CHI to Host the 6th Immunogenicity and Bioassay Summit 2014 Headlined by Eight FDA Presenters and over 250 Attendees

Bringing Industry, Academia and Regulatory Authorities Together to Produce Safe and Efficacious Products for the Clinic and Beyond

NEEDHAM, MA, USA, July 29, 2014 /EINPresswire.com/ -- Cambridge Healthtech Institute (CHI) is pleased to release the final agenda for its Sixth Annual Immunogenicity and Bioassay Summit 2014 to be held on November 17-19, 2014 at the Hyatt Regency Bethesda, Bethesda, MD.

“Year after year, the attendance at this three-track event remains strong and the feedback positive,” said Nicole Lyscom, Ph.D., Conference Director, CHI. “Developing biologics is a challenging business and it’s highly rewarding to get technical know-how and advice from the top people in the field. At this event they will provide case studies and discussions on all the challenges such as immunogenicity and bioassays for safety and efficacy, risk assessment strategies, and means of predicting and avoiding immunogenicity. I am excited to be back in Bethesda because the location encourages participation from the FDA, USP, and NIH, and attracts many industry participants.”

Immunogenicity Assessment & Clinical Relevance (November 17-18)

Conference Highlights:

-- Keynote Presentations: "Strategy for Immunogenicity Risk Assessment," featuring Steven Swanson, Ph.D.,
Amgen and “The Impact of Quality Attributes on Immunogenicity,” featuring Susan Kirshner, Ph.D., CDER/FDA

-- Overcoming the challenges of immunogenicity assessment from all the leaders in the field: Pfizer, GSK,
Genentech, Amgen, Regeneron, BMS, MedImmune, Novartis

-- Focus on a range of products: IgGs including IgG4, interferon beta, enzyme replacement therapy and
Genentech’s Knob-and-Hole bi-specific

-- Examination of neutralizing antibody assays, always a challenge for the industry, with special focus on
addressing drug interference and improving drug tolerance

-- Regulatory perspectives for biosimilars from Bridget Heelan, M.B., Ph.D., Parexel, (ex-MHRA)

-- Choice of 6 Problem Solving Roundtable Discussions: Featuring Laurie Graham, Ph.D., FDA/CDER, Steven J.
Swanson, Ph.D., Amgen, Inc, Francesca Civoli, Ph.D., Amgen, Inc., Jim McNally, Ph.D., Pfizer, Inc.,

Harry
Yang, Ph.D., MedImmune, LLC, Laura Salazar-Fontana, Ph.D., CDER/FDA, and Bridget Heelan, Ph.D., Parexel
(ex-MHRA)

Immunogenicity Prediction & Mitigation (November 18-19)

Conference Highlights:

-- Keynote Presentation: " Immune Tolerance Induction for Therapeutic Proteins: The FDA Perspective,"
featuring Amy Rosenberg, Ph.D., FDA/CDER

-- The impact of impurities will be discussed by Daniela Verthelyi, Ph.D., of the FDA, and studies on the
impact of aggregates will be reported by Roche and MedImmune

-- Different approaches to immune suppression, deimmunization and tolerance induction from Amgen, FDA, NIH,
Apitope, Selecta Biosciences, and the Universities of Rhode Island and Bristol

-- Panel Discussion: “Development and Application of Humanized Mice for Immunogenicity Predictive Studies”
moderated by Jack Ragheb, Ph.D., FDA/CDER

-- Problem Solving Roundtable Discussions: Featuring Vibha Jawa, Ph.D., Amgen, Inc; Jack Ragheb, Ph.D.,
FDA/CDER; Daniela Verthelyi, Ph.D., FDA/CDER; Lydia Haile, Ph.D., FDA/CDER; Tim Hickling, Ph.D., Pfizer,
Inc.; and David C. Wraith, Ph.D., Apitope International NV

Optimizing Bioassays for Biologics (November 18-19)

Conference Highlights:

-- Keynote Presentations: “Characterization of Response of Multiple Domain Biotherapeutics,” featuring Jaya
Goyal, Ph.D., Biogen Idec and “The Science and Regulation of Potency Assays for Assessing the Quality of
Biopharmaceuticals,” featuring Baolin Zhang, Ph.D., FDA

-- FDA and United States Pharmacopeial Convention will weigh in on new guidelines as well as provide insight
into what they consider a well-characterized biologic

-- Comparability and characterization case studies with cell based and non-cell-based assays from Morphotek,
Inc. and Genentech

-- New technologies and bioassay formats will be presented along with recommendations for implementation to
ensure a steady drug development pipeline from AdiMab, LLC, Novartis, MedImmune LLC, Novartis,

Precision
Bioassay, Inc., and PerkinElmer

-- Problem Solving Roundtable Discussions: “Strategies for Assay Selection, Validation and Maintenance,”
featuring ImmunoGen, Inc. and Novartis

Writers and editors are invited to attend. To request a press pass, contact Lisa Scimemi, lscimemi@healthtech.com.

For more details and to register, visit http://www.ImmunogenicitySummit.com

About Cambridge Healthtech Institute (http://www.chicorporate.com)

Cambridge Healthtech Institute (CHI), founded in 1992, is the industry leader in providing superior-quality scientific information to eminent researchers and business experts from top pharmaceutical, biotech, and academic organizations. Delivering an assortment of resources such as events, reports, publications and eNewsletters, CHI's portfolio of products include Cambridge Healthtech Institute Conferences, Barnett Educational Services, Insight Pharma Reports, Cambridge Marketing Consultants, Cambridge Meeting Planners, Cambridge Healthtech Media Group, and The Knowledge Foundation.

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