Global Regulatory Summit

In conjunction with the iSBTc Annual Meeting Oct 29-Nov 2, 2008

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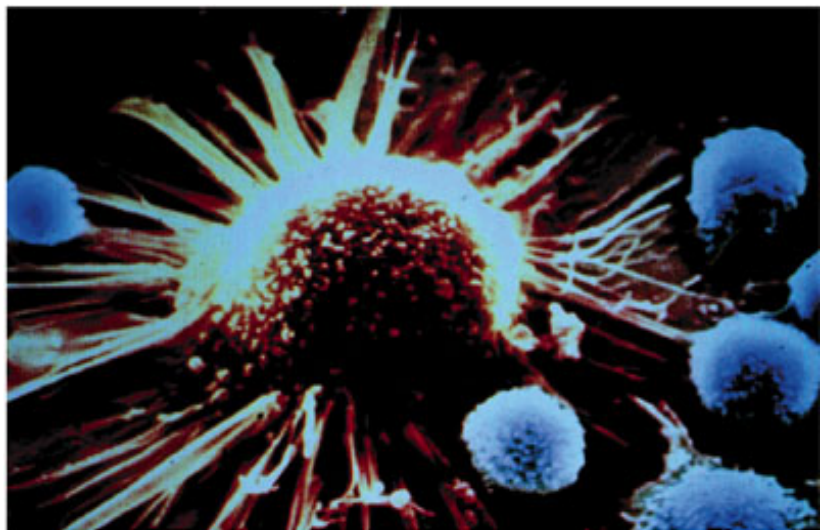
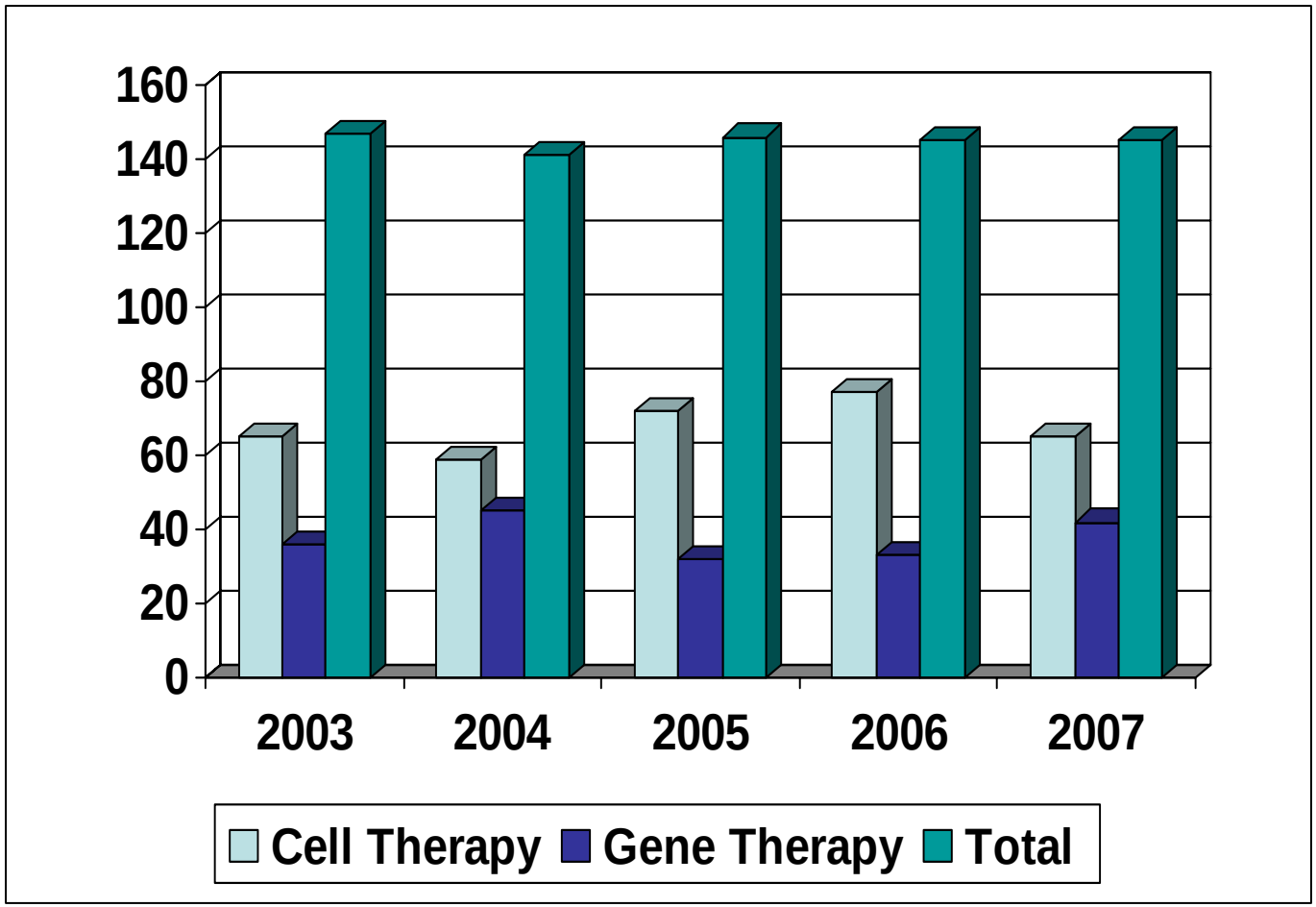


Oncology Biologics

- Cancer vaccines
- Immunotherapy
- Gene modified cells or vectors
- Oncolytic viruses, bacteria etc.
- Monoclonal antibody
- Therapeutic Proteins
- Combination therapy and products

FDA/CBER New Applications FY 2003-2007



FDA/CBER Regulated Cancer Vaccines INDs

- Approx. 180 active therapeutic cancer vaccine INDs regulated by FDA
- Most sponsors are academic
- Approx. 14 Phase III trials
- No cancer vaccine or immunotherapy products licensed in USA

Outline of GRS Session

- Longer Presentations from US, Europe and Japan
- Key presentations by regulatory leaders from Canada, India, China, and Switzerland
- Panel Discussion

Presentations

- United States:
  - CMC: Keith Wonnacott, Ph.D. - FDA
  - Preclinical: Yongjie Zhou, Ph.D. - FDA
  - Clinical: Ke Liu, M.D., Ph.D. - FDA
- Europe:
  - New Regulations for “Advanced Therapies” Patrick Celis, Ph.D. EMEA
  - Considerations in product development
    Thomas Hinz, Ph.D. Paul-Ehrlich
- Japan
  - Cancer Vaccines and Immunotherapy
    Mr. Masatoshi Narita – PMDA

Presentations contd.2

- Canada
  - Gina Coleman, MD – Health Canada
- India
  - Bindu Dey, PhD – Department of Biotechnology
- China
  - Luo Jianhui, MD – Center for Drug Evaluation, SFDA
- Switzerland
  - Andreas Marti, PD, PhD – Swissmedic

Panel Discussion

- Panelists include representatives from all participating countries
- Questions for regulatory panelists to address
- Audience questions

- All speakers available to answer your questions