Janice A. Lansita, Ph.D., DABT

SENIOR MANAGING SCIENTIST

CONTACT INFORMATION

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PROFESSIONAL PROFILE

Dr. Janice Lansita is a senior managing scientist with ToxStrategies and is located in Baltimore, MD. She is a board certified toxicologist with 10 years of experience in pharmacology/toxicology. She has worked in both the biopharmaceutical industry and at the U.S. Food and Drug Administration (USFDA). As a regulatory toxicologist in the biopharmaceutical industry, Dr. Lansita worked on projects involving development of various biological products including monoclonal antibodies, fusion proteins and cytokines for different indications (e.g., oncology, asthma, rheumatology, and multiple sclerosis). Dr. Lansita has extensive experience in the design, monitoring, and interpretation of nonclinical toxicology studies (GLP and non-GLP). In addition, she has authored the nonclinical sections of various regulatory documents including pre-Investigational New Drug (IND) packages, INDs, Investigator Brochures, annual reports, and package inserts/product labels for biopharmaceuticals. At the USFDA in the Center for Drug Evaluation and Research (CDER), Dr. Lansita served as a pharmacology/toxicology reviewer and was responsible for reviewing the nonclinical data packages (i.e., pharmacology, pharmacokinetics, and toxicology) of small molecule and biologic products submitted by sponsors to support the safety of various drugs including anti-virals, special pathogens, transplant, and ophthalmology products. In this role, Dr. Lansita participated in meetings with sponsors (e.g., pre-IND, Type A, and Type C) and reviewed pre-IND packages, INDs, and NDAs /BLAs for both small molecule and biological products. She has a comprehensive understanding of the regulatory requirements as well as the Agency's current expectations for nonclinical drug development. Additionally, she has worked with sponsors to address scientific challenges related to the development of drug candidates, including clinical hold issues, or issues that may impact clinical development, and has insight into the current USFDA regulatory perspectives relevant to the review of nonclinical studies for biopharmaceuticals/pharmaceuticals. During her time at the USFDA, Dr. Lansita contributed to the nonclinical sections of various USFDA guidance documents (including the draft guidances documents, *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product* and *HIV: Developing Anti-retroviral Drugs for Treatment*). She also assisted in addressing the public comments for the *S6 Addendum to Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals* and the draft USFDA guidance for *HCV: Developing Anti-retroviral Drugs for Treatment*. In addition, during her tenure with the USFDA, Dr. Lansita taught an educational course to FDA reviewers on the nonclinical review of biologic products and served as Co-Chair of the Pharmacology/Toxicology Coordinating Committee's Nonclinical Biologics Subcommittee comprised of pharmacology/toxicology reviewers with expertise in biological products across the CDER review Divisions.

Dr. Lansita is a Diplomate of the American Board of Toxicology, and member of the Society of Toxicology.

EDUCATION AND DEGREES EARNED

1998 - 2004 **Massachusetts Institute of Technology**, Cambridge, MA
Biological Engineering Division
Ph.D., Toxicology, June 2004.

1993 - 1997 **Barnard College, Columbia University**, New York, NY
Department of Chemistry
B.A., Biochemistry, May 1997. Minor, Environmental Science

PROFESSIONAL EXPERIENCE

2009 – 2014 **Pharmacologist/Toxicologist**
U.S. Food and Drug Administration, Center for Drug Evaluation and Research (CDER)

2004 – 2008 **Toxicologist – Scientist II**
Biogen Idec, Cambridge, MA
Preclinical and Clinical Development Sciences, Pharmacotoxicology

CERTIFICATIONS

Diplomate, American Board of Toxicology (2009-present)

PROFESSIONAL AWARDS AND HONORS

2012 CDER Group Recognition Award - Biosimilar Scientific Considerations Draft Guidance Working Group, presented at the CDER Group and Team Walk of Fame Honor Awards

2004 MIT Student Leader Award for Outstanding Graduate Resident Tutor

2002 - 2004 Biogen Idec - MIT Fellowship

2003 American Association for Cancer Research Scholarship

2002 Keystone Symposia Scholarship: "Stem Cells, Origins, and Fates"

2001 - 2002 Anna Fuller Fund Pre-doctoral Fellowship in Molecular Oncology

1995 - 1997 Student Government Leadership Award

1994, 1996 Dean's List

PROFESSIONAL ASSOCIATIONS/ACTIVITIES

- Co-Chair of the CDER Pharmacology/Toxicology Coordinating Committee (PTCC) Nonclinical Biologics Subcommittee, 2012-2014.
  - Responsible for organizing meetings, agenda topics and leading discussions relevant to the nonclinical review of biologics for a group of ~35 pharmacology/toxicology reviewers across Divisions in CDER.
- Associate Member, Society of Toxicology, 2005-present.
- BioSafe General Membership, 2004 and present.

SUMMARY OF EXPERTISE

Pharmacology/Toxicology Reviewer at USFDA

- Extensive experience reviewing nonclinical packages (pharmacology, pharmacokinetics, toxicology) of small molecule and biologic products for anti-viral, special pathogen, transplant and ophthalmology products
  - Pre-IND packages
  - INDs
  - NDA and BLA submissions
  - Briefing packages for different USFDA meetings (i.e., Type A, B, C)
  - Participant in USFDA meetings with sponsors (e.g., pre-IND, end-of-Phase 2, pre-NDA/BLA, etc.)
  - Reviewed products under the Animal Rule
  - Reviewed product under parallel scientific advice with EMA
- Taught educational course to USFDA reviewers on "Recent Updates to the Nonclinical Review Process of Biologic Products in CDER"
- Experience conducting comprehensive analyses and written reviews of nonclinical (pharmacology, pharmacokinetic, and toxicology) studies for numerous pre-IND packages INDs, and NDAs/BLAs
- Primary pharmacology reviewer for the approvals of Simeprevir for the treatment of chronic Hepatitis C infection and Belatacept for the prophylaxis of renal transplant rejection
- Expertise in the integrated interpretation of nonclinical safety data and providing recommendations to the USFDA review team and management to inform clinical trials and patient safety
- Experience reviewing and authoring nonclinical sections for product labels/package inserts for marketed products
- Provided written and verbal guidance to sponsors at formal meetings (Type A, B and C) to guide nonclinical development including clinical holds and nonclinical study design advice.
- Contributed to or authored nonclinical sections of draft USFDA guidance documents including: *Scientific Considerations in Demonstrating Biosimilarity to a Reference Product; HIV: Developing Anti-retroviral Drugs for Treatment, and Herpes: Developing Anti-retroviral Drugs for Treatment*. Helped to address public comments to *ICH S6(R1)*, *Preclinical Safety Evaluation of Biotechnology-Derived Pharmaceuticals* and the draft USFDA guidance *HCV: Developing Anti-retroviral Drugs for Treatment*

Biopharmaceutical/Pharmaceutical Industry

- Experience in the design and monitoring of non-GLP and GLP toxicology studies including the review, analysis and interpretation of data to inform preclinical and clinical development
- Led cross-functional preclinical sub-team to evaluate a surrogate model approach for a species-specific recombinant monoclonal antibody for oncology using in vitro and in vivo GLP and non-GLP studies to support the development of the lead clinical candidate. Led additional preclinical subteam to successful IND and clinical trial application (CTA) filing
- Authored regulatory documents and briefing packages including: Type C, IND, end-of-phase 2 (EOP2), pre-IND, Investigator Brochures, EU regulatory responses

- Served as the toxicology representative on numerous cross-functional drug development program teams; investigational drug products included monoclonal antibodies, cytokines, bi-specific antibodies, and fusion proteins for oncology, asthma/allergy, rheumatoid arthritis and multiple sclerosis
- Served as the toxicology representative at various meetings with the USFDA such as pre-IND, IND, and EOP2 meetings

CONFERENCES AND MEETING PRESENTATIONS

2013 **American College of Toxicology Annual Meeting, Symposium: Translating Nonclinical Cardiovascular Toxicity Findings into Clinical Trial Design, Session Chair**

Oral Presentations

2013 **American College of Toxicology Annual Meeting, Symposium: Impact of Combination Toxicology Studies on Pharmaceutical Development: Careful Consideration of Study Objectives, Timing, and Design**
Lansita, JA
Oral Presentation: A Regulatory Perspective on Combination Toxicology Studies

2012 **American College of Toxicology Annual Meeting, Symposium: Harmonization of Risk Assessment Approaches Across Regulatory Agencies: Best Science and Next Steps**
Lansita, JA and Jacobs, A
Oral Presentation: A Regulatory Perspective on Risk Assessment Models

2012 **FDA, Biologics Course, Recent Updates to the Review Process of Biologics at CDER**
Lansita, JA
Oral Presentation: Recent Updates to the Nonclinical Review Process of Biologic Products in CDER

2010 **American College of Toxicology, Educational Workshop Course**
Lansita, JA
Oral Presentation: Use of the Nonhuman Primate in the Safety Assessment of Biologics - A Regulatory Perspective

2008 **Boston Area Pharmaceutical Toxicology Group**
Lansita, JA
Oral Presentation: Preclinical Assessment of a Surrogate Model

2007 **Gordon Research Conference, Adverse Drug Reactions**
Lansita, JA
Oral Presentation: Preclinical Evaluation of a Species Restricted Monoclonal Antibody Therapeutic

2005 **Charles River Preclinical Services Symposium on Biotechnology Derived Therapeutics and Pharmaceuticals and Immunomodulation**
Lansita, JA
Oral Presentation: Developmental Reproduction Toxicity Studies of LFA-3/IgG1 Recombinant Human Fusion Protein

2005 **Society of Toxicology, Annual Meeting**
Lansita, JA and Clarke, J
Oral Presentation: Alternative Methods for the Safety Evaluation of Biological Therapeutic Products — Surrogate Antibodies and Beyond

2004 **British Association for Cancer Research, Stem Cells & Telomerase: Targets for transformation & therapeutic applications**
Lansita, JA, Merok, JR, Tunstead, JR, and Sherley, JL
Oral Presentation: Characterization of the Immortal Strand Mechanism

2002 **Keystone Symposia: Stem Cells, Origins, and Fates**
Merok, JR, Tunstead, JR, **Lansita, JA**, and Sherley, JL
Oral Presentation: Demonstration of Immortal DNA Strand Co-Segregation in Cells with Asymmetric Stem Cell Kinetics

POSTER PRESENTATIONS

2007 **Society of Toxicology, Annual Meeting**
Lansita, JA, Rinaldi, N, Goyal, J, Polack, E, Ryan, S, et al.
Poster: In vitro and In vivo Comparability Assessment of a Potential Surrogate Preclinical Toxicology Model

2006 **Society of Toxicology, Annual Meeting**
Lansita, JA, Tenhoor, C, Hutto, D, Palmer, V, Graff, C, Clarke, J
Poster: Developmental Reproduction Toxicity Study Of Alefacept

2005 **American College of Toxicology, Annual Meeting**
Lansita, JA, Hutto, D, Cooper, M, Palmer, V, Polack, E, Rowell, T, Clarke, J
Poster: Increases in Serum Transaminases Related to Ketamine Anesthesia in Chimpanzees

2005 **Society of Toxicologic Pathology, Annual Meeting**
Lansita, JA, Hutto, D, Cooper, M, Palmer, V, Polack, E, Rowell, T, Clarke, J
Poster: Increases in Serum Transaminases Related to Ketamine Anesthesia in Chimpanzees

2004 **International Society for Stem Cell Research 2nd Annual Meeting**
Lansita, JA, Wang, T, Ellis, J, and Sherley, JL
Poster: Investigation of Non-Random Chromosome Segregation Associated with Adult Stem Cell Asymmetric Self-renewal

2003 **American Association for Cancer Research 94th Annual Meeting**
Lansita, JA, Geiser, H, Reinhold, V, Sherley, JL
Poster: Physicochemical Demonstration of Immortal DNA Strand Co-Segregation in Cells that Cycle with Asymmetric Stem Cell Kinetics

2002 **Aspen Cancer Conference:**
Mechanisms of Toxicity, Carcinogenesis, Cancer Prevention, and Cancer
Lansita, JA, Merok, JR, and Sherley, JL
Poster: Isolation and Detection of Immortal DNA Strands in Cells that Cycle with Asymmetric Stem Cell Kinetics

2002 **Keystone Symposia: Stem Cells, Origins, and Fates**
Lansita, JA, Merok, JR, and Sherley, JL
Poster: Physicochemical Demonstration of Immortal DNA Strand Co-Segregation in Cells that Cycle with Asymmetric Stem Cell Kinetics

2001 **Cold Spring Harbor Meeting: DNA Replication**
Lansita, JA, Merok, JR, and Sherley, JL
Poster: Physicochemical Demonstration of Immortal DNA Strand Co-Segregation in Cells that Cycle with Asymmetric Stem Cell Kinetics

PUBLICATIONS

Buckley L, Chapman K, Burns Naas LA, Todd M, Martin P, **Lansita J**, " Considerations Regarding Nonhuman Primate Use in Safety Assessment of Biopharmaceuticals," Int J Toxicol. 2011 Oct;30:583-90.

Merok, JR, **Lansita, JA**, Tunstead, JR, Sherley, JL, "Cosegregation of Chromosomes Containing Immortal DNA Strands in Cells that Cycle with Asymmetric Stem Cell Kinetics," Cancer Res., 62, 6791-6795, 2002.

PUBLISHED ABSTRACTS

Lansita, JA, Merok, JR, and Sherley, JL, "Physicochemical Demonstration of Immortal DNA Strand Segregation," in "Mechanisms of Toxicity, Carcinogenesis, Cancer Prevention and Cancer Therapy: Abstracts of the Seventeenth Aspen Cancer Conference," Tox. Path., 31, 163-164, 2003.

Merok, JR, Tunstead, JR, **Lansita, JA**, and Sherley, JL, "Demonstration of an Immortal DNA Strand Mechanism in Cells That Cycle with Asymmetric Stem Cell Kinetics-Implications for Mechanisms of Human Cancer and Aging," in "Mechanisms of Toxicity, Carcinogenesis, Cancer Prevention and Cancer Therapy: Abstracts of the Seventeenth Aspen Cancer Conference," Tox. Path., 31, 165-166, 2003.