DOING BUSINESS IN JAPAN WORKSHOP
Cognate Bioservices Ballroom | 7:15am – 8:45am
In Partnership with the Forum for Innovative Regenerative Medicine (FIRM)

An Evolving Market – Innovations for Industrialization Platforms and the Latest Rise of Commercialization

Chair:
Masayuki Nomura, Ph.D., General Manager, Business Development and Licensing Department, Healthcare R&D Center, Corporate R&D, Asahi Kasei Corporation

7:15am – 7:20am | Welcome Remarks
Speaker:
Tetsuya Tanaka, Director, Bio-Industry Division, Ministry of Economy, Trade and Industry, The Government of Japan

7:20am – 7:35am | Evolving Market and Industrialization Platform for Innovative Regenerative Medicine in Japan
Speaker:
Yoshitsugu Shitaka, Ph.D., President, Astellas Institute for Regenerative Medicine (AIRM)

7:35am – 8:05am | Update on Regulatory Landscape of Regenerative Medicine
Speaker:
Yoshiaki Maruyama, Ph.D., Review Director, Office of Cellular and Tissue-GENE-BASED MEDICINE DEVELOPMENT WORKSHOP
Aviara Salon A | 7:15am – 8:45am
Sponsored by Aldevron

7:15am – 8:00am | Session 1: It’s Never Too Soon – Considerations for Gene Therapy Manufacturing in the Early Stages of Development
The success of gene therapy has resulted in significant benefits for patients and tremendous growth in the number of programs in development. Many programs have been granted accelerated designations (RMAT, etc.) and have the potential to reach patients far faster than the traditional drug development timeline. Given the accelerated development and the complexity of gene therapy manufacturing, strategies to produce the therapy and manage the supply chain must be considered very early in the development process. This session will discuss how programs with limited time and resources can address manufacturing challenges and review some lessons learned from those in the field.

Chair:
Gregory MacMichael, Ph.D., President, CMC BioServices

Speakers:
Michelle Berg, President, GMP Nucleic Acids, Aldevron
Jeffrey Castelli, Ph.D., Chief Portfolio Officer and Head of Gene Therapy, Amicus Therapeutics

DEVELOPING A ROBUST EVIDENCE PACKAGE TO PREPARE FOR MARKET ENTRY WORKSHOP
Aviara Salon B | 7:15am – 8:45am
Sponsored by IQVIA

When you think of bringing a new therapy to market, payers, regulators, providers, and other stakeholders are requiring robust information on effectiveness as well as the overall impact of use to understand the true value for patients and impact on the wider healthcare system. Understanding what stakeholders are looking for as part of their review process is crucial to successfully develop and communicate your value message. Careful planning during clinical development is key to develop an evidence package that is useful for regulatory filing as well as discussions with payers and providers. This panel will discuss elements and generation of this evidence package

Welcome Remarks:
George Smith, Ph.D., Senior Director, Cell and Gene Therapy Center, IQVIA
Chair:
Adrian McKemey, Ph.D., SVP, Consulting Services, IQVIA
Speakers:
Stewart Abbot, Ph.D., Chief Operating and Scientific Officer, Adicet Bio
John Doyle, Dr.P.H., VP, Global Healthcare Innovation Lead, Pfizer
Manuel Duenas, VP, Market Access, Atara Biotherapeutics
8:05am – 8:25am | Japan’s First Gene Therapeutic Drug
Speaker: Ei Yamada, Ph.D., President and CEO, AnGes, Inc.

8:25am – 8:45am | CAR-T Therapy Development in Japan
Speaker: Yoshie Tsurumaki, Japan Head, SCM CAR-T, CAR-T Supply Chain Management Group, Cell and Gene Franchise, Oncology Division, Novartis Pharma K.K.

8:00am – 8:45am | Session 2: Customized Solutions for Genetic Medicines – Navigating the GMP Supplier Landscape

For most translational research units, bringing a genetic medicine to the clinic requires the support of several outside partners. Researchers need to procure custom GMP raw materials (plasmid DNA, guide RNA, Cas9 Nuclease) as well as outsourced GMP services (cell therapy manufacturing). All of these services carry a cost and significant timelines. From the end-user perspective, it is necessary to balance these costs and timelines in order to enter the clinic and begin treating patients on time. From the supplier perspective, it is important to innovate and provide clients with flexible products and services. The purpose of this panel is to bring these two perspectives together to inform the audience of best practices in outsourcing to avoid delays and best provide support to translational clients.

Chair: Alan Trounson, Ph.D., CEO, Cartherics
Speakers:
Delfi Krishna, Ph.D., Director, Cell and Gene Therapy Platform, R&D Strategy, Portfolio and Operations, GSK
Annalisa Lattanzi, Ph.D., Translational Program Manager for Therapeutic Genome Editing, Stanford University School of Medicine – Pediatrics
Max Sellman, Client Relations Manager, Aldevron
Keith Thompson, CEO, Cell and Gene Therapy Catapult
Chy-Anh Tran, Director, Operations and cGMP Facilities, Stanford Laboratory for Cell and Gene Medicine

Felix Hsu, SVP and Global Head of Advanced Therapies, WuXi AppTec
Chris McClain, VP, Sales and New Business Development, Be The Match BioTherapies
Aiman Shalabi, VP, R&D, Cell and Gene Therapies, GlaxoSmithKline

9:00am | GENERAL SESSION AND PARTNERING OPENS

9:00am – 9:15am WELCOME REMARKS {BlueRock Therapeutics Ballroom}
Speaker: Janet Lambert, CEO, Alliance for Regenerative Medicine (ARM)

9:15am – 10:15am PLENARY SESSION: THE CELL AND GENE THERAPY SECTOR’S COMMERCIAL TRAILBLAZERS {BlueRock Therapeutics Ballroom}
Being first isn’t always easy. Hear from the sector’s pioneers as they share valuable lessons learned along the path to commercialization and discuss the outlook for the coming year.

Chair: 
Matthew Patterson, Chairman and CEO, Audentes Therapeutics

Speakers: 
Vijay Chiruvolu, SVP, Global Process Development – Cell Therapy, Kite a Gilead company
Rachelle Jacques, CEO, Enzyvant
David Lennon, Ph.D., President, AveXis
Ron Philip, Chief Commercial Officer, Spark Therapeutics
Jeff Walsh, Chief Strategy Officer, bluebird bio

10:15am – 10:45am | MORNING BREAK
Sponsored by PeproTech, POMS and PTC Therapeutics

10:45am – 12:00pm | CONCURRENT TRACKS

FEATURED FIRESIDE CHAT: BREXIT’S EFFECT ON CELL AND GENE THERAPY REGULATION {BlueRock Therapeutics Ballroom}
10:45am – 11:15am
Chair:
Jacqueline Barry, Ph.D., Chief Clinical Officer, Cell and Gene Therapy Catapult
Speaker:
Christiane Niederlaender, Ph.D., Director, AMBR-Consulting; Former Senior Quality Assessor for Biologics, Medicines and Healthcare Products Regulatory Agency (MHRA); Former Member, Committee for Advanced Therapies (CAT), European Medicines Agency (EMA)

COMPANY PRESENTATIONS {Cognate Bioservices Ballroom}
10:45am Caladrius Biosciences
11:00am AIVITA Biomedical

COMPANY PRESENTATIONS {BlueRock Therapeutics Ballroom}
11:15am Atara Biotherapeutics
11:30am bluebird bio
11:45am Gamida Cell

COMPANY PRESENTATIONS {Cognate Bioservices Ballroom}
11:15am Medeor Therapeutics
11:30am B-Mogen Biotechnologies
11:45am BlueRock Therapeutics

12:00pm – 1:15pm | LUNCH
Sponsored by Dark Horse Consulting

1:15pm – 3:30pm | CONCURRENT TRACKS

PANEL: MYTH VS. REALITY – IMPLEMENTING PAYMENT ARRANGEMENTS FOR CELL AND GENE THERAPIES {BlueRock Therapeutics Ballroom}
1:15pm – 2:15pm
Payers and therapeutic developers are starting to implement payment-over-time and pay-for-performance arrangements. Where does the reality on the ground diverge from common perception? What role are third parties playing today and what needs to change in order for these arrangements to be widespread?

Chair:
Roger Longman, Founder and Chairman, Real Endpoints

Speakers:
John Coombs, Pharm.D., Patient Access Lead, U.S. CAR-T, Novartis

COMPANY PRESENTATIONS {Cognate Bioservices Ballroom}
1:15pm Senti Biosciences
1:30pm PDC*line Pharma
1:45pm ExCellThera
2:00pm Tmunity Therapeutics
C. Bernie Good, M.D., Senior Medical Director, Center for Value-Based Pharmacy Initiatives, UPMC Health Plan  
Bill Martin, VP, Pharma Strategy and Account Management, Express Scripts

COMPANY PRESENTATIONS {BlueRock Therapeutics Ballroom}
2:15pm Homology Medicines
2:30pm Flexion Therapeutics
2:45pm uniQure
3:00pm REGENXBIO
3:15pm Sangamo Therapeutics

COMPANY PRESENTATIONS {Cognate Bioservices Ballroom}
2:15pm MaxCyte
2:30pm CARISMA Therapeutics
2:45pm Poseida Therapeutics
3:00pm Zelluna Immunotherapy
3:15pm MolMed

3:30pm – 4:00pm | AFTERNOON BREAK  
Sponsored by PeproTech, POMS and PTC Therapeutics

4:00pm – 6:00pm | CONCURRENT TRACKS

PANEL: CELL AND GENE THERAPY FOR NEUROLOGICAL PRODUCT INDICATIONS {BlueRock Therapeutics Ballroom}
4:00pm – 5:00pm
Durable treatments for the complex range of diseases affecting the central nervous system have long been an area of focus for the medical community. With advances in gene and cell therapy, there is a growing range of therapeutic strategies which may provide long awaited relief to myriad patient populations. This panel will review the state of development and clinical progress for these next-generation durable treatments for CNS conditions.

Chair:
Timothy Schroeder, Founder and CEO, CTI Clinical Trial & Consulting

Speakers:
Jon Garen, Chief Business Officer, uniQure  
Sheila Mikhail, President and CEO, AskBio  
Emile Nuwaysir, Ph.D., President and CEO, BlueRock Therapeutics  
Andre Turenne, President and CEO, Voyager Therapeutics

COMPANY PRESENTATIONS {BlueRock Therapeutics Ballroom}
5:00pm Orchard Therapeutics
5:15pm Oxford Biomedica
5:30pm AVROBIO
5:45pm LogicBio

COMPANY PRESENTATIONS {Cognate Bioservices Ballroom}
5:00pm FUJIFILM Cellular Dynamics
5:15pm AGTC
5:30pm IVERIC bio
5:45pm Opsis Therapeutics

6:00pm | PROGRAM AND PARTNERING CLOSES

6:30pm – 9:30pm | NETWORKING BASH  
Sponsored by CCRM
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<td>6:45am</td>
<td>Registration and Breakfast</td>
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<td>Sponsored by KBI Biopharma</td>
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<td>7:15am</td>
<td>CONCURRENT WORKSHOPS</td>
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<td><strong>IDENTIFYING PITFALLS WITHIN GENE THERAPY DEVELOPMENT AND HOW TO</strong></td>
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<td><strong>OVERCOME THEM WORKSHOP</strong></td>
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<td>Cognate Bioservices Ballroom</td>
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<td><strong>Sponsored by Thermo Fisher Scientific</strong></td>
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<td>This session will cover recent advancements in gene therapy with</td>
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<td>insights from gene therapy developers and CDMOs on common pitfalls</td>
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<td>and how to avoid and overcome them. Join this interactive session</td>
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<td>to learn about their strategies and lessons learned. Topics</td>
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<td>discussed will range from insourcing vs. outsourcing, building</td>
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<td>reliable and scalable processes, and their vision for the future of</td>
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<td>gene therapy.</td>
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<td><strong>Chair:</strong></td>
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<td></td>
<td>Amy Butler, VP and General Manager Cell Biology, Thermo Fisher Scientific</td>
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<td><strong>Speakers:</strong></td>
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<td>Timothy Miller, Ph.D., Co-Founder, President, and Chief Scientific Officer, Abeona Therapeutics</td>
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<td>Nicole O’Brien, Ph.D., Senior Director, Technical Program Design, Viral Vector Services, Thermo Fisher Scientific</td>
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<td>Robert Pietrusko, Pharm.D., SVP, Regulatory Affairs and Quality Assurance, Voyager Therapeutics</td>
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<td>Jeff Walsh, Chief Strategy Officer, bluebird bio</td>
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<td>Ran Zheng, Chief Technical Officer, Orchard Therapeutics</td>
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<td>7:45am</td>
<td><strong>REAL WORLD EVIDENCE TO DRIVE ACCEPTANCE AND UPTAKE OF CELL AND GENE THERAPY: LESSONS AND BEST PRACTICES WORKSHOP</strong></td>
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<td>Aviara Salon A</td>
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<td>Cell and gene therapies offer transformative or curative potential, but</td>
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<td>you must prove it. Real world evidence (RWE) is a foundational tool</td>
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<td>to address uncertainty around asset value across the product</td>
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<td>lifecycle, from early development to expanded access. This is</td>
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<td>especially true in the case of therapies whose value proposition</td>
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<td>hinges on magnitude and duration of effect. Global regulatory</td>
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<td>agencies and payers are also weighing in and shifting RWE from</td>
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<td>“nice to know” to “got to have”, solidifying RWE as an essential</td>
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<td>to new cell and gene therapy strategy. Despite this momentum in RWE</td>
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<td>use, methods, stakeholder expectations, and “what good looks like”</td>
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<td>are still evolving. This workshop will discuss what RWE is, when</td>
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<td>and how to use it, and consider evolving lessons and best practices</td>
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<td>for cell and gene therapies.</td>
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<td><strong>Chair:</strong></td>
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<td>Eric Faulkner, VP, Real World Value and Strategy and Executive Director, Precision and Transformative Medicine Center of Excellence, Evidera</td>
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<td>Ramesh Arjunji, Senior Director, Health Economics and Outcomes, AveXis</td>
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<td>Jane Barlow, M.D., Senior Advisor, MIT Center for BioMedical Innovation/NEWDIGS</td>
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<td>Francesca Cook, Senior Director, Pricing and Market Access, REGENXBIO</td>
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<td>Bhash Parasuraman, Ph.D., VP, Patient and Health Impact, Rare Disease Business Unit, Pfizer</td>
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<td>Mark Rothera, President and CEO, Orchard Therapeutic</td>
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<td><strong>ALIGNING CLINICAL, MANUFACTURING, AND LOGISTICS PLATFORMS TO TREAT PATIENTS AT SCALE WORKSHOP</strong></td>
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<td>Aviara Salon B</td>
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<td><strong>Sponsored by World Courier</strong></td>
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<td>For advanced therapies to become a true industry, developers need</td>
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<td>to align the three platforms of manufacturing (closed and automated</td>
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<td>process), clinical (safe and efficacious) and logistics (seamless</td>
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<td>connection to patients). Without this alignment, companies risk</td>
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<td>creating a life changing therapy that can’t be made, or manufacturing</td>
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<td>a therapy that can’t be delivered. This workshop will look to</td>
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<td>understand the challenges in coordinating development across these</td>
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<td>platforms, providing lessons learned to help companies create</td>
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<td>therapies that can easily scale into globally viable commercial</td>
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<td><strong>Welcome Remarks</strong></td>
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<td>Simon Ellison, Cell and Gene Therapy Service Director, World Courier</td>
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<td>7:25am</td>
<td><strong>Presentation 1</strong></td>
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<td>Phil Vanek, Ph.D., General Manager, Cell and Gene Therapy Strategy, GE Healthcare</td>
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<td><strong>Presentation 2</strong></td>
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<td><strong>Speaker:</strong></td>
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<td>Dominic Clark, Ph.D., Global Head of Cell Therapy, HemaCare; Co-Chair, Process and Product Development Committee, International Society for Cell and Gene Therapies (ISCT)</td>
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<td><strong>Presentation 3</strong></td>
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<td><strong>Speaker:</strong></td>
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<td>Jacqueline Barry, Ph.D., Chief Clinical Officer, Cell and Gene Therapy Catapult</td>
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<td>7:55am</td>
<td><strong>Moderated Discussion with All Speakers</strong></td>
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<td>9:00am</td>
<td>GENERAL SESSION AND PARTNERING OPENS</td>
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<td>9:00am</td>
<td><strong>OVERVIEW OF THE ALLIANCE FOR REGENERATIVE MEDICINE’S INITIATIVES</strong></td>
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<td><strong>Speakers:</strong></td>
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<td>Janet Lambert, CEO, Alliance for Regenerative Medicine (ARM)</td>
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Matthew Patterson, Chairman, Alliance for Regenerative Medicine (ARM); Chairman and CEO, Audentes Therapeutics

PANEL: CLINICIANS WORKING WITH CAR-T THERAPIES {BlueRock Therapeutics Ballroom}  
9:15am – 10:15am  
Thousands of patients have now been treated with CAR-T therapies. Find out what unique challenges and rewards come with providing these treatments from those on the front lines, and learn what the experience to date suggests about the widespread use of CAR-T.

Chair:  
Gregory Hale, M.D., Senior Medical Director, Hematology and Oncology, Medpace

Speakers:  
Prasad S. Adusumilli, M.D., Head, Solid Tumors Cell Therapy, Cellular Therapeutics Center; Vice Chair, Department of Surgery, Deputy Chief, Thoracic Surgery, Memorial Sloan Kettering Cancer Center  
Dimitrios Tzachanis, M.D., Ph.D., Associate Clinical Professor of Medicine, UC San Diego Blood and Marrow Transplant Program  
John A. Zaia, M.D., Aaron D. Miller and Edith Miller Chair in Gene Therapy; Director, Center for Gene Therapy, City of Hope

COMPANY PRESENTATIONS {Cognate Bioservices Ballroom}  
9:15am Novadip Biosciences  
9:30am VERIGRAFT  
9:45am PolarityTE  
10:00pm Celsense

10:15am – 10:45am | MORNING BREAK  
Sponsored by PeproTech, POMS and PTC Therapeutics

10:45am – 12:15pm | CONCURRENT TRACKS

FEATURED SPEAKER: ADVANCING GENE THERAPIES GREAT AND SMALL {BlueRock Therapeutics Ballroom}  
10:45am – 11:15am  
Speaker:  
Peter Marks, M.D., Ph.D., Director, Center for Biologics Evaluation and Research, U.S. Food and Drug Administration

COMPANY PRESENTATIONS {Cognate Bioservices Ballroom}  
10:45am Cells for Cells  
11:00am ReNeuron

PANEL: WHEN DOES INVESTING IN CELL AND GENE THERAPY MAKE BUSINESS SENSE? {BlueRock Therapeutics Ballroom}  
11:15am – 12:15pm  
The cell and gene therapy industry is undergoing a critical inflection point as is evident in large financing deals, exciting clinical data and landmark regulatory approvals. However assets also face challenges such as high development costs and significant manufacturing complexities. Through a presentation and panel discussion, this session will define drivers of cost of development and cost of goods and provide a framework for assessing investment potential of cell and gene therapy assets.

Chair:  
Delfi Krishna, Ph.D., Director, Cell and Gene Therapy Platform, R&D Strategy, Portfolio and Operations, GSK

COMPANY PRESENTATIONS {Cognate Bioservices Ballroom}  
11:15am Regenerative Patch Technologies  
11:30am Caribou Biosciences  
11:45am Synpromics  
12:00pm Prevail Therapeutics
Speakers:
Brian Bronk, Ph.D, Head of Business Development, Rare Diseases and Blood Disorders, Global Business Development and Licensing, Sanofi
Bradley Campbell, President and Chief Operating Officer, Amicus Therapeutics
Jerel Davis, Ph.D., Managing Director, Versant Ventures
Mitchell Finer, Ph.D., Chief Scientific Officer, ElevateBio; President, ElevateBio Base Camp
Toby Freyman, Ph.D., Senior Director, Center for External Innovation; Head of Rare Disease Business Development, Takeda Pharmaceuticals International

12:15pm – 1:30pm | LUNCH
Sponsored by Homology Medicines

1:30pm – 2:45pm | CONCURRENT TRACKS

SPOTLIGHT SESSION: THE EVOLUTION OF CELL AND GENE THERAPY IN CHINA {BlueRock Therapeutics Ballroom}
1:30pm – 2:00pm
Senior executives active in the region will share their experience and outlook on the cell and gene therapy industry in China, with advice for those considering expansion or are new to the market.

Chair:
Li Chen, Ph.D., VP, Gene Synthesis and Mol LCS, BID, LSG, Thermo Fisher Scientific

Speakers:
Felix Hsu, SVP and Global Head of Advanced Therapies, WuXi AppTec
Yuling Li, CEO, Zhejiang Innoforce Pharmaceuticals Co. Ltd.
BG Rhee, Ph.D., CEO, SCM Lifescience; Chairman, Council for Advanced Regenerative Medicine (CARM) Korea

COMPANY PRESENTATIONS {Cognate Bioservices Ballroom}
1:30pm
Sigilon Therapeutics
1:45pm
ViaCyte

2:00pm
Amicus Therapeutics
2:15pm
Adaptimmune
2:30pm
Autolus

3:15pm – 6:00pm | CONCURRENT TRACKS

PANEL: THE IMPACT OF UNIVERSAL DONOR CELLS AND iPSCs ON THE CELL THERAPY INDUSTRY {BlueRock Therapeutics Ballroom}
3:15pm – 4:15pm
Since the discovery of pluripotent stem cells in the early 1980’s, the promise of fit-to-purpose cell replacement therapy has occupied the imaginations of many in the medical and patient communities. Progress was slowed by both technical and ethical challenges, but with the discovery of the iPSC source in 2006, many of these hurdles were overcome and the pace of research and clinical development accelerated dramatically. Further, genetic and biomaterials modification to this limitless supply of...
cells has opened new doors to allogeneic stem cell-derived cell therapy, including the associated promise of lower costs and higher accessibility. This panel will explore the ways in which iPSCs, and more specifically iPSCs modified for allogeneic use, have changed the way in which we think about the commercial viability of cell therapies.

Chair:
Robert Preti, Ph.D., President and CEO, Hitachi Chemical Advanced Therapeutics Solutions; GM, Hitachi Chemical Regenerative Medicine Business Sector

Speakers:
Stewart Abbot, Ph.D., Chief Operating and Scientific Officer, Adicet Bio
Usman Azam, M.D., President and CEO, Tmunity Therapeutics
Tim Lu, M.D., Ph.D., Co-Founder and CEO, Senti Biosciences
Bastiano Sanna, Ph.D., CEO, Semma Therapeutics
Dan Shoemaker, Ph.D., Chief Scientific Officer, Fate Therapeutics

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6:00pm | PROGRAM AND PARTNERING CLOSES

7:30am – 9:30am | REGISTRATION AND BREAKFAST
Sponsored by Polyplus-transfection

9:00am | GENERAL SESSION AND PARTNERING OPENS

9:00am – 9:15am | OVERVIEW OF THE ARM FOUNDATION FOR CELL AND GENE MEDICINE {BlueRock Therapeutics Ballroom}
Speakers:
Morrie Ruffin, Co-Founder and Senior Advisor, Alliance for Regenerative Medicine; Executive Director, ARM Foundation for Cell and Gene Medicine
Stewart Parker, Chairperson, ARM Foundation for Cell and Gene Medicine

9:15am – 10:45am | CONCURRENT TRACKS

EMILY WHITEHEAD’S JOURNEY TO CAR-T {BlueRock Therapeutics Ballroom} |
9:15am – 9:45am

Speakers:
**PANEL: A LOOK INTO THE CRYSTAL BALL – WHAT DOES THE FUTURE HOLD FOR GENE EDITING?** *(BlueRock Therapeutics Ballroom)*
9:45am – 10:45am
This dynamic panel discussion featuring executives from leading gene editing companies will explore the major milestones and advances anticipated in the near term (12 month), midterm (5 year), and long term (10+ year) timeframes for these promising therapies. This session will also consider how the rapidly evolving climate surrounding these technologies will potentially impact the future of the sector’s success.

*Chair:*
  Robert Smith, SVP, Global Gene Therapy Business, Pfizer

*Speakers:*
  Cindy Collins, CEO, Editas Medicine
  Michael Dombeck, SVP, Corporate Development, Precision BioSciences
  Sandy Macrae, Ph.D., President and CEO, Sangamo Therapeutics
  Arthur Tzianabos, Ph.D., President and CEO, Homology Medicines

**COMPANY PRESENTATIONS** *(Cognate Bioservices Ballroom)*
10:00am  Giner Life Sciences
10:15am  CCRM
10:30am  American Gene Technologies

**10:45am – 11:00am | MORNING BREAK**
*Sponsored by PeproTech, POMS and PTC Therapeutics*

**11:00am – 12:00pm | CONCURRENT TRACKS**

**PANEL: INNOVATION AROUND MANUFACTURING TECHNOLOGIES** *(BlueRock Therapeutics Ballroom)*
11:00am – 12:00pm
In biotechnology, a good idea born in a lab too often fails to make it to clinical and commercial reality due to challenges in scalability, production, and characterization. For cell, gene, and tissue engineered products these challenges are particularly acute. It has even reached the point in which investors have begun seek a scalable platform over a promising idea. This panel will explore the next-generation technologies enabling the scalable, transferable, and cost-effective manufacture of regenerative medicine products and discuss the ways in which the regenerative medicine industry must continue to develop fit-for-purpose platforms to address sector specific CMC challenges.

*Chair:*
  Kelvin Lee, Ph.D., Institute Director, National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL)

*Speakers:*
  Nina Bauer, Ph.D., Chief Commercial Officer, FloDesign Sonics
  Jian Irish, Ph.D., SVP, Global Head of Manufacturing, Kite Pharma, a Gilead Company
  Jerry Keybl, Ph.D., Head of Cell and Gene Therapy Manufacturing, MilliporeSigma

**COMPANY PRESENTATIONS** *(Cognate Bioservices Ballroom)*
11:00am  Astellas Institute for Regenerative Medicine
11:15am  Capricor Therapeutics
11:30am  StemBioSys
11:45am  Immusoft