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SMi Presents the...

European BioNetworks Summit

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Marriott Regents Park Hotel, London, UK

7TH - 8TH JULY 2014

Chairperson:
Sanj Singh, President and CEO, **Ade Therapeutics**

Key Speakers Include:

- **Simone Breitkopf,** Head Governmental and Public Affairs, Pricing and Reimbursement, **Alcon Pharma GmbH (Novartis Group)**
- **Lubor Gaal,** Head of Europe, Business Development, **Bristol Myers Squibb**
- **Dr Robert Williams,** Chief Development Scientist, Drug Development Office, **Cancer Research UK**
- **Mika Partanen,** Deputy Director, Global Competitive Insights, **Bayer Pharma**
- **Dr. Michael Meyers,** Vice President of Scientific Innovation, Oncology, **Johnson and Johnson**
- **Davidson Ateh,** Chief Executive Officer, **BioMoti**
- **Professor Joseph Sweeney,** Professor of Catalysis and Chemical Biology, Department of Chemical Sciences, **University of Huddersfield**
- **Jorgen Drejer,** Chief Executive Officer, **Aniona**
- **Adrian Dawkes,** Vice President, **PharmaVentures**

...and many more!

Business Benefits:

- **12 big pharma and biotech companies on the speaker platform!**
- Network and learn from your **future partners**
- **The must attend event** showcasing how biotech, pharma, academic and funding organisations can create winning strategic **partnerships from modern day collaborations**
- Hear cutting edge **presentations and key cases studies** from leading industry and academic experts
- Learn about the latest developments pertaining to **strategic partnering and funding**

PLUS INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOP

Wednesday 9th July 2014, Marriott Regents Park Hotel, London, UK

Cost Effective Pathway to Early Clinical Development to Support Regulatory Approvals and Commercial Partnering

Workshop Leaders: **Carla Bennett,** Senior Clinical Research Consultant, **QRC Consultants Ltd**
Dr Sarah Nicholson, Senior Regulatory Consultant, **QRC Consultants Ltd**
8.30am - 12.30pm

www.bio-networks.com

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European BioNetworks Summit

Day One | Monday 7th July 2014

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Sanj Singh, President and CEO, **Ade Therapeutics**

STAKEHOLDER UPDATES — PART 1

9.10 **OPENING ADDRESS**
Looking at the crystal ball... scenario development for enhanced business development and licensing strategies
- Developing a clear understanding of why the scope and the time frame for business development activities is the key first step in scenario development
- Avoiding corporate blind spots by involving outsiders in the identification/prioritization of key business development-related uncertainties and leading indicators
- Understanding why scenario development is not an exact science: judgment may sometimes beat complex analytical models and techniques, especially when time frames are tight
- Updating scenarios on a regular basis and establishing an early opportunity identification system

Mika Partanen, Deputy Director, Global Competitive Insights, **Bayer Pharma**

9.50 **Going back to school... introducing academic partnerships as the way forward**
- Understanding why discovery and early stage drug development collaborations with academia are more popular than ever
- Risk sharing in drug development – a 'not for profit' perspective
- Scientific, technical and business challenges in cross sector collaboration

Dr Robert Williams, Chief Development Scientist, Drug Development Office, **Cancer Research UK**

10.30 **Morning Coffee**

11.00 **The new innovation kettle - a biotech perspective**
- New deal structures for innovation in drug discovery
- Maximising innovation and productivity in partnerships
- Expected trends for drug discovery business models:
- Venture capitalist, government funding, pharma partnering, spin out, joint ventures

Jorgen Drejer, Chief Executive Officer, **Aniona**

11.40 **Six things every business development person should know about improving licensing outcomes** — ROUND TABLE
- Pitfalls and benefits of exclusive licenses, be sure you know what you are getting into
- Master, sub, territory, indication...
- Reviewing external innovations and licensing opportunities abroad

Timothy Herpin, Head of Transactions (UK), Business Development, **AstraZeneca**

12.20 **Networking Lunch**

1.20 **When alliances don't work out - addressing the issues and developing solutions**
- Choosing a partner with a higher probability of alignment on the key deal points
- At the outset of the partnership – contractual preparation for all potential outcomes
- Identifying and managing issues as they happen
- After the breakup

Dimitri F. Dimitriou, Chief Executive Officer, **ImmuPharma plc** & Managing Partner, **DyoDelta Biosciences Ltd**

2.00 **Co-developing with academia... an academics perspective!** — ROUND TABLE
- Measuring the pros and cons of establishing partnerships with academia
- Understanding the legal considerations of partnering with academia
- Are all academia worth partnering with...what are the red flags and how do we choose

Professor Joseph Sweeney, Professor of Catalysis and Chemical Biology, Department of Chemical Sciences, **University of Huddersfield**

2.40 **Afternoon Tea**

PRICING & REIMBURSEMENT - HOME AND ABROAD

3.10 **To pay or not to pay... that is the question!**
- Understanding how to develop successful pricing and reimbursement strategies – considering the ethical challenges
- Analysing trends in pricing and use of health technology assessment for reimbursement decision making
- Understanding how to successfully secure reimbursement
- Reviewing current drug pricing policies
- The big question – does the industry need a different way of thinking about reimbursement requirements?

Sanj Singh, President and CEO, **Ade Therapeutics**

3.50 **Fear no more the heat of the sun'... four ways to tackle reimbursement in emerging markets**
- Reviewing the implications for market growth and business development
- Monitoring how healthcare systems in emerging markets (China, India, Brazil, Russia, Mexico and Turkey) are evolving
- Exploring how this is impacting on the expected growth of markets for innovative companies at home
- Reviewing the prospects for drug and business development for these markets

Simone Breitkopf, Head Governmental and Public Affairs, Pricing and Reimbursement, **Alcon Pharma GmbH (Novartis Group)**

4.30 **The 4 musketeers... 'one for all and all for one' – how can pharma, biotech, academia and venture capitalists live by this motto!** — PANEL DISCUSSION
- Reviewing the various collaboration opportunities to increase R&D and innovation
- Seeking out partners with complementary strengths to lead innovation
- Creating a flexible, independent and lean structure amongst partners that allows for rapid decision making
- Maximizing the potential gains from successful R&D and business development relationships
- Understanding how to mitigate the risks of partnering to:
  - maximize ROI
  - boost creativity

Lubor Gaal, Head of Europe, Business Development, **Bristol Myers Squibb**
Timothy Herpin, Head of Transactions (UK), Business Development, **AstraZeneca**
Jorgen Drejer, Chief Executive Officer, **Aniona**
Dr Robert Williams, Chief Development Scientist, Drug Development Office, **Cancer Research UK**
Sofia Ioannidou, Investment Director, **Edmond de Rothschild Investment Partners**
Professor Joseph Sweeney, Professor of Catalysis and Chemical Biology, Department of Chemical Sciences, **University of Huddersfield**

5.30 **Chairman's Closing Remarks and Close of Day One**

8.30 **Registration & Coffee**

9.00 **Chairman's Opening Remarks**
Sanj Singh, President and CEO, **Ade Therapeutics**

STAKEHOLDER UPDATES

PART 2

9.10 **Biomarker-pharma partnering - an ideal partnership?**
- Understanding the impact of early diagnosis/prognosis on clinical decisions
- Pinpointing opportunities for biomarker integration into discovery, preclinical and clinical development
- Cdx as enabling technology not restricting market
- Introducing surrogate biomarkers for efficacy monitoring/therapy switching in the clinical testing and application market

Mark Eccleston, External Collaborations Manager, **Volition RX**

9.50 **Trends in academic-industry collaborations**
- Identifying the recent trends that we have observed in academic/industry collaborations
- Understanding what the academic medical centers are hoping to achieve from these collaborations
- What are the benefits to each of the partners?

Dr Diane Harbison, Head of Business Development, Edinburgh BioQuarter, **The University of Edinburgh**

10.30 **Morning Coffee**

11.00 **Introducing open innovation to facilitate R&D success**
- Examining current open innovation business models being employed
- Reviewing the advantages of this novel discipline
- Recognizing how alliance management is a key contributor to the success of open innovation collaborations

Dr. Michael Meyers, Vice President of Scientific Innovation, Oncology, **Johnson and Johnson**

11.40 **The big question! - how to get noticed by the big league players**

ROUND TABLE

- What does a small/medium pharma-biotech need to do to get on "Big Pharma's" radar?
- What will this mean for the company
- Case study

Lubor Gaal, Head of Europe, Business Development, **Bristol Myers Squibb**

12.20 **Networking Lunch**

FINANCING & FUNDING

1.20 **The state, the private investor and the early stage bioentrepreneur**
- State funding and selection of early stage drugs/technology in the UK and elsewhere
- Discussing private sector investment and capital efficient collaboration models to ensure success
- Understanding the key role of the early stage bioentrepreneur in realising technology translation

Davidson Ateh, Chief Executive Officer, **BioMoti**

2.00 **Where and how are licensee's & acquirers spending their money? An overview of deal trends, structures and deal values**
- How do the deals Big Pharma have been doing signal their strategic Intent
- Are option deals becoming more important as less upfront cash is risked
- When is a licensing deal really an M&A deal
- What is the optimum time in the development path to do your deal

Adrian Dawkes, Vice President, **PharmaVentures**

2.40 **Afternoon Tea**

MARKET AND GLOBAL DEVELOPMENTS

3.10 **Identifying and dealing with the best opportunity worldwide: the challenge of global biopharma**
- Structuring the best scouting network around the globe
- Matching the time dimension and keep momentum along the deal making process
- "Qualification" and "cultivation": combining the pharma strategy and partnering strategy of a biotech

Patrick Tricoli, Global R&D, External Innovation, Scouting and Partnering International, **Sanofi**

3.50 **Structure based molecular design approaches in the development of small molecules leads**
- Discussing our approach to fragment based in silico modeling
- Setting up a cross departmental drug discovery platform: bringing clinicians and biologists together
- Leveraging internal partnerships and collaborations to accelerate drug design

Professor Colin Fishwick, Head of Organic Chemistry, School of Chemistry, **University of Leeds School of Chemistry**

4.30 **Enabling next generation PCR**
- Discussing how PCR remains core to molecular diagnostics, describing the following enhancements to standard amplification protocols
- Analyzing multiplexed real-tiime detection of many different targets in single, closed tube format
- Increased analytical sensitivity for target amplification of circulating tumour specific DNA
- Increased analytical specificity in base calling of amplified and next-gen sequenced ctDNA

Eddie Blair, Chief Executive Officer, **GeneFirst**

5.10 **Chairman's Closing Remarks and Close of Day Two**

Supported by

HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 9th July 2014
8.30am - 12.30pm
Marriott Regents Park Hotel, London, UK

A: Cost Effective Pathway to Early Clinical Development to Support Regulatory Approvals and Commercial Partnering

Workshop Leaders:
Carla Bennett, Senior Clinical Research Consultant,
QRC Consultants Ltd
Dr Sarah Nicholson, Senior Regulatory Consultant,
QRC Consultants Ltd

Overview of workshop:

In this interactive workshop we will share our experiences with regulatory strategies to reach the clinic, set-up of clinical trials and how some common pitfalls can be easily avoided. In particular we will focus on cost effective solutions that will benefit your company regarding clinical programme timelines and compliance in preparation for inspections and commercial due diligence.

QRC Consultants is a team of experienced QA, regulatory and clinical research professionals.

Why you should attend:

It can be hard to balance costs, timelines and regulatory compliance for a company taking its first steps towards the clinic. With over 25 years of experience of doing just this, we would like to share some tried and tested solutions to help you get off to a great start.

Programme

8.30 Registration and coffee

9.00 Opening remarks

9.10 Session 1 - Regulatory Strategy (whistle-stop tour of CTAs, SMEs, Orphan Drug designations and getting Scientific Advice)

9.50 Session 2 – How to Utilise Effective Feasibility Assessments

10.30 Coffee Break

11.00 Session 3 – How-to guide on Quality Management Systems that are fit for purpose and cost effective

11.40 Session 4 - Risk Adaptive Approaches

12.20 Closing Remarks

12.30 Close of Workshop

About the workshop hosts:

Carla Bennett graduated from the University of Cardiff with a BSc (Hons) and has over 12 years' experience within the pharmaceutical industry, specialising in the management of clinical trials with novel products, including stem cell and gene therapies. Carla has worked in both small and large pharmaceutical companies and CROs.

Sarah Nicholson graduated from the University of Manchester with a PhD in Neuroscience and has worked within the industry for over 12 years. Sarah is experienced in all aspects of regulatory affairs including Scientific Advice, ODDs and CTAs and has worked in both pharma and CRO environments.

SMi PHARMACEUTICALS FORWARD PLANNER 2014

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10 – 11 February 2014, London

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24 – 25 February 2014, London

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Superbugs and Superdrugs - A Focus on Antibacterials
5 – 6 March 2014, London

Imaging in Cancer Drug Development
12 – 13 March 2014, London

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12 – 13 March 2014, London

Adaptive Designs
24 – 25 March 2014, London

Paediatric Clinical Trials
31 – 1 April 2014, London

Pre-Filled Syringes USA
31 March – 1 April 2014, USA

APRIL

Asthma & COPD
2 – 3 April 2014, London

Biosimilars USA
7 – 8 April 2014, USA

MAY

Big Data in Pharma
12 – 13 May 2014, London

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19 – 20 May 2014, London

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19 – 20 May 2014, London

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Conference: Monday 7th July & Tuesday 8th July 2014, Marriott Regents Park Hotel, London, UK Workshop: Wednesday 9th July 2014, London

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