2013 Program

Tuesday, September 10, 2013

7:00–8:30 AM **Biopharm Innovation in Japan: A Discussion with Dr. Kurokawa – By Invitation Only**

Dr. Kurokawa has kindly agreed to host a breakfast discussion in Japanese for Japanese-speaking attendees of the Health Sciences Dialogue. This discussion will focus on measures to unlock and support biopharmaceutical innovation.

In order to participate in the breakfast discussion, you must first register with the 2013 Health Sciences Dialogue. As seating is limited, please send an email request to Kazumi Teune at kazumi@japanphilly.org and wait for her confirmation for your seating.

日本のバイオファーマにおけるイノベーション：黒川清先生とのディスカッション朝食会
このほど日本から参加される黒川先生が、ヘルスサイエンスダイアログ参加者を対象に、日本語でディスカッションができる機会を設けてくださいます。バイオファーマにおけるイノベーションの構造を、どのように分析しサポートするかに焦点をあてます。

朝食会へのご招待は、２０１３年度ヘルスサイエンスダイアログに参加登録された方だけに限らさせていただきます。

席数が非常に限られておりますので、以下まで、メールで早めに朝食会への参加希望を連絡願います。折り返しこちらから、お席が確保できたかの有無について連絡させていただきます。
場合によっては、申し込みがお受けできないこともあるかもしれませんので、その点を前もってご了解ください。

担当：フィラデルフィア日米協会：チュー二かずみ kazumi@japanphilly.org

9:00 AM **Welcome Remarks**

- **Koichi Ai**, Director, Japan Information Center, Consulate-General of Japan in New York

9:00–10:10 AM **Economic and Policy Trends That Will Impact Dealmaking in 2014**

2013 is shaping up to be the hottest market for life sciences deals in perhaps decades – on both sides of the Pacific. The surge in the market began in Japan last November, as reported in *BioCentury*, driven by the groundbreaking work being done there in the area of stem cell research. In May the IPO window for American biotech opened wide almost twenty companies debuting in the first half of the year and almost a dozen still in the queue. Venture investment and M&A activity are also picking up steam.

Has a combination of scientific milestones, economic reforms, and the fact that the US is finally reworking its dysfunctional health care delivery system created a sea-change that will change the investment climate for life sciences? Or are we at the apex of another bio-boom? This panel will discuss the economic, scientific, and political fundamentals that are impacting markets and dealmaking.

Moderator:

- **Glen Giovannetti**, Global Life Sciences Leader, EY

Panelists:

- **Daniel D. Adams**, Executive Chairman and Global Head of Business Development, Protein Sciences
- **Ben Bonifant**, Partner, Triangle Insights Group, LLC

- **David Nash, MD, MBA**, Dean, Jefferson School of Population Health, Thomas Jefferson University
- **Dennis J. Purcell**, Senior Managing Director, Aisling Capital, LLC

10:15–11:10 AM

Beware of GAPs in Your Supply Chain

Outsourcing products and services has become a common strategy used by all types of manufacturers looking to reduce costs. Pharmaceutical manufacturers, particularly those operating in trans-Pacific markets, frequently source materials for their supply chain in global markets where regulatory infrastructures are still developing.

However, some high profile issues regarding the quality of food and drugs sourced in these markets caused US Congress to include new provisions in the Food and Drug Administration Safety and Innovation Act (FDASIA) concerning supplier controls for drugs and the pharmaceutical industry and FDA to consider additional mechanisms to ensure the quality of the global source of drugs, including the use of comprehensive quality agreements and global auditing of suppliers. Additional requirements are expected to be put in place in the years to come.

This panel will discuss these new supplier control requirements, approaches to managing supplier quality, and how the new requirements and emphasis will impact the timing and costs of joint ventures and other alliance agreements.

Moderator:

- **Kathleen M. Sanzo**, Partner, Morgan Lewis & Bockius LLP

Panelists:

- **Brian Johnson**, Senior Director / Pfizer Supply Chain Security, Pfizer Global Supply
- **Howard Sklamberg**, JD, Director, Office of Compliance, Centre for Drug Evaluation and Research, FDA

11:15–12:00 PM Company Presentations

12:00–1:25 PM

Fireside Chat With Dr. Kiyoshi Kurokawa: How Can Japan Better Foster Innovation?

Dr. Kurokawa, a globally recognized health care KOL, is Professor of the National Graduate Institute for Policy Studies and Science Advisor to the Cabinet of Japan. Additionally, he was recently named Chair of the Board of the Global Health Innovative Technology Fund, the first public-private partnership in Japan. He is deeply committed to tapping the innovative potential of Japanese industry, scientists and academicians and will share with us his thoughts on how we can best leverage the knowledge and talent in Japan to address key global problems such as health care. Dr. Kurokawa received the 2012 Scientific Freedom and Responsibility Award from the American Association for the Advancement of Science (AAAS).

Co-Moderators:

- **David Flores**, Co-Founder, President & Chief Executive Officer, BioCentury Publications Inc.
- **Howard Brooks**, Partner, Americas Life Sciences Sector Leader, EY

Interviewee:

- **Kiyoshi Kurokawa, MD, MACP**, Professor, National Graduate Institute for Policy Studies, Former Science Advisor, National Diet, Japan & Chairman, Global Health Innovative Technology Fund

1:30–2:00 PM Company Presentations

2:00–2:55 PM

Building a Global Commercial Infrastructure in an Increasingly Competitive Environment

Once upon a time if a drug was safe and effective all a pharma company had to do was get it on the market and see if it turned into a blockbuster. Not anymore. The pressures facing the pharmaceutical industry around the world are well documented: the rise of generics, the lack of R&D productivity, and pricing pressure are just some of the challenges driving consolidation in the industry. How does a small to mid-sized pharma company position itself for success in this environment?

To thrive, pharma companies need to bring a new degree of creative thinking to their organizations. What is the best way for a Japanese company to expand into the US market, license products, co-locate, or develop a sales partnership? And should drug

companies be diversifying outside of therapeutics to medical devices, digital health products, or even comprehensive health services? This panel will explore how pharmaceutical companies will create value in the future, while also considering the practical issues of how to strike a balance between executing on both a strategic and a tactical level.

Moderator:

- **James J. Dolan**, Senior Vice President, Licensing and Business Development, Purdue Pharma L.P.

Panelists:

- **William H. Carson, M.D.**, President and Chief Executive Officer, Otsuka Pharmaceutical Development & Commercialization, Inc.
- **Grace Pan**, Litigation Partner, Kaye Scholar LLP
- **Richard Russell**, Executive Vice President and Chief Commercial Officer, Sunovion Pharmaceuticals Inc.
- **Craig Skenes**, Senior Director, Business Development, Santen Inc.
- **Gunther Winkler, PhD**, Principal, ASPB Consulting LLC (previously Senior Vice President -- Asia Pacific, Biogen Idec)

3:00–3:55 PM **Market Hot-Spot: Highlight on Oncology, Where is the Action and Why?**

The oncology deal space has been very active over the past several years for Japanese Pharma, including licensing and M&A, ranging from small, early stage collaborations with biotechs in the US, EU and Japan, to mega deals including acquisitions of major US biotechs like OSI and Millennium. More recently, the Japanese biotech industry has been quite hot (perhaps experiencing its own bubble), with public companies seeing steep rises in their valuations, driven by dozens of deals with various global players for products, platforms and services, together with increasing interest from global VCs in investing in Japanese biotech.

This panel reflects some of this activity, with the Japanese biotech PRISM Pharma having completed a deal with Eisai on its beta catenin inhibitor for cancer and continuing to attract significant investment, and the US biotech Verastem having done one as well with Eisai around the related wnt pathway. Astellas has been one of the more active players on the large pharma side, with deals such as that with Aveo and the acquisition of OSI, and a just announced strategic alliance with Amgen, Amgen being a prolific oncology deal maker itself.

This panel will discuss the acceleration of innovation and partnering, the international deal making climate overall, and access to capital issues that both prompt these deals and help to finance them.

Moderator:

- **Jeffrey M. Bockman, PhD**, Vice President, Defined Health

Panelists:

- **Joe Brindisi**, Vice President, Business Development, PRISM Pharma Co., Ltd.
- **Gary Gabrielsen**, Vice President, Business Development & Alliance Management, Astellas US
- **Daniel Paterson**, Chief Business Officer, Verastem, Inc.

4:00–5:00 PM **The Evolution of Japanese Pharma Companies In a Global Environment and their Expansion Strategies**

As part of a push to globalize after the turn of the millennium, many Japanese pharmaceutical companies adopted Western business cultures and brought in American managers. This is in stark contrast to the trend 20 years earlier when American companies, particularly manufacturers were aggressively adopting Japanese management practices. This panel will discuss what cultural attributes are important to make an organization truly global. Should some functions such as sales and business development be “westernized” while others such as research and manufacturing remain native? Does a truly global company in the 21st Century meld the best attributes of Eastern and Western culture? The panelists will discuss their experiences working with major Japanese pharmaceutical firms as they were evolving into global players.

Moderator:

- **Ben Perkins**, Partner & Senior Managing Director, Life Sciences Mergers & Acquisitions, EY

Panelists:

- **Joseph S. McCracken**, DVM, Global Head, Business Development and Licensing, Roche (Retired)

- **Terence G. Porter, PhD**, Vice President, Search & Evaluation, Global Business Development, Takeda Pharmaceuticals International, Inc.
- **Tamao Watanabe**, Managing Officer, Head of Global Business Development and Licensing, Kyowa Hakko Kirin (KHK)
- **Chihiro Yokota, RPh**, Corporate Executive, Global Head of Business Development and Licensing & Alliances, Astellas Pharma Inc.

5:00–7:00 PM Networking Reception

Wednesday, September 11, 2013

9:00–10:10 AM **The Bubbling-Up of Asian Biopharma: Approaches for Building Value**

Asian biotech stocks have been enjoying a surge this year that began last November, as reported by BioCentury, when Professor Shinya Yamanaka received a Nobel Prize for his work reprogramming mature cells to become pluripotent stem cells. Structural economic reforms in major Asian markets have fueled a continued rally in the overall market and biotech in particular – particularly in Japan.

The recent run-up in prices has largely been driven by retail investors who are less likely than their institutional counterparts to hold their positions long-term, particularly in a volatile sector like biotech. Some Asian biotech execs are confident that U.S. institutional investors are poised to come into the market and support prices. But others warn that a shakeout or major consolidation will come before the end of the year. This panel will explore the question, is this a bubble or are these higher valuations justified and sustainable.

Moderator:

- **David Flores**, Co-Founder, President & Chief Operating Officer, BioCentury Publications Inc.

Panelists:

- **Yuan-Hua Ding, PhD**, External R&D Innovation -- Asia/Pacific, Pfizer Worldwide R&D
- **Jamie Egan**, Senior Vice President, Corporate Development, Agnes-MG, Inc.
- **Lynn D. Kramer, MD FAAN**, Chief Clinical Officer and President, Neuroscience & General Medicine, Eisai, Inc.
- **Tadashi Matsumoto**, PhD MBA, President & CEO, ReqMed Company Ltd.

10:15–11:10 AM **Comparative Regulatory Machinery: Making It Work On Both Sides of the Pacific**

Operating across borders in the pharmaceutical business requires a clear understanding of diverse regulatory regimes. In cultures as different as the US and Japan, that can be quite a challenge. Japan, for example, has clear regulatory and clinical guidelines leading to drug approvals. In the US, the FDA encourages companies to interact with their scientists throughout the development process to best assure that pre clinical and clinical programs satisfy existing guidelines, or qualify for accelerated approvals or other special designations that can significantly shorten time to approval. In China, the CFDA clearly differentiates between domestic and foreign-originated products, giving the former a favored status in the time aloted for IND approvals, etc. In addition, China is in the process of reforming the CFDA to be more like its Western counterparts in the ways it operates and approves new therapeutics.

Organizations seeking to market in these countries need to be able to navigate these different regulatory regimes. In addition, after a product is approved post-market surveillance and incident reporting requirements vary significantly. This panel will explore these differences and discuss what you need to know to build a a company and regulatory organization that can succeed on both sides of the Pacific.

Moderator:

- **Stephen Paul Mahinka**, Partner, Morgan Lewis & Bockius LLP

Panelists:

- **Haroon Hashmi**, Independent Consultant
- **Keiko Oishi**, Senior Managing Director, CMIC Co., Ltd. (Japan)
- **Jurij Petrin, MD**, President and Founder, Pharmaceutical Regulatory Services, Inc.

11:15–12:00 PM Company Presentations

12:00–1:25 PM **Luncheon & Roundtable Discussions With the Experts**

1:30–2:00 PM Company Presentations

2:00–2:55 PM **Investors Speak: What Opportunities Are They Looking for and What Do They Want To See?**

Both large and small Japanese biotechs have traditionally suffered from a combination of a conservative culture and public policies that do not fostered innovation and risk taking. We've seen investor interest in publicly-traded companies increase in recent months, but what about private companies? The government enacted economic reforms to spur investment, particularly in health care. And it is starting to undertake policy reforms aimed at encouraging innovation. Has the time come for meaningful cross-border investment between in small to mid-sized biotech? Our panel of investors will discuss what they want to see not only in specific companies, but in the economy as a whole.

Moderator:

- **Kimberly Ha**, Global Editor, BioPharm Insight

Panelists:

- **Les Funtleyder**, Managing Director, Poliwogg
- **Hingge Hsu, MD**, Partner, Fidelity Biosciences
- **Yuji Iizawa, DVM, PhD**, Senior Investment Director, Takeda Ventures, Inc.
- **Goro Takeda**, Managing Partner, FinTech Global Capital/Venture Partner, Sofinnova Venture
- **Wei Zhang, PhD**, Head, Corporate Development, Good Start Genetics Inc.

3:00–3:55 PM **Japanese Bioventure Companies: Growing in the States**

Early-stage Japanese biotechs are increasingly setting up shop in the US to gain better access to customers, capital and talent with entrepreneurial experience. Japanese entrepreneurs are taking technologies developed in Japan creating businesses either headquartered or with a substantial presence in the US. The factors driving this trend range from the mundane, such as being in the same time zone as their customers, to the subtle and complex, such as operating in an environment that not only tolerates risk but often encourages it.

Our panelists will discuss the issues their organizations weighed in deciding to locate in the US. Will it become routine for Japanese biotech start-ups to locate in the US or do these companies represent a temporary trend that will evaporate as Japan becomes more start-up friendly?

Moderator:

- **Kathleen M. Shay**, Partner, Duane Morris LLP

Panelists:

- **Joe Brindisi**, Vice President, Business Development, PRISM Pharma Co., Ltd.
- **Scott A. Siegel, PhD**, Managing Director, Milestone Life Sciences, LLC

4:00–5:00 PM **Health Sciences Dialogue Picks the Most Interesting East-West Deals of 2013**

Working with BioCentury, Health Sciences Dialogue has reviewed East-West deals, alliances and investments that have been announced in the past 18 months and identified those that we think were the most interesting. The objective is not to necessarily focus on the biggest deals, but on the deals that made a difference. Our panel of veteran dealmakers will discuss how these paradigm shifting transactions will influence the structure of East-West ventures going forward.

Moderator:

- **Jeffrey R. Greene**, Global Transaction Advisory Leader, Life Sciences, EY

Panelists:

- **James Foley, PhD**, Managing Director, Aqua Partners LLC
- **John M. Gill**, President and Chief Executive Officer, TetraLogic Pharmaceuticals
- **Lynn D. Kramer, MD FAAN**, Chief Clinical Officer and President, Neuroscience & General Medicine, Eisai, Inc.
- **David Lilley**, Board Member, SFJ Pharmaceuticals

5:00–6:00 PM Closing Reception

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PHOTO GALLERY

Click here to view photos from our 2013 event.

NEWS FROM BIOCENTURY

BHV, Islet report Phase IIb data for SGLT2 inhibitor
04/16: BHV Pharma Inc. (Research Triangle Park, N.C.) and Islet Sciences Inc. (OTCBB:ISLT) reported data on Wednesday from a pair of double-blind, dose-ranging Phase IIb trials evaluating... **more**

J&J reports first simeprevir sales
04/15: Johnson & Johnson (NYSE:JNJ) reported 1Q14 earnings on Tuesday, including $354 million in worldwide sales of Olysio simeprevir in the HCV drug's first full quarter of sales. U.S. sales... **more**

WuXi snags AZ's Yang as COO
04/15: WuXi PharmaTech Inc. (NYSE:WX) hired Steve Yang as EVP and COO. Yang was VP and head of the Asia and emerging markets innovative medicines unit (iMED) at AstraZeneca plc (LSE:AZN; NYSE:AZN... **more**

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