There will be four half-day CE sessions in 2009, two concurrent morning courses and two concurrent afternoon courses.

**CE 1 (Sunday AM)**

**Cancer Therapeutics, Development Strategies in the Era of Targeted Therapies**

*Co-chairs:*
Page Bouchard, DVM, DACVP, *Archemix Corp*
David Epstein, *OSI Therapeutics*

**Session outline:**
- Emerged and emerging Biology for the Next Wave of Targeted Cancer Therapies
- Regulatory Considerations in Development of Cancer Therapeutics
- Safety Assessment Considerations and Strategies for Targeted Small Molecule Cancer Therapeutics

**Break (30 minutes)**
- EGFr antagonists, What Have We Learned and Where Do We Go Now
- Anti-Angiogenesis, Avastin and Beyond
- Immunomodulation and Cancer Therapy, It’s Been a Long Road
- Inhibitors of the Ubiquitin Proteasome Pathway, Deconvolution of the Biology and Toxicology of a Novel and Pleotropic Pathway
CE 2 (Sunday AM)

**Drug-induced Hematotoxicity - What's new?**

*Co-chairs:*
*Nancy Everds, DVM, DACVP, Amgen Inc.*
*Frances Clemo, BS, DVM, PhD, DACVP, Pfizer Inc.*

Hematotoxicity is a common dose-limiting side effect of drugs in preclinical and clinical studies, especially for cancer therapeutics and other drugs that affect cell proliferation. Currently, there are several marketed drugs that are aimed to ameliorate cytopenias in cancer patients through stimulation of hematopoiesis.

This course will cover a range of topics, including fundamentals of hematotoxicity, specialized research tools available to investigate hematotoxicity, preclinical issues with selected chemotherapeutics, and clinical management of hematotoxicity related to anti-cancer drugs.

- General mechanisms of hematologic toxicities
- Specialized tools used to investigate hematologic toxicities
- Risks and benefits of therapeutic use of hematopoietic stimulating agents
- Risk management of preclinical drug-induced cytopenias

CE 3 (Sunday PM)

**Mechanism-based Adverse Events Associated with Chemotherapy**

*Chair:*
*Carl Alden, DVM, DACVP, Millennium Pharmaceuticals Inc.*

The majority of drugs in development now in the US are targeted in the oncology therapeutic area. With the emerging improvements in cancer therapy an increasing awareness of the toxicities associated with chemotherapy can be anticipated. Examples include long term adverse events such as cognitive function impairment (chemo brain) and congestive heart failure. Equally critical, mechanism based adverse effects may limit the opportunity of the patient to benefit from therapy such as is the case with chemotherapy induced peripheral neuropathy. While the oncologist has excellent awareness and ability to manage the traditional cytotoxic chemotherapeutic effects on the gastrointestinal tract and bone marrow, future novel therapeutic targets will hopefully reduce the treatment residua of current chemotherapeutics. The purpose of the workshop will be to provide an overview of cytotoxic drug effects in the brain and peripheral nervous system and in the cardiovascular system.

- Chemobrain
- Chemotherapeutic peripheral neuropathy
- Congestive Heart Failure and Chemotherapy
• Liver toxicity in cancer patients

**CE 4 (Sunday PM)**

**Drug Development for Pediatric Populations**

*Co-chairs:*

*Ian Pyrah, BVM&S, PhD, MRCVS, FRCPath, Amgen Inc.*  
*Kevin McDorman, DVM, PhD, DACVP, Charles River Laboratories*

Availability of safe and efficacious drugs for children is a current hot topic in society and reflected by increased regulatory demands. The development of drugs for children poses a number of challenges that must be understood and overcome to obtain adequate information in drug safety and efficacy and product labeling. Appropriate preclinical toxicology studies are a component of this package. However, there is limited experience and precedence in the design and interpretation of such toxicity studies in juvenile animals and other systems. This course will provide updated information on regulations and current thinking on preclinical development of drugs for children, providing examples of successful pediatric drug development, as well as examples where concerns for the use of certain classes of drugs exist in the marketplace.

• Current Issues with Pediatric Drug Use

• Regulatory History and Hurdles of Pediatric Drug Development

• Concerns for Development and Use of Immunosuppressants in Pediatric Populations

• Study Design Concepts in Juvenile Toxicity Studies

• Experience of Juvenile Toxicity Studies from a Pathologist’s Perspective