

# CELL & GENE THERAPY FORUM 2010

From promise **to products**

# VACCINE FORUM WASHINGTON 2010

Driving **progress**

## Day 1 - Monday 25th January 2010

### Morning plenary session

How will cell therapies, gene therapies and tissue-engineered products fit in to a reforming healthcare picture?  
Examining the commercialization strategies of companies in pivotal trials

- What degree of benefit will they need to deliver to secure reimbursement?

### Followed by your choice of three highly interactive parallel sessions:

#### Focus session 1

An in-depth examination of autologous and allogeneic cell therapy business models: What are the keys to achieving commercial viability?

#### OR | Focus session 2

Gene therapy clinical update: Analyzing recent clinical success stories in key therapeutic areas to inform your trial design strategy

#### OR | Workshop\*

Providing practical insights into how to build a commercially focused cell/gene therapy or tissue engineered product company from the ground up

- What are the key business challenges you will face at each stage of R&D, and how can you prepare to meet them?

### Followed by afternoon plenary session

What traditional and alternative funding options are now open to academics and companies seeking to translate preclinical cell/gene therapy and tissue engineered product candidates to Phase IIa and beyond?

### Morning plenary session

How are we doing with pandemic planning?

- Are we making the right decisions on vaccine strategy and funding to rapidly deal with outbreaks of new strains?

### Followed by your choice of three highly interactive parallel sessions:

#### Focus session 1

Clinical trial strategy and regulatory pathways for pandemic influenza vaccines

#### OR | Focus session 2

Optimizing your value proposition and positioning strategy for new vaccines

- Case studies of recent launches

#### OR | Workshop\*

Vaccines for major public health needs: Analyzing the latest clinical results for nosocomial infections

### Followed by afternoon plenary session

How will pandemic influenza change the technology, manufacturing and economic landscape of the vaccine industry?

## Day 2 - Tuesday 26th January 2010

### Morning plenary session

How will big pharma drive the continuing maturation of the cell and gene therapy sector?

### Followed by your choice of three highly interactive parallel sessions:

#### Focus session 1

Driving the product characterization and optimization of cell & gene therapies through scale-up

#### OR | Focus session 2

What breakthroughs are being achieved in defining the Mechanism of Action (MoA) of cell therapies as they advance towards and through the clinic?

#### OR | Workshop\*

Regulatory 'surgeries'

### Followed by afternoon plenary session

How are regulatory frameworks and guidelines for cell/gene therapies and tissue-engineered products continuing to evolve on a global basis?

- Delivering the latest updates from the US, Europe, Asia and Oceania

### Morning plenary session

Defining the business models that are most likely to deliver affordable vaccines for major global unmet needs

### Followed by your choice of three highly interactive parallel sessions:

#### Focus session 1

What evidence is now available showing commercial promise for cell culture manufacturing?

#### OR | Focus session 2

How are translational science and biomarkers being applied to development pathways for novel adjuvants and delivery systems?

- What is the regulatory response?

#### OR | Workshop\*

Prophylactic and therapeutic vaccines for chronic viral infectious diseases: Where are the breakthroughs in terms of understanding of immunity?

### Followed by afternoon plenary session

Therapeutic cancer vaccines: Now that licensure is a reality, how will these products be commercialized, and what does this mean for the vaccines sector as a whole?

## Day 3 - Wednesday 27th January 2010

### Morning plenary session

Picking the winners: Assessing the prospects of - and progress with - emerging technologies

- What are the keys to accessing Government funding in order to help realize their potential?

### Followed by your choice of three highly interactive parallel sessions:

#### Focus session 1

Delivering strategic solutions to the key cost control issues and risk management conundrums with cell and gene therapy products

- How to minimize Cost of Goods (CoG)?
- Build or buy?
- How to efficiently source both capacity and materials?

#### OR | Focus session 2

Stem cell therapy clinical strategy and data update

- How are leading candidates performing in the clinic?
- Addressing key fundamental questions regarding the sourcing and delivery of stem cells

#### OR | Workshop\*

Overcoming the remaining challenges with viral and non-viral delivery platforms for gene and RNAi therapies

### Morning plenary session

Analyzing the impact of the Obama administration's healthcare regime on the evolution of priorities for vaccines

### Followed by your choice of three highly interactive parallel sessions:

#### Focus session 1

Evaluating progress in influenza vaccine R&D: Advancing 2nd generation DNA vaccines, and striving for cross protection and the universal vaccine

#### OR | Focus session 2

How close are malaria and flavivirus vaccines to the market?

- Analyzing the latest clinical data for breakthroughs and next steps

#### OR | Workshop\*

Financing and partnerships to bring novel enabling technologies to market for developed and developing world vaccine needs

\* Denotes a highly interactive session for a maximum of 30 people