NanoMed Digest
Nanomedicines Alliance Newsletter **September 2012**

SAVE THE DATES: Nanomedicines Alliance Symposium

The Nanomedicines Alliance is hosting an industry symposium 6-7 March 2013 in Rockville, MD, USA, entitled "**Nanomedicines: Charting a Roadmap to Commercialization."**

Speakers include industry members, FDA representatives, and academia.

Registration is open now. Be sure to take advantage of the early bird rates.

See page 6 of the newsletter for more details and page 7 for a draft program. See page 11 for Call for Posters. Check the website for updated information: http://www.nanomedicines-alliance.org/

REGULATORY AND LEGISLATIVE DEVELOPMENTS

Nanotechnology Awareness Low

Recently published results of a poll conducted by Harris Interactive, a U.S. based research organization, demonstrates that awareness of nanotechnology is low among American adults. However, among those who are aware of nanotechnology opinions and attitudes toward nano vary significantly. While adults in the 65+ age group were the least aware of nanotechnology, those who knew of nanotechnology were more optimistic about its potential than other age groups. This group of Americans was also the most keen to see nanotechnology applied to healthcare.

A summary report of the results can be downloaded here:
http://www.harrisinteractive.com/vault/Harris%20Poll%2052%20-%20Nanotechnology_9%206%2012.pdf

New UK Guidance Issued on Work Safety with Nanomaterials

The UK Nanosafety Partnership Group (UKNSPG) has issued new guidance on safety practices when working with nanomaterials for research and development. The document aims to provide guidance on how research institutions and academia can ensure occupational health and compliance with legal obligations while conducting research on nanomaterials. Nanomaterials covered in the guidance include particles, fibres, powders, tubes, wires, aggregates, and agglomerates.

The guidance document can be found here:
http://www.safenano.org/Portals/3/SN_Content/Documents/Working%20Safely%20with%20Nanomaterials%20-%20Release%201%200%20-%20Aug2012.pdf

German Environment Agency Issues Report on Nano in Environment

The German Federal Environment Agency has published a guidance on nanomaterials in the environment. This document investigates the applicability of the OECD Guidelines for the Testing of Chemicals to nanomaterials, in particular the guidelines relating to soil and sewage plant tests. Three TiO_2 nanomaterials were tested for their environmental behaviour and safety.

The full report can be found here:
http://www.umweltdaten.de/publikationen/fpdf-l/4301.pdf

Call for Experts on Safety Assessment of Nano in Cosmetics

The European Commission has issued a call for experts to assist the work of the Scientific Committee on Consumer Safety (SCCS), conducting safety assessments of nanomaterials in cosmetic products. Article 16 of the Cosmetic Regulation EC No. 1223/2009 requires manufacturers of any cosmetics containing nanomaterials to notify the EC six months before being placed on the market. If there are any concerns, the EC will request the SCCS for an opinion. The Commission has identified a need for external experts to assist in the work of the SCCS based on the expected volume of such notifications.

More information can be found here:
http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm

NIST Issues New Reference Materials for Tox Studies

The National Institute of Standards and Technology (NIST) has issued a new nanoscale reference material, a titanium oxide commonly known as P25. The NIST suggests this compound can be used to study the morphologic, elemental composition and surface area of any nanomaterial. A protocol for preparing samples for studies has been released at the same time.

OECD Releases Brochure on Nanomaterials

The Organisation for Economic Cooperation and Development (OECD) has issued a brochure outlining the achievements and conclusions of the OECD Working Party on Manufactured Nanomaterials, established six years ago. The brochure outlines that the OECD has come to the conclusion that while they may need to be adapted for the specific characteristics of nanomaterials, the approaches for testing of traditional chemicals are generally appropriate for assessing the safety of nanomaterials. The document also underscores the need for continuing research on the possible health and environmental effects of nanotechnology and nanomaterials, highlighting the OECD's Sponsorship Programme for the Testing of Manufactured Nanomaterials.
The brochure can be found here:
http://www.oecd.org/chemicalsafety/safetyofmanufacturednanomaterials/Nano%20Brochure%20Sept%202012%20for%20Website%20%20(2).pdf

Nanomed 2020 to Bring More Nanomedicines for European Patients

Nanomed2020, a project supported by the European Commission under FP7, began on 1 September 2012 and will last for 18 months. The project aims to identify key areas of nanomedicine and new ideas for translating nanomedicine research into clinical use, providing recommendations to the European Commission for bringing these novel therapies to the patients. The project intends to involve all stakeholders involved in the nanomedicines development process, including industry, academia, healthcare practitioners and institutions, and public authorities.
More information on the project can be found here:
http://www.etp-nanomedicine.eu/public/news-events/news/start-of-nanomed-2020

NRC Releases Pre-Publication Report on Science For Environmental Protection, Investigates Nanotechnology

The National Research Council released in September a pre-publication version of a report entitled "Science for Environmental Protection: The Road Ahead." This report was requested by the EPA to assess EPA's capabilities to "develop, obtain, and use the best available scientific and technologic information and tools to meet persistent, emerging, and future mission challenges and opportunities." The document analyses nanotechnology as one area where emerging science can be utilised for regulatory and policy decision-making, noting that EPA missed the opportunity to support research that examines the effect of nanomaterials on environmental health and safety.
The report can be found here:
http://www.nap.edu/catalog.php?record_id=13510

Reviews and Other Publications of Interest

The European Commission's Recommendation on the Definition of Nanomaterials Makes an Impact. Nanotoxicology, posted online 17 September 2012. Hubert Rauscher, Birgit Sokull-Klüttgen, Hermann Stamm.
http://informahealthcare.com/doi/abs/10.3109/17435390.2012.724724

Join the Dialogue. Nature Nanotechnology, posted online 19 August 2012.
http://www.nature.com/nnano/journal/v7/n9/full/nnano.2012.150.html?WT.ec_id=NNANO-201209

Control of Protein-Binding Kinetics on Synthetic Polymer Nanoparticles by Tuning Flexibility and Inducing Conformation Changes of Polymer Chains. Journal of the American Chemistry Society, 19 September 2012, Vol. 134, No. 37, pp. 15209-15212. Yu Hoshino, Masahiko Nakamoto, and Yoshiko Miura. http://pubs.acs.org/doi/pdfplus/10.1021/ja306053s

A Dense Poly(Ethylene Glycol) Coating Improves Penetration of Large Polymeric Nanoparticles Within Brain Tissue. Science Translational Medicine, 29 August 2012, Vol. 4,

No. 149. Elizabeth A. Nance, Graeme F. Woodworth, Kurt A. Sailor, Ting-Yu Shih, Qingguo Xu, Ganesh Swaminathan, Dennis Xiang, Charles Eberhart, and Justin Hanes. http://stm.sciencemag.org/content/4/149/149ra119

Common Pitfalls in Nanotechnology: Lessons Learned from NCI's Nanotechnology Characterisation Laboratory. Integrative Biology, published online 14 June 2012. Rachel M. Crist, Jennifer Hall Grossman, Anil K. Patri, Stephan T. Stern, Marina A. Dobrovolskaia, Pavan P. Adiseshaiah, Jeffrey D. Clogston, and Scott E. McNeil. http://pubs.rsc.org/en/Content/ArticleLanding/2012/IB/c2ib20117h?goback=%2Egde_4224128_member_166207806

Magnetoporation and Magnetolysis of Cancer Cells via Carbon Nanotubes Induced by Rotating Magnetic Fields. Nano Letters, 10 October 2012, Vol. 12, No. 10, pp. 5117-5121. Dun Liu, Lijun Wang, Zhigang Wang, and Alfred Cuschieri. http://pubs.acs.org/doi/pdfplus/10.1021/nl301928z

PEGylated PRINT Nanoparticles: The Impact of PEG Density on Protein Binding, Macrophage Association, Biodistribution, and Pharmacokinetics. Nano Letters, 10 October 2012, Vol. 12, No. 10, pp. 5304-5310. Jillian L. Perry, Kevin G. Reuter, Marc P. Kai, Kevin P. Herlihy, Stephen W. Jones, J. Chris Luft, Mary Napier, James E. Bear, and Joseph M. DeSimone. http://pubs.acs.org/doi/pdfplus/10.1021/nl302638g

Nanostructured Thin Film Polymer Devices for Constant-Rate Protein Delivery. Nano Letters, 10 October 2012, Vol. 12, No. 10, pp.5355-5361. Daniel A. Bernards, Kevin D. Lance, Natalie A. Ciaccio, and Tejal A. Desai. http://pubs.acs.org/doi/pdfplus/10.1021/nl302747y

Behaviour and Anti-Glioma Effect of Lapatinib-Incorporated Lipoprotein-Like Nanoparticles. Nanotechnology, 2 November 2012, Vol. 23, No. 43. Huile Gao, Zhi Yang, Shijie Cao, Zhangjie Xi, Shuang Zhang, Zhiqing Pang, and Xinguo Jiang. http://iopscience.iop.org/0957-4484/23/43/435101/pdf/0957-4484_23_43_435101.pdf

Quantitative Molecular Profiling of Biomarkers for Pancreatic Cancer with Functionalised Quantum Dots. Nanotechnology, Biology, and Medicine, October 2012, Vol. 8, No. 7. Kwan Hyi Lee, Justin F. Galloway, Jeaho Park, Charlene M. Dvoracek, et. al. http://www.nanomedjournal.com/article/S1549-9634(12)00012-3/abstract

REVIEW: NTS-Polyplex: a Potential Nanocarrier for Neurotrophic Therapy of Parkinson's Disease. Nanotechnology, Biology, and Medicine, October 2012, Vol. 8, No. 7. Daniel Martinez-Fong, Michael J. Bannon, Louis-Eric Trudeau, Juan A. Gonzalez-Barrios, et al. http://www.nanomedjournal.com/article/S1549-9634(12)00085-8/abstract

Targeted Cargo Delivery Using a Rotating Nickel Nanowire. Nanotechnology, Biology, and Medicine, October 2012, Vol. 8, No. 7. Li Zhang, Tristan Petit, Kathrin E. Peyer, Bradley J. Nelson. http://www.nanomedjournal.com/article/S1549-9634(12)00097-4/abstract

REVIEW: Nanostructuring Molecular Materials as Particles and Vesicles for Drug Delivery, Using Compressed and Supercritical Fluids. Nanomedicine, September 2012, Vol. 7, No. 9, pp.1391-1408. Elisa Elizondo, Jaume Veciana, Nora Ventosa. http://www.futuremedicine.com/doi/pdf/10.2217/nnm.12.110

REVIEW: Clues for Biomimetics from Natural Composite Materials. Nanomedicine, September 2012, Vol. 7, No. 9, pp. 1409-1423. Shaul Lapidot, Sigal Meirovitch, Sigal Sharon, Aron Heyman, David L. Kaplan, Oded Shoseyov. http://www.futuremedicine.com/doi/pdf/10.2217/nnm.12.107

REVIEW: Magnetic Nanoparticle-based Approaches to Locally Target Therapy and Enhance Tissue Regeneration *In Vivo*. Nanomedicine, September 2012, Vol. 7, No. 9, pp. 1425-1442. Richard Sensenig, Yulia Sapir, Cristin MacDonald, Smadar Cohen, Boris Polyak. http://www.futuremedicine.com/doi/pdf/10.2217/nnm.12.109

REVIEW: Iron Oxide-based Nanostructures for MRI and Magnetic Hyperthermia. Nanomedicine, September 2012, Vol. 7, No. 9, pp. 1443-1459. Ingrid Hilger, Werner A. Kaiser. http://www.futuremedicine.com/doi/pdf/10.2217/nnm.12.112

CONFERENCES AND WORKSHOPS

Fifth Annual Nanotechnology and Nanomedicine Symposium, September 21-22, 2012, Louisville, Kentucky

- Nanoparticulate drug delivery systems
- Nano education and intellectual property
- Nano medicine/nano toxicology
- Nano fabrication and Characterisation
- Manufacturing & Mechanical Properties of Nanomaterials

http://www.sullivan.edu/pharmacy/NANO-index.asp

2012 Workshop on Nanoinformatics for Biomedicine, October 4-7, 2012, Philadelphia, PA.

- Nanomaterial-biological interactions
- Translational nanoinformatics
- Ethical and social issues

http://workshops.i-a-i.com/nanoinfo2012

International Conference on Nanotechnology in Medicine, November 7-9, 2012, London, UK.

- Tissue engineering and biomaterial science
- Nanoscale tissue scaffolds
- Nanoscale biomaterial surface modification
- Targeted drug delivery
- Nano-vehicle delivery systems
- Diagnosis and imaging

http://www.nanomed.uk.com/about.html

Nanosafe 2012, November 13-15, 2012, Grenoble, France

- Exposure assessment
- Characterisation, detection, and monitoring
- Nanomaterials life cycle
- Toxicology
- Environmental impact
- Nanoparticle release from consumer products
- Personal protective equipment
- Secure industrial production
- Safety parameters evaluation
- Standardisation, regulations

http://www.nanosafe.org/scripts/home/publigen/content/templates/show.asp?P=121&L=EN&ITEMID=65

BioNanoMed 2013, March 13-15, 2013, Krems, Austria.

- Novel nanomedical solutions-advances in nanomedicine
- Regenerative nanomedicine
- Nano-bio-technology based diagnostics
- Nano-bio-technology based therapy
- Aspects of nano safety
- Nano-imaging technologies in medicine

http://www.bionanomed.at/

19th Congress of the International Society for Aerosols in Medicine, April 6-10, 2013, Chapel Hill, North Carolina.

- Inhaling nanoparticles by accident on purpose—challenges and opportunities for toxicology and therapeutics

http://www.med.unc.edu/isam2013/scientific-program

REFERENCE SECTION

Nanobio- and Nanomedicine Companies

Listed alphabetically:
http://www.nanowerk.com/nanotechnology/nanomaterial/nanobiomedicine_a.php

Nano Organizations

- National Center for Toxicological Research (NCTR): http://www.fda.gov/AboutFDA/CentersOffices/NCTR/default.htm
- National Nanotechnology Initiative (NNI): http://www.nano.gov/
- Nano Science and Technology Consortium (NSTC): http://www.nstc.in/
- Nano Science and Technology Institute (NSTI): http://www.nsti.org/
- The Nanotechnology Institute (NTI): http://nanotechinstitute.org/

Nano Journals

- American Chemical Society -- Nano Letters: http://pubs.acs.org/journal/nalefd
- Institute of Physics – Nanotechnology: http://iopscience.iop.org/0957-4484/
- Journal of Nanoscience and Nanotechnology: http://www.aspbs.com/jnn/
- NanoTrends - A Journal of Nanotechnology and its Applications: http://www.nstc.in/journal/default.aspx
- BCC Research -- Nanotechnology Reports: http://www.bccresearch.com/index/category/code/nanotechnology
- Nanomedicine: Nanotechnology, Biology, and Medicine: http://www.nanomedjournal.com/home

Nanomedicine:
http://www.futuremedicine.com/page/about.jsp
Nature Nanotechnology:
http://www.nature.com/nnano/focus/highlights/index.html?WT.mc_id=NM1110CT010

CONTACT

For further information, or if you have any questions about the Nanomedicines Alliance, please contact the Nanomedicines Alliance Secretariat at 1-202-230-5607 or info@nanomedicines-alliance.org

DC01/ 3017796.1

Nanomedicines Alliance

www.nanomedicines-alliance.org

Save the Date and Invite your Colleagues!!

Nanomedicines Alliance Industry Symposium

NANOMEDICINES: CHARTING A ROAD TO COMMERCIALIZATION

Wed-Thurs, 6-7 March 2013

Hilton Washington DC/Rockville, Maryland USA

Symposium will address:

- Designing nanomedicines
- Preclinical pharmacology
- Chemistry, Manufacturing, and Controls
- Toxicology/ADME
- Clinical Studies

through

- Podium presentations
- Breakout sessions
- Poster sessions

You will benefit from this Symposium if you work in

- Pharmaceutical industry
- Biotech industry
- Regulatory agency

Or are interested in

- Industry perspectives
- Manufacturing nanomedicines
- Future of nanomedicines
- Networking

To Register: https://www.signmeup.com/86831

Early Bird **(To take advantage of the Early Bird Rate, please register by November 30, 2012):**

$500 (industry)
$400 (academia)
$250 (government)

Please contact the Alliance Secretariat at dede.godstrey@dbr.com or +1-202-230-5607 for more information

Nanomedicines Alliance Industry Symposium Program:

NANOMEDICINES: CHARTING A ROADMAP TO COMMERCIALIZATION

Wednesday-Thursday, 6-7 March 2013
Hilton Washington DC/Rockville, Maryland

DAY 1: WEDNESDAY, MARCH 6, 2013

OPENING REMARKS 9:00-9:15 AM

PLENARY LECTURE 9:15-10:00 AM

Mark Davis, Ph.D. (California Institute of Technology)

SECTION 1: DESIGNING NANOMEDICINES 10:00-11:15 AM

Section Leaders: Anil Diwan, Ph.D. (Nanoviricides, Inc.) & Mostafa Analoui, Ph.D. (Livingston Healthcare)

"Nanomedicine" has evolved from a concept to a well-structured approach to architecting drugs that can have many different desirable properties. Advances in this field promise to enable total tailoring of: (a) how a drug is protected from bodily metabolism and clearance, and conversely the bodily systems from the drug, (b) where the drug is delivered- at specific tissue, cell or sub-cellular systems, directly onto a pathogen such as a bacterium, a virus particle, or even beta-amyloid plaque or other debris, (c) how long it resides in the body, and (d) how it is removed from the body. Such control also enables using as drugs hitherto extremely difficult molecules to drug with, such as hydrophobic small chemicals, proteins, enzymes, catalytic antibodies, immunoconjugates, antibodies, mi-si-RNA, dsRNA, ssDNA, dsDNA, and their modifications. Such precise control would also revolutionize vaccines as we know them today. Many of the drugs in use today are already nanomedicines. Advanced nanomedicines that incorporate one or more additional aspects from the feature list are now in development. Such drugs will require significant collaborative design efforts that span fields from biology to chemistry to physics to engineering. In this section we will illustrate some of the interesting developments in this area.

Topics:

- **Passive v. Active targeting**
- **Immunoavoidance or immunorecognition**
- **Biodegradable v. not biodegradable**

Panelists:
Edith Mathiowitz, Ph.D. (Brown University)
Justin Hanes, Ph.D. (Johns Hopkins University)
Frank Bedu-Addo , Ph.D. (PDS Biotechnology Corp.)

- **Special Report: Summary of TONIC workshop on EPR**
  Uma Prabhakar, Ph.D. (Office of Cancer Nanotechnology Research, NCI-NIH)

COFFEE 11:15-11:30 AM

SECTION 2: PRECLINICAL PHARMACOLOGY 11:30 AM-12:30 PM

Section Leaders: Benjamin Yerxa, Ph.D. (Liquidia Technologies) & Randall Barton, Ph.D. (Nanoviricides, Inc.)

The promise of nanotechnology to revolutionize medicines in the 21st century is being established in nonclinical animal studies. The effective translation of that knowledge to safe and effective human medicines requires appropriate tools & model systems that can measure the value of nanotech approaches in sensitive and specific ways.

11:30 – 11:50 AM

- **Evaluation of the mononuclear phagocyte system (MPS) and effects on nanoparticle pharmacokinetics and pharmacodynamics in preclinical animal models and in patients**
  William C. Zamboni, PharmD, Ph.D. (The University of North Carolina at Chapel Hill)

11:50 AM – 12:10 PM

- **The Translational Capability of Animal Models**
  Jeff Madwed, Ph.D. (Merck & Co., Inc.)

12:10 – 12:30 PM

- **Improved Performance of Novel Nanomedicines in Preclinical Systems**
  Joseph DeSimone, Ph.D. (The University of North Carolina at Chapel Hill)

LUNCH 12:30-1:30 PM

SECTION 3: CMC 1:30-2:30 PM

Section Leaders: Henry A. Havel, Ph.D. (Eli Lilly & Company) & Marc Wolfgang (Cerulean Pharma Inc.)

Successful regulatory approval of nanomedicines will require that the unique CMC technical challenges of these products (e.g. characterization, analytical methods, manufacturing, specifications, sterility assurance) be addressed to ensure patient safety and efficacy. Just as for traditional products, the overall control strategy will need to be science- and risk-based, build on product experience during clinical trials, and incorporate laboratory and manufacturing scale results. Through better understanding of the fundamental aspects of the manufacturing process, health authorities will have the information necessary for a comprehensive review of the sponsor's application for marketing approval. Since a central tenet of these reviews is that they will be product- and process-specific, it is not expected that specific rules can be developed for application to all nanomedicines. Instead, general principles pertinent to CMC challenges will be described and illustrated by case studies.

1:30 – 1:50 PM

- **Analytical characterization tools unique to nanomedicines**
  Scott McNeil , Ph.D. (Nanotechnology Characterization Laboratory)

1:50 – 2:10 PM

- **Managing scale-up challenges for nanomedicines**
  Jeff Hrkach, Ph.D. (BIND Biosciences)

2:10 – 2:30 PM

- **Yield, cost, and economic considerations of nanomedicine manufacturing**
  Marc Wolfgang (Cerulean Pharma Inc.)

BREAKOUT SESSIONS 2:30-3:30 PM

Breakout 1: Designing Nanomedicines

Moderators: Anil Diwan, Ph.D. (Nanoviricides, Inc.) & Mostafa Analoui, Ph.D. (Livingston Healthcare)

Breakout 2: Preclinical Studies
Moderators: Benjamin Yerxa, Ph.D. (Liquidia Technologies) & Randall Barton (Nanoviricides, Inc.)
Breakout 3: CMC
Moderators: Banu Zolnik , Ph.D. (Food & Drug Administration), Henry Havel, Ph.D. (Eli Lilly & Company), & Marc Wolfgang (Cerulean Pharma Inc.)

COFFEE	3:30-4:00 PM

REPORT FROM BREAKOUT SESSIONS	4:00 – 5:15 PM

Report from Breakout 1: Designing Nanomedicines
Report from Breakout 2: Preclinical Studies
Report from Breakout 3: CMC

POSTER SESSION/COCKTAIL HOUR	5:15-7:15 PM

DAY 2: THURSDAY, MARCH 7, 2013

SECTION 4: TOXICOLOGY/ADME	8:30-9:30 AM

Section Leaders: Gregory L. Finch, Ph.D. (Pfizer) & Vijay Reddy, Ph.D. (Eli Lilly & Company)

Nonclinical studies to evaluate the toxicological properties as well as absorption, distribution, metabolism, and excretion (ADME) patterns of nanomedicines are needed to support safe clinical development and product registration. While the basic principles of these studies apply equally to nanomedicines and more traditional investigational drugs, the in vivo tracking of nanomedicines may present special challenges. From a toxicity perspective, the standard approaches calling for testing in disciplines such as genotoxicity, general toxicity, developmental/reproductive toxicity, safety pharmacology, phototoxicity, and carcinongenicity appear generally well-suited to a safety evaluation of nanomedicines. In some cases, however, special concerns regarding interaction with the immune system and compatibility with the blood system may exist depending on the specific nature of a nanomedicine.

Topics
8:30 – 8:50 AM
- **Biodistribution: Where is the material going and how do we show that**

8:50 – 9:10 AM
- **Interactions with the Immune System**
  Marina Dobrovolskaia, Ph.D. (Nanotechnology Characterization Laboratory)

9:10 – 9:30 AM
- **Nanotoxicology Toxicity Screening: An Old Dog Learns a New Trick**
  Michael Mirsky, DVM, Ph.D. (Pfizer)

SECTION 5: CLINICAL STUDIES **9:30-10:50 AM**

Section Leaders: Benjamin Yerxa, Ph.D. (Liquidia Technologies) & Meliessa G. Hennessy, MPH (Cerulean Pharma Inc.)

Nanometer scale medicines are not new. Yet, opportunity exists to apply advances in specific nano-scale engineering principles to improve existing pharmaceutical products and introduce novel medicines through the construct of targeted, vehicle/carrier enhanced, or hybrid NCEs. In reformulating existing products what constraints will limit the streamlining of clinical development plans? And with NCEs what unique tools, adaptive trial designs, and other innovations will enhance our ability to license safe and effective nanomedicines?

9:30 – 9:50 AM

- **Value of Phase 0 studies in nanomedicines**
  Edward G. Garmey, M.D. (Cerulean Pharma Inc.)

9:50 – 10:10 AM

- **Streamlining of clinical trial design (particularly reformulating well tested products)**
  Dirk Reitsma, M.D. (PPD)

10:10 – 10:30 AM

- **Pharmaceutical perspective on clinical development of nanomedicines**
  Neil Desai, Ph.D. (Celgene)

10:30 – 10:50 AM

- **Japanese perspective on clinical trials of nanomedicines**
  Hiroyuki Hanada (NanoCarrier Co., Ltd.)

COFFEE **10:50-11:00 AM**

BREAKOUT SESSIONS **11:00 AM-12:00 PM**

Breakout 4: Toxicology/ADME
Moderators: Nakissa Sadrieh, Ph.D. (Food & Drug Administration), Gregory L. Finch, Ph.D. (Pfizer, Inc.) & Vijay Reddy, Ph.D. (Eli Lilly & Company)
Breakout 5: Clinical Studies
Moderators: Benjamin Yerxa, Ph.D. (Liquidia Technologies) & Meliessa Hennessy, MPH (Cerulean Pharma Inc.)

COFFEE **12:00 -12:20 PM**

REPORT FROM BREAKOUT SESSIONS **12:20-1:05 PM**

Report from Breakout 4: Toxicology/ADME
Report from Breakout 5: Clinical Studies

CONCLUDING REMARKS **1:05-1:15 PM**

NANOMEDICINES ALLIANCE
WWW.NANOMEDICINES-ALLIANCE.ORG

CALL FOR POSTERS

NANOMEDICINES ALLIANCE 2013 SYMPOSIUM

6-7 March 2013

The Nanomedicines Alliance is inviting abstract submissions for posters for its 2013 Symposium: *Nanomedicines: Charting a Road to Commercialization* to be held on **Wednesday—Thursday, March 6-7, 2013**, in Rockville, Maryland, USA (http://www.nanomedicines-alliance.org/events.html).

Individuals and groups interested in presenting posters should e-mail an informative abstract to dede.godstrey@dbr.com **before December 7, 2012**, with the words 'Poster Abstract for Nanomedicines Symposium' in the subject line. A final decision about acceptance or non-acceptance of a proposed poster will be communicated to the corresponding author by **December 17, 2012**.

Posters should convey sound scientific work within the scope of the Symposium as reflected in the Symposium's title. Sample topics of interest include designing nanomedicines, preclinical pharmacology, chemistry, manufacturing & controls, clinical studies and toxicology/ADME.

For poster abstract guidelines, see:
(http://www.nanomedicines-alliance.org/events.html)

Questions: Contact the Nanomedicines Alliance Secretariat
+1(202) 230-5607 • dede.godstrey@dbr.com