

Aastrom



Uncertainty, Risk & Convergence: A Cell Therapy Example

Medical Technology Leadership Forum

Panel – Scientific, Development & Business Strategies for Converging Biologics with Devices

June 5, 2007

Uncertainty, Risk & Convergence

Patient hope

Cures vs. Continuous care

Technology adoption

Data vs. Emotion

Culture fit

Device vs. Pharma/Biotech

Regulatory hurdles

Traditional drugs/devices vs. Cells vs. Combination products

Convergence opportunities

Today vs. Tomorrow

Aastrom Mission

Improving lives through regenerative medicine

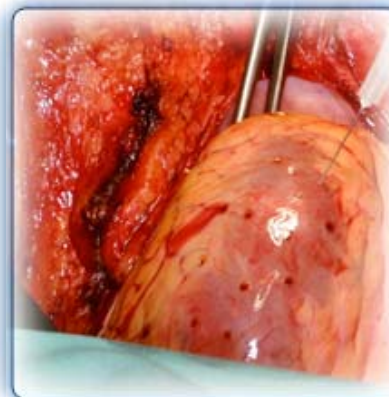
Therapeutic Interests



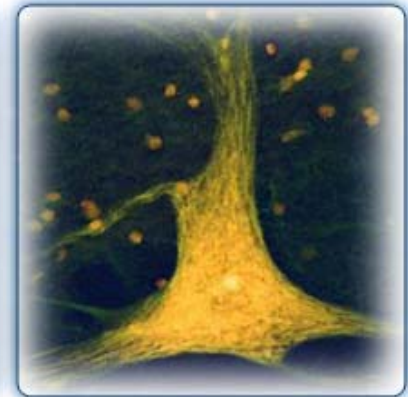
Bone



Vascular



Cardiac



Neural

Technology Adoption

New medical technology adoption is usually conservative

Slow build of knowledge generation via academia, clinical research and intro into the clinic

NIH and publicly-funded research programs

Adoption of stem cells aggravated by emotions and uninformed public and political opinions

Stem cell “noise level” is too high for any single entity to have significant impact

Where Does Cell Therapy Fit?

Device companies

- Relatively high appetite for risk

- Long clinical development timelines are alien to many

- Some are culturally adverse to biologics

- Many focused on 510(k) devices and 6 month product cycles

Large pharma/biotech

- Starving for new products

- Many already have internal cell therapy programs

- Will watch the clinical data flow very carefully

All potential partnerships

- Need to understand scale-up/manufacturing and business models

- IP Landscape

Partnering Issues

Management should be very cautious

Consider why and when a strategic partnership is desirable

Prepare to “go it alone”

Significant risks to partnering

Fit is vital

Balance/share economic risks

Augmentation vs. Replacement

Attitude drives behavior

Potential to impair the company from new financing or additional relationships

US Regulatory Uncertainty

Few regulatory precedents exist in US

Further drives the uncertainty discount

First product through FDA (whatever it is) will drive value for the sector

Disconnect in US between stem cells as biologic drugs and stem cells as output from devices - *BLA vs 510(k)*

Combination product convergence

Cells + Devices...Drugs...Tissues...etc.

Challenge: Are regulations evolving in step with medical innovations?

Global Regulatory Differences

Regulatory environment outside the US is very different

Some EU countries differentiate autologous cells and have minimal regulations

In Germany, reimbursement established for stem cells + coronary artery bypass grafting (CABG) treatment

In Asia, regulatory environment highly variable

Convergence Examples

Aastrom's TRC-based (Tissue Repair Cell) products autologous cells – are being used at the repair site in combination with:

- Human tissue products (cadaveric material) in the US

- Void-filling medical devices (ceramic matrices) in the EU

The Future ...?

Augmentation...evolution

Delivery devices - specialized catheters to deliver cells

Growth factors - combined with cells to control behavior

Transplanted tissues - aid tissue integration and viability

Replacement...extinction

No more pills and scalpels

Biologic analogs

Assume earlier risk to acquire/partner ahead of value-driving events

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