Veloxis – fast facts

Veloxis Pharmaceuticals is a specialty pharmaceutical company listed on NASDAQ OMX Copenhagen, currently focused on building a clinical and market-stage pharmaceutical business around its late stage transplant immunosuppression product candidate LCP-Tacro™.

LCP-Tacro™ is being developed as a once-daily dosage version of tacrolimus for the treatment of kidney and liver transplant patients. One phase 3 clinical study in kidney transplant patients has been completed and another has completed enrolment of patients with top line results expected by mid-2013.

Veloxis uses its proprietary MeltDose® technology, which has been validated in clinical studies and through FDA approval of the dyslipidemia product Fenoglide®, to improve absorption and enhance the bioavailability of existing marketed drugs.

Based on encouraging data from the first phase 3 study and an extensive phase 2-programme, the European regulatory filing of LCP-Tacro™ has been accelerated to around mid-2012, while filing in the U.S. is projected for the second half of 2013.

In order to maximise the full value of the LCP-Tacro™ programme, Veloxis has decided to build and develop its own commercial infrastructure in the key U.S. transplant market, while seeking partners to commercialise the product outside the U.S.

LCP-Tacro™ is targeting a global market of around USD 4.4 billion.

Compared with the current leading transplant drug, Astella's twice-daily version of tacrolimus (Prograf), Veloxis believes that LCP-Tacro™ may have the following potential benefits:

- Once-daily dosing
- Improved systemic absorption
- Improved bioavailability and thus lower dose
- Limited variability in the concentration of tacrolimus (lower peak-to-trough fluctuation)

SUMMARY

LCP-Tacro™

- ✓ Significant sales potential
- ✓ Potential 'best-in-class' profile
- ✓ Optimized, branded version of the #1 transplant drug

Proprietary technology platform (MeltDose®)

- ✓ MeltDose® is proven clinically and commercially with dyslipidemia product Fenoglide®
- ✓ Low cost / transferable
- ✓ Patent protected

Low risk

- ✓ No New Chemical Entity risk
- ✓ Late-stage efforts
- ✓ Focus on established markets with medical and commercial needs

History
Veloxis was founded as LifeCycle Pharma in 2002 as a spin-off from H. Lundbeck. In 2011 the name was changed to Veloxis. The underlying technology platform was developed to address a critical roadblock experienced by pharmaceutical companies related to poor oral absorption (bioavailability) of otherwise high-potential drugs

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