2013 Oncology Pharmacy Specialty Recertification Home Study Syllabus Learning Objectives

Breast Cancer

Chad Barnett, Pharm.D., BCOP Clinical Pharmacy Specialist The University of Texas M.D. Anderson Cancer Center Houston, Texas

Learning Objectives:

- 1. Evaluate the clinical outcomes data related to the use of pertuzumab for the treatment of human epidermal growth factor receptor 2 (HER2)-positive metastatic breast cancer (MBC).
- 2. Outline the clinically relevant toxicities of pertuzumab.
- 3. Discuss how results from this study may be incorporated into patient care decisions for the treatment of HER2-positive MBC.

Chronic Myeloid Leukemia

Christopher A. Fausel, Pharm.D., BCOP Clinical Manager, Oncology Pharmacy Indiana University Simon Cancer Center Indianapolis, Indiana

Learning Objectives:

- 1. Describe the relevant end points in evaluating efficacy in comparative trials of patients with chronic myeloid leukemia.
- 2. Explain the relative clinical benefit of advanced tyrosine kinase inhibitors compared with imatinib as tested in phase III clinical trial design.
- 3. Assess the appropriateness of the trial primary end points for clinical response.
- 4. Contrast the difference in toxicities for bosutinib and imatinib.

Gynecologic Cancers

Dayna L. McCauley, Pharm.D., BCOP Clinical Pharmacist Division of Gynecologic Oncology Stony Brook University Hospital Stony Brook, New York

- 1. Determine the expected effect on progression-free and overall survival when bevacizumab is added to standard chemotherapy for the primary management of ovarian cancer.
- 2. Determine which subsets of patients with ovarian cancer are most likely to benefit from adding bevacizumab to standard chemotherapy.
- 3. Describe the expected toxicities when bevacizumab is added to standard chemotherapy for the primary treatment of ovarian cancer.
- 4. List the conditions with the most impact on the cost-effectiveness modeling for bevacizumab in the primary management of ovarian cancer.
- 5. List the conditions that must be met for bevacizumab to be cost-effective in the primary management of ovarian cancer.

Head and Neck Cancer

John Valgus, Pharm.D., BCOP, CPP Hematology/Oncology Clinical Pharmacist Practitioner University of North Carolina Hospitals and Clinics Clinical Assistant Professor UNC Eshelman School of Pharmacy Chapel Hill, North Carolina

Learning Objectives:

- 1. Describe the impact of smoking on cancer progression and death in patients with oropharyngeal cancer.
- 2. Identify the role of p16 in determining the risk of smoking in patients with oropharyngeal cancer.
- 3. Develop a rationale for smoking cessation recommendations in patients with oropharyngeal cancer.

Hematopoietic Stem Cell Transplantation

Julianna Merten, Pharm.D., BCPS, BCOP Clinical Pharmacy Specialist Mayo Clinic Rochester, Minnesota

Learning Objectives:

- 1. Describe the efficacy of lenalidomide maintenance therapy after stem cell transplantation (SCT).
- 2. Evaluate the risks of lenalidomide maintenance therapy after SCT.
- 3. Compare and contrast the patient populations and study design for two clinical trials of patients receiving lenalidomide maintenance after SCT.

Lung Cancer

R. Donald Harvey, Pharm.D., FCCP, BCOP Assistant Professor, Hematology/Medical Oncology Director, Phase I Clinical Trials Section Winship Cancer Institute of Emory University Atlanta, Georgia

- 1. Describe the potential therapeutic role of an agent targeting multiple human epidermal growth factor receptor subtypes.
- 2. Identify non-small cell lung cancer (NSCLC) patient populations most likely to benefit from therapy with the small molecule inhibitor dacomitinib.
- 3. Evaluate the adverse event profile and efficacy data comparing dacomitinib with erlotinib in advanced NSCLC.

Multiple Myeloma

Tippu Khan, Pharm.D., BCOP Clinical Pharmacist University of North Carolina Hospitals and Clinics Chapel Hill, North Carolina

Learning Objectives:

- 1. Explain the goals of maintenance in patients with multiple myeloma.
- 2. Evaluate the efficacy of post-hematopoietic cell transplantation (HCT) thalidomide maintenance in patients with multiple myeloma.
- 3. Explain the relative clinical benefit of using lenalidomide maintenance therapy post-HCT in patients with multiple myeloma.
- 4. Develop monitoring plans for toxicity based on the specific regimen chosen for maintenance therapy.

Oncology Drug Literature: Biostatistics and Study Design

Linda S. Tyler, Pharm.D. Administrative Director, Pharmacy Services University of Utah Hospitals & Clinics Salt Lake City, Utah

Learning Objectives:

- 1. List two reasons that drugs shown to be effective may be less effective than initially believed, and identify these limitations in trial data.
- 2. Explain why, when trials are terminated early, the results may overestimate treatment effects, and assess how this affects the statistical results.
- 3. Estimate the probability that ineffective drugs may be shown effective by chance alone.
- 4. Describe and interpret the Cochran Q test and I^2 statistic used to assess heterogeneity in metaanalyses.

Pancreatic, Stomach, and Liver Tumors

Andrea Landgraf, Pharm.D., BCOP Clinical Pharmacy Specialist The University of Texas M.D. Anderson Cancer Center Houston, Texas

- 1. Identify the patients most likely to benefit from trastuzumab therapy.
- 2. Evaluate the clinical outcomes data related to the use of trastuzumab for treatment of metastatic gastric cancer.
- 3. Describe the impact on toxicity when trastuzumab is added to chemotherapy for treatment of metastatic gastric cancer.

Pain Management

John Valgus, Pharm.D., BCOP, CPP Hematology/Oncology Clinical Pharmacist Practitioner University of North Carolina Hospitals and Clinics Clinical Assistant Professo UNC Eshelman School of Pharmacy Chapel Hill, North Carolina

Learning Objectives:

- 1. Review the evidence to support various opioids in the treatment of cancer pain.
- 2. Identify management strategies for opioid-related adverse drug reactions.
- 3. Define the role of nonopioid and adjuvant medications in the treatment of cancer pain.

Pediatric Cancer

Mark T. Holdsworth, Pharm.D., BCOP Associate Professor University of New Mexico Albuquerque, New Mexico

- 1. Discuss the contemporary pharmacotherapy components for pediatric high-risk neuroblastoma and the limitations with these approaches.
- 2. Describe how emerging antibody therapeutic approaches can be combined with contemporary pharmacotherapy and may lead to improved outcomes.
- 3. Describe the different mechanisms by which standard posttransplant therapy (i.e., isotretinoin) and immunotherapy work to complement each other in treating residual neuroblastoma.
- 4. Explain why there are few randomized controlled studies of new agents performed in neuroblastoma or pediatrics in general.
- 5. Compare isotretinoin dosing employed for neuroblastoma with the U.S. Food and Drug Administration (FDA)-approved dose.
- 6. Discuss the demographic characteristics of the two groups being compared in the study of immunotherapy versus standard therapy.
- 7. Explain why the decision by the COG (Children's Oncology Group) Data Safety and Monitoring Committee in 2009 has not resulted in FDA approval of this form of immunotherapy for neuroblastoma.
- 8. Compare and contrast event-free survival with overall survival.
- 9. Describe the difference between stage 4 and 4S neuroblastoma, and explain why the latter has a better prognosis.
- 10. Discuss the treatment-related toxicities that are encountered with immunotherapy for neuroblastoma and how they pertain to the two different immunotherapeutic adjuvants employed in the trial.
- 11. Compare and contrast the differences between treatment-related toxicities associated with immunotherapy with those caused by standard induction chemotherapy regimens employed earlier in the treatment of these patients with neuroblastoma.
- 12. Provide details of potential fatal medication errors involved with immunotherapy for neuroblastoma.

Pharmacology

Patrick Medina, Pharm.D., BCOP Associate Professor University of Oklahoma College of Pharmacy Oklahoma City, Oklahoma

Learning Objectives:

- 1. Outline the mechanism of action, pharmacokinetics, and pharmacodynamics of available and investigational therapies that target the human epidermal growth factor receptor 2 (HER2).
- 2. Describe the mechanisms and clinical relevance of resistance associated with trastuzumab therapy in breast cancer.
- 3. Discuss how dual blockade of the HER2 receptor is clinically relevant in treating breast cancer.
- 4. Summarize the androgen synthesis pathway and explain its importance in castration-resistant prostate cancer (CRPC).
- 5. Appraise the proposed benefits of next-generation androgen synthesis inhibitors in treating CRPC.
- 6. Explain the mechanism of action of new agents used to treat CRPC.

Prostate Cancer

Sachin Shah, Pharm.D., FCCP, BCOP Associate Professor Texas Tech University Health Sciences Center–School of Pharmacy Dallas/Fort Worth, Texas

Learning Objectives:

- 1. Evaluate recent clinical advances in patients with metastatic prostate cancer.
- 2. Explain the activity and toxicity of newly approved agents in the treatment of prostate cancer.
- 3. Develop treatment regimen plans for patients with metastatic castration-resistant prostate cancer.

Skin Cancer

Val R. Adams, Pharm.D., FCCP, BCOP Associate Professor University of Kentucky College of Pharmacy Lexington, Kentucky

- 1. Describe the toxicity seen with dabrafenib therapy and the prophylactic measures/treatments for it.
- 2. From the inclusion/exclusion criteria, describe the tests and results that would make a patient eligible to receive dabrafenib.
- 3. Outline a treatment plan and patient counseling for an individual with metastatic melanoma who is going to receive dabrafenib.
- 4. Describe the signaling pathway targeted with trametinib and features that allow individual selection for therapy.
- 5. Discuss the toxicity seen with trametinib compared to dacarbazine.
- 6. Outline a treatment plan and patient counseling for an individual with metastatic melanoma who is going to receive trametinib.

Symptom Management

Myke R. Green, Pharm.D., BSPharm, BCOP Oncology Clinical Pharmacy Specialist University Medical Center/Arizona Cancer Center Tucson, Arizona

- 1. Critically analyze, evaluate, and interpret oncology clinical trials.
- 2. Design and justify principles of chemotherapy-induced symptom management
- 3. Apply chemotherapy-induced symptom management axioms