

## The ISCT Commercialization Committee: 1 Year On

About a year ago we had the good fortune to connect with some very motivated members of ISCT with great commitment towards advancing translational cell therapy. Working with ISCT Executive leadership, an Industry Task Force (ITF) was created to assess reciprocal value between industry and ISCT, which then led to construction of an Industry Community network and revamping of the ISCT Commercialization Committee (CC).

It seems just a short while ago that we stood in front of the ISCT 2010 Annual meeting delegates, on behalf of the ITF, and laid out a vision on how ISCT as an organization could achieve greater strategic alignment with its industry members. We all recognize that the future of cell therapy is completely dependent on successful late stage clinical development reflecting the unity of translational investigators, regulators, and industry.

### Recommendations and conclusions from the ITF included that a new Commercialization Committee be developed to:

- foster new ISCT relationships with therapeutic and stem cell societies
- foster educational workshops and forums to cross-educate and standardize global practices in cell therapy
- create industry subcommittees to address priority initiatives, with clear benchmarks and global implementation
- establish a framework for a greater industry community within ISCT – opening doors for industry to share the new vision for commercialization of cell therapy emphasizing the regenerative medicine space.

A founding Commercialization Committee membership was chartered to construct tangible steps to move these principles forward. Strong support was received from ISCT Executive leadership, and actions consistent with the strategic vision of the society have been executed over the last year. As a credit to committee membership, consistent engagement and contributions to this program have validated these objectives and rewarded our efforts.

Very importantly, this committee has fostered new relationships across geographies and an increased international visibility for ISCT and its strategic goals.

## KEY ACHIEVEMENTS MAY 2010 TO MAY 2011

### 1. Identified leadership roles for industry in the Organization including the Executive, Advisory, Regional and Scientific committees.

### 2. Raised the profile of industry as a key link in the ISCT global translational hub of regulatory policy makers and institutional stem cell centers through publications, press releases and interviews:

- ❖ Publications:
  - A changing time: the International Society for Cellular Therapy embraces its industry members. *Cytotherapy*, 2010; 12: 853–856
  - The International Society for Cellular Therapy: evolving to meet the demands of the Regenerative Medicine Industry. *Regen Med.* 2011 Mar;6(2):163-6.
  - Cell Therapies; Commercializing a New Class of Biopharmaceuticals. *BPI Supplement* March 2011
- ❖ Press Releases:
  - "International Society for Cellular Therapy (ISCT) joins forces with Roche and Genzyme to launch Cell Therapy Industry Partnership August 2010
  - International Society for Cellular Therapy (ISCT) Launches Inaugural Cell Therapy Commercial Development Focus Group on Peripheral Vascular Disease, January 2011
- ❖ Contributing ISCT interviews for articles in *Science* and *Nature Biotech*

### 3. Provided global front row insight to drive key development decisions through the launch of:

- ❖ ISCT Commercial Development Focus group Series
  - In keeping with its commitment to connect industry, regulatory experts, therapeutic societies and translational centers to advance emerging cellular therapies, the CC launched its first commercial development focus group addressing cell therapies for Peripheral Vascular Disease (PVD) in January 2011 and plans for future forums targeting cell therapies for Inflammatory Bowel disease (IBD), stroke and graft versus host disease (GVHD) by the year end.



❖ ISCT BMCOGS global roundtables.

- Also launching this year is the BMCOGS subcommittee's global roundtable series on Cell Therapy Business Models and Reimbursement and a related series of informational documents on current policy and challenges for reimbursement determination in the various international regions. The first roundtable addressing issues and implications for experimental reimbursement codes for cell therapy in the US is confirmed for Sept 14 2011 in partnership with NMDP.

**4. Developed industry relevant education on Cell Therapy Commercialization:**

- ❖ Strategies for Commercialization Track at the 2011 Annual meeting
- ❖ Process and Product Development webinar series:
  - Cell Therapy Bioprocessing February 8 2011
  - Potency Testing March 9 2011
  - Immunotherapeutics September 7 2011
  - hESC Manufacturing November 9 2011

**5. ISCT Cell Therapy Bioprocessing Tools and Reagents Database- a service for members and the community at large.**

Launching in Rotterdam, this is a no-cost opportunity for companies producing the tools and reagents to upload and promote the availability and application of their products. For end users, it provides a central location for cell therapy bioprocessing tools and reagents for you to find and compare product options, AND to rate and comment on your experience with the product. This will give new users and the product companies valuable feedback.

**6. Created a Cell Therapy Industry Community:**

Where innovators, researchers and investors, service providers and customers have the opportunity to connect, share expertise and address the obstacles to commercialization as a group with common challenges and the common goal of getting therapies to patients. Dialogue is facilitated through project collaborations, online and with our in person networking events such as the one being hosted here in the De Dolen. This has already proven to be an effective driver for new ISCT membership.

**So what's in store for the next 12 months?**

Check out the ISCT website where we have listed our goals for this year which promise more access to experts, expanded international activity in Asia, more industry education and resources and alliances with other key industry organizations. In addition look out for resources that provide guidance and help remove ambiguity in the area of Potency Testing for cell therapy products.

The priorities of the group are driven by our members so if you want to see a business issue critical to you addressed then we encourage you get involved.

We send our thanks to all the Commercialization Committee and sub-committee members who contributed to these great achievements and our Industry Community members, represented here by their logos.

We look forward to continued work with you and the ISCT leadership team over the next year as a collective motivated by the common goal of getting innovative cell therapies into clinics for patients.

Best wishes,

**Robert Deans, PhD**

*Executive VP Regenerative Medicine,  
Athersys, Inc  
Chair, ISCT Commercialization Committee*

**Francesco Lanza, MD**

*Head - Section of Hematology and BMT Unit,  
Hospital of Cremona, Italy  
Co-Chair, ISCT Commercialization Committee*

**Richard Maziarz, MD**

*Medical Director, Adult BMT Program  
Oregon Health and Science University, USA  
Co-Chair, ISCT Commercialization Committee*

