



Veloxis Pharmaceuticals A/S

2015 First Half Report

Investor Conference

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Forward-Looking Statements

This presentation contains forward-looking statements. All statements other than statements of historical facts included in this presentation are forward-looking statements that are subject to certain risks, trends and uncertainties that could cause actual results and achievements to differ materially from those expressed in such statements. These risks, trends and uncertainties are in some instances beyond our control.

Words such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “will” and other similar expressions identify forward-looking statements, although not all forward-looking statements contain these identifying words. In particular, any statements regarding potential future regulatory approvals for ENVARSUS XR® (formerly LCP-Tacro™), and commercial forecasts are considered forward-looking statements. These forward-looking statements involve substantial risks and uncertainties and are based on our assessment and interpretation of the currently available data and information, current expectations, assumptions, estimates and projections about our business and the biopharmaceutical and specialty pharmaceutical industries in which we operate.

Important factors that may affect our ability to achieve the matters addressed in these forward-looking statements include, but are not limited to our ability to obtain regulatory approval for, and commercialize, ENVARSUS XR®; our ability to hire and retain personnel in a competitive industry; our reliance on third parties to manufacture and distribute ENVARSUS XR®; competition from existing therapies and therapies that are currently under development, including Prograf® (tacrolimus), Advagraf® /Astagraf XL® (tacrolimus), generic tacrolimus products, and Nulojix® (belatacept); whether we are able to obtain additional financing, if needed; risks of maintaining protection for our intellectual property; risks of an adverse determination in intellectual property litigation; and risks associated with stringent government regulation of the biopharmaceutical industry.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements, which speak only as of the date hereof. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. We do not have a policy of updating or revising forward-looking statements and, except as required by law, assume no obligation to update any forward-looking statements.



Agenda

- Veloxis Key Updates
- ENVARBUS XR Status Update
- Financials 1H 2015
- Summary

Key Updates

- U.S. FDA approval achieved
 - Envarsus XR is indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations
- Envarsus XR granted U.S. orphan drug exclusivity for the approved indication
- U.S. commercial infrastructure preparations on track for product launch readiness
 - Majority of Field Force hired, on-board and being product trained
- Clinical differentiating data continuing to be generated
 - Results released: ASTCOFF PK study comparing all three major brand formulations of tacrolimus
 - ENVARSUS XR demonstrates exhibits a differentiated pharmacokinetic profile when compared to twice-daily tacrolimus (Prograf®) or the once-daily tacrolimus product (Astagraf XL®).
- EU commercialization activities progressing successfully
 - Envarsus EU launch roll-outs continue in line with plans via Chiesi
 - 6 Countries launched to date
 - Good sales coverage and positive initial reception by prescribers

ENVARUS XR Status Update



U.S. Regulatory Update

- On June 12, Litigation with FDA completed
 - Based upon the outcome of the litigation, Veloxis filed for the “conversion” indication for Envarsus XR with the FDA
- On July 10, 2015 U.S. FDA approved marketing authorization of Envarsus XR (tacrolimus extended-release tablets)
 - Indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release formulations in combination with other immunosuppressants
- On August 14, 2015, U.S. orphan drug exclusivity granted
 - For prophylaxis of organ rejection in patients who convert from immediate-release tacrolimus
 - Entitles Veloxis to a waiver of the FDA prescription drug user fees for Envarsus XR
 - Potential tax incentives
 - U.S. orphan indication exclusivity protection for up to seven years

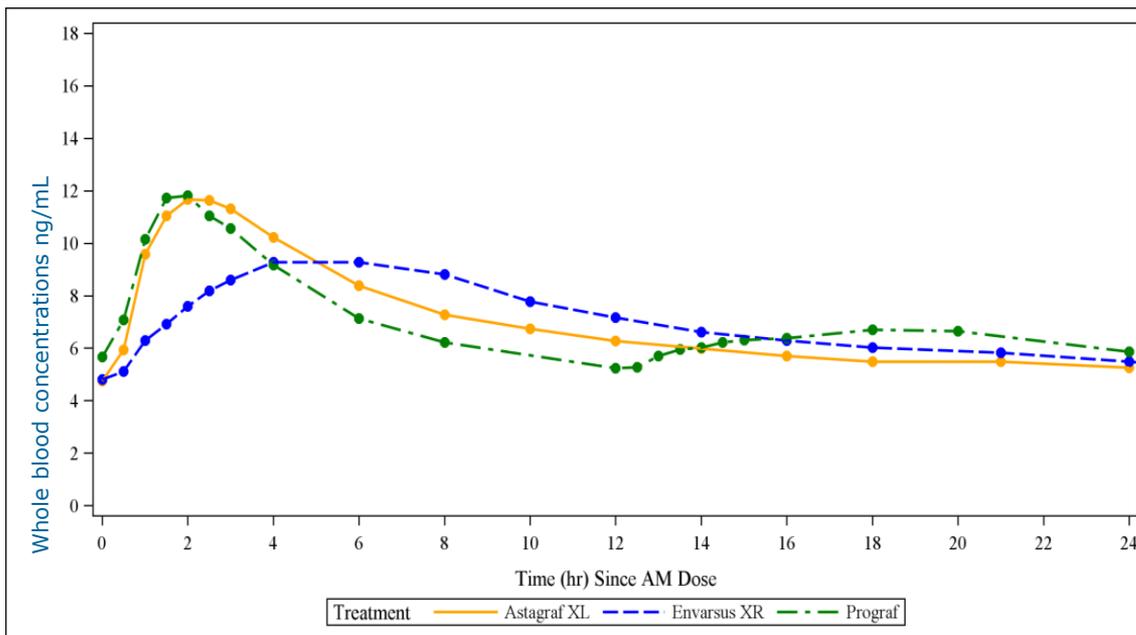


ENVARUSUS XR Clinical Update – ASTCOFF Study

- A Steady-state Comparison Of all FK-506 Formulations
 - Head to head comparison of the PK profile of ENVARUSUS XR compared to Prograf twice-daily and Astagraf XL once-daily in ONE study
 - Results to be presented at European Society for Transplantation, September, 2015
 - Primary end-points announced July 2015 demonstrated:
 - Envarsus PK parameters differed significantly from other formulations, while Advagraf and Prograf tended to be similar to each other.
 - Greater absorption (>30% reduction in dose required for equal blood levels)
 - Reduced Peak-to-Trough fluctuation (30% reduction in peak)
 - Peak concentration at 6 hours (vs 2 hours)

ASTCOFF – Pharmacokinetics

Envarsus XR once-daily vs Prograf twice-daily vs Astagraf XL once-daily in Stable Kidney Patients, at Steady State



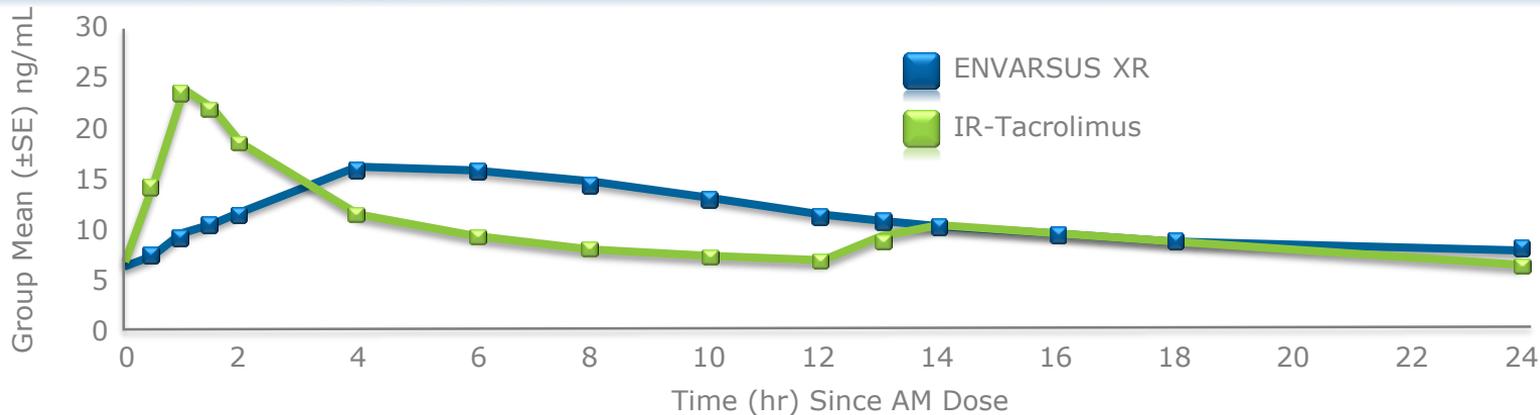
- This study supports the following recommended total daily dose conversions rates:
 - Prograf to Advagraf +8%
 - Prograf to Envarsus -30%
 - Advagraf to Envarsus -36%

ENVARUSUS XR Clinical Update – ASERTAA Study

- A Study of Extended Release Tacrolimus in African Americans
 - Phase IIIb/IV study of Envarsus in African-American (AA) kidney transplant recipients
 - Study primary elements complete
 - Results presented at American Transplant Congress in May 2015
- High unmet needs in the African-American transplant population
 - 30% of US kidney transplant recipients
 - Rapid metabolizers of tacrolimus
- Pharmacokinetic (PK) comparison of ENVARUSUS XR to twice daily immediate-release tacrolimus (IR-Tac)
 - Two sequence, cross-over design study

ENVARSUS XR benefits demonstrated in Pharmacokinetic parameters for AA patients

Tacrolimus Plasma Concentration by Time



- 20% lower dose required for ENVARSUS XR
- ENVARSUS XR is associated with a reduction in peak blood levels of approximately 30%
- Reduced intra-day fluctuations by ~50%
- Tacrolimus exposure was consistently maintained in the absence of dose adjustments post conversion for IR-Tac
- PK benefits most marked in high-risk rapid metaboliser patients

ENVARSUS XR Update –U.S. Commercial



- Commercial preparation activities on track
- Majority of US Commercial Team hired and on-boarded
 - Sales team of 18 FTEs
 - Competitive size compared with other transplant companies
 - From all major transplant Companies: Astellas, BMS, Novartis, Pfizer, Roche
 - Cumulative 130 years of experience commercializing Transplant products
 - Targeting top 140 key Transplant Centers (80% of Transplants)
- Promotional materials and activities being finalized
- KOL engagement fully underway
- Payer interactions initiated
- Medical support functions in place



Market Dynamics

- Maintenance Population

(US and EU each ~ 180k kidney patients)

- Switching will not take place frequently in truly stable patients
- Patients who may potentially benefit
 - Poorly compliant patients
 - High metabolizers, high-dose patients
 - African-American patients
 - Patients with significant tremors
- Patients will be converted over time as they come in for follow-on visits or as concerns arise

20-50% of patients

Envarsus Update – E.U. Commercial

- Launch Roll-Out continues to be on track through partner Chiesi working in close collaboration with Veloxis
- Six countries now launched
 - Full coverage of all transplant centres in initial launch countries
 - Market feedback
 - Interest in the unique profile and technology of Envarsus
 - Customers expressing interest to start using Envarsus
- Additional key markets to launch in 2H 2015
 - Based on local pricing negotiation requirements

Financial Results



First six month 2015 results in line with expectations

Full year outlook improved

MDKK	First six months		Full year 2014	Full year outlook 2015	
	2015	2014		New & improved	Previous
Revenue	9,6	24,4	123,4		
Production costs	(5,8)	-	(3,2)		
Gross profit	3,8	24,4	120,2		
Sales and marketing	(19,5)	(13,7)	(41,3)		
Research and development	(39,1)	(51,0)	(90,1)		
General and Administration	(27,6)	(17,7)	(47,4)		
Operating loss	(82,4)	(58,0)	(58,6)	(175) - (205)	(200) - (240)
Net loss	(66,1)	(53,1)	(36,3)	(155) - (185)	(195) - (235)
Cash position ending	191,1	264,2	270,4	100 - 130	55 - 95

Summary



Summary

- ENVARSUS XR in the United States
 - FDA Approval received
 - Veloxis preparing to market and sell directly in the attractive U.S. market
- Envarsus in Europe
 - Approved and successfully launched for Kidney and Liver Transplants
 - Chiesi Farmaceutici marketing and selling
- Partners being identified to market in other regions
- Funding options (debt, equity, deal-making) to address future capital requirements are being actively assessed

Q & A

Thank you for your attention!

