Human Bioengineered Blood Vessels are Being Investigated as Lower Extremity Bypass and Dialysis Access: Why and Prospects for the Future

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Disclosure Information

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Disclaimer:
The Humacyte investigational bioengineered vessel is an investigational biologic currently being studied in Poland and the US to evaluate its potential safety and preliminary efficacy when used as a vascular access in patients with End Stage Renal Disease requiring hemodialysis and in patients with Peripheral Arterial Disease.

This investigational product has not been submitted for regulatory approval by the FDA or any other regulatory authority. Both the clinical significance of the data reviewed in this presentation, and any potential future indication(s), warnings, precautions, and adverse reactions are unknown at this time.

This presentation includes unpublished data as of September, 2015.

Polymer scaffold is designed to guide tissue shape ...

... and designed to degrade ...
No Cells Pre-Implant

Smooth muscle Alpha Actin

CD 31 (endothelial)

6 Month Explant (Animal Model)

Initial Clinical Outcomes of First-in-Man Human Implants (6 months)

- No indication of immune response
- No change in PRA Class I Reactivity [N=6]
- No dilatation or aneurysms [N=25]
- Flow rates suitable for dialysis [N=25]

Lawson et al., American Heart Association Meeting, Dallas TX, 2013

Szczecin Poland: October 11, 2013
Interim Analysis of Investigational Bioengineered Vessels in PAD

Survival distribution function

Time [days] to loss of assisted patency

Patients at Risk

0 100 200 300 400 500 600 700

Secondary Patency

Primary Patency

Why and Prospects for the Future...

- Off-the-shelf bioengineered vascular tissues are possible
- Non-immunogenic, integrate with native tissue, repopulate and remodel
- Post-implant with increased strength and little intimal hyperplasia
- Phase II clinical trial underway in Poland and the US for patients with ESRD requiring hemodialysis access and in patients with PAD
- Phase III clinical trials in hemodialysis access are planned in 2016

Humacyte Investigational Bioengineered Vessel may one day offer patients with an alternative option for dialysis access and peripheral arterial disease

We would like to thank those patients who have enrolled ongoing studies evaluating this investigational vessel