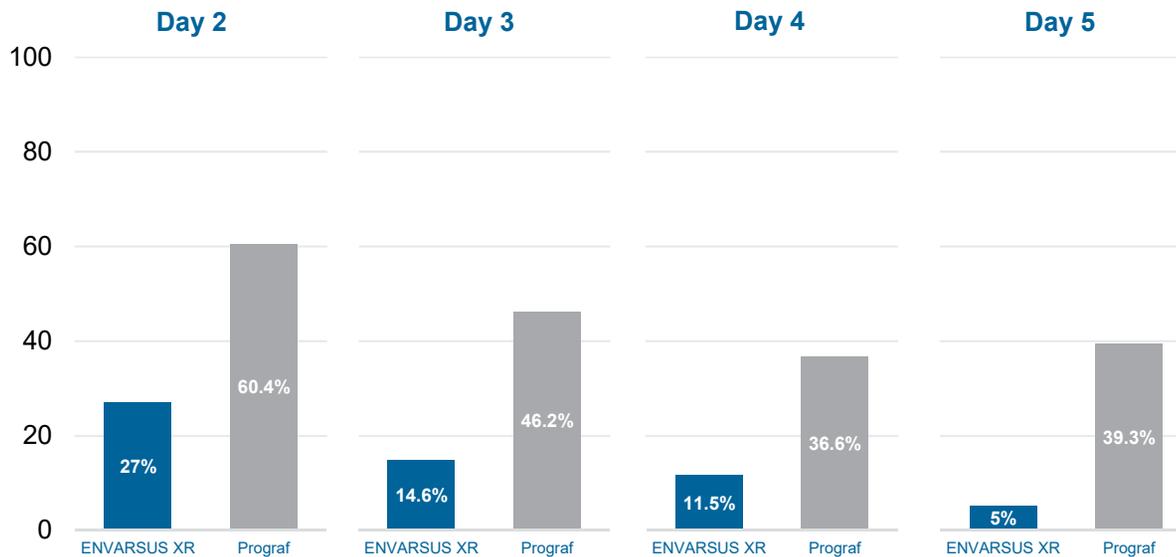
FDA approval for the prophylaxis of organ rejection in **de novo** kidney transplant patients in combination with other immunosuppressants



Approval in de novo patients is key to accelerating long-term growth for ENVARSUS XR

De Novo Use of ENVARSUS XR Provides Unique Delivery and Improved Bioavailability of Tacrolimus, Allowing for a Higher Starting Dose Post-Transplant and Results in Less Patients Under Target Trough at Day 5 with Similar Safety Profile as IR-Tac

Percent of patients with tacrolimus trough concentrations of <6ng/mL



Tacrolimus levels in the early post transplant period are correlated with acute rejection

ENVARSUS XR consistently achieves higher trough concentrations relative to Prograf on Days 2 through 5 post-transplant

Data on File. Veloxis Pharmaceuticals. October 2018.

ENVARUSUS XR Showed Lower Treatment Failure Rates in High-Risk Patients in a Pooled Analysis at 12 Months

In a pooled analysis, Treatment Failure was lower in patients greater than 65 years ages and African-American patients treated with ENVARUSUS XR at 12 months (N=861)

Age <65 yrs. -0.51% (-5.30%, 4.26%)

Age ≥65 yrs. -13.46% (-25.27%, -0.78%)

African American -13.82% (-27.22%, -0.31%)

Non-African American -0.00% (-4.75%, 4.75%)

Female -5.59% (-12.96%, 1.92%)

Male -0.55% (-5.08%, 6.13%)

De novo recipients -1.14% (-7.73%, 5.47%)

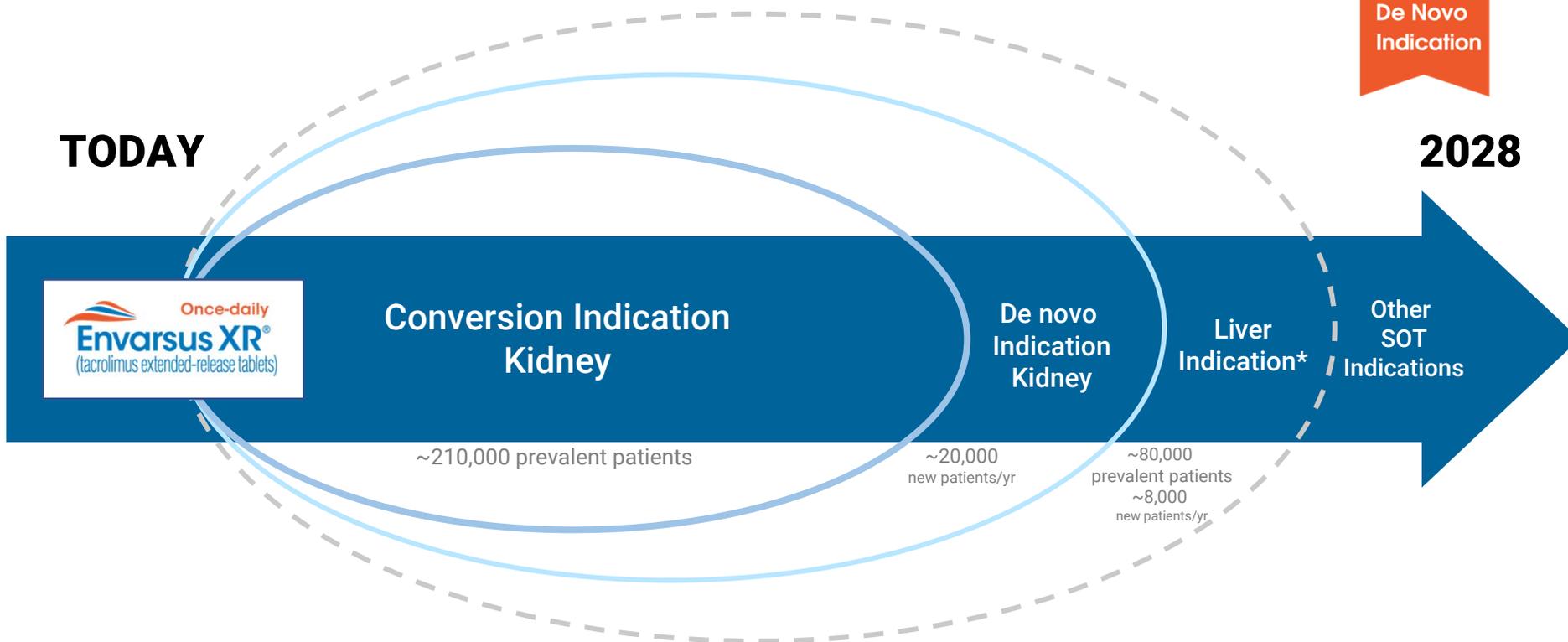
Conversion recipients -1.85% (-6.17%, 2.13%)

-24% -12% 0% 12%



Bunnapradist et al. *Transplant International* 2016

Potential Avenues For ENVARSUS XR Growth



*Approved in EU. Not Approved in US.

Financial Highlights

\$ millions	9 Months 2018	FY 2017	FY 2016
US revenue	\$23.8	\$17.6	\$6.5
EU revenue	3.9	4.3	2.7
Upfront milestones (one-time revenue)	-	8.3	-
RoW revenue	-	0.6	-
Revenue	\$27.7	\$30.2	\$9.2
Gross profit	22.5	25.0	6.2
SG&A	(26.7)	(32.5)	(34.3)
R&D	(0.5)	(0.9)	(0.6)
Operating income(loss)	\$(4.7)	\$(8.4)	\$(28.8)

Major institutional shareholders: Lundbeck A/S, Novo A/S	Cash \$30.6M at 9/30/2018	Long-term debt (Athyrium) \$60M at 9/30/2018	Accessible \$250M NOLs
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Management Team with a Proven Track Record

<p>Craig A. Collard <i>President & Chief Executive Officer</i></p>				
<p>Ira Duarte <i>Chief Financial Officer</i></p>				
<p>Ulf Meier-Kriesche, MD <i>Chief Scientific Officer</i></p>				
<p>Mark Hensley <i>Chief Commercial Officer</i></p>				
<p>Brett Fleshman <i>VP, Strategy & Corporate Development</i></p>				
<p>Stacy Wheeler <i>VP, Operations</i></p>				
<p>Noel Barnard <i>VP, Legal Affairs</i></p>				

Cohesive commercially-oriented management team with significant overlapping pharma experience

Key Takeaways

01

Continue to convert generic Tac to ENVARSUS XR

02

Obtain De Novo label expansion

03

Pursue additional transplant indications

04

Leverage MeltDose drug delivery technology to develop new products or collaborations

05

Target M&A to leverage hospital-based commercial infrastructure

06

Experienced management with significant overlapping experience

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in Transplant.**

