**Mission**

The mission of the Head and Neck Cancer Program at the University of Colorado Cancer Center is to provide the highest quality multidisciplinary care to patients, while conducting innovative research and educational programs to improve outcomes.

The Head and Neck Cancer program includes:
- Physicians and other health providers from five different disciplines (medical oncology, radiation oncology, surgical oncology, speech rehabilitation and nutrition), all specializing in Head and Neck cancers.
- Multidisciplinary tumor boards, where patients and other cases are discussed by multiple specialists in one place.
- Cutting-edge research trials for patients with all stages of head and neck cancer.
- Tumor banking, basic research and translational research initiatives.
- Educational programs.

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**In the Spotlight**

**Research Funding**
The Head and Neck Program is preparing to submit a Specialized Program or Research Excellence grant application, which is the largest (and very prestigious) grant for cancer research.

**Philanthropy**
4th Annual Naren A. Vora Memorail Golf Tournament will be held June 11, 2011, at the Racoon Golf Course. This is a continuing commitment from Rahool and Kuntal Vora in memory of their father, Naren Vora to support our Research Program.

**Clinical Trials**
An exciting new clinical trial will explore the combination of Cetuximab and the Hedgehog Inhibitor IPI-926 in recurrent Head and Neck Cancer: we have generated evidence showing that this combination exerts an anti-Cancer Stem Cell effect.

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**Head and Neck Cancer Program Clinics**

**Medical Oncology**
Chemotherapy, both standard and investigational, for HNC cancers.

**Faculty:**
Antonio Jimeno, M.D., Ph.D.
Madeleine Kane, M.D., Ph.D.

**Referrals:** 720-848-0300
(Christine Miller and Sarabertha Lenz)

**Clinical Trial Contact:**
Ryan Helber 720-848-0736 or Ryan.Helber@ucdenver.edu; or see individual trials for contact information.

**Radiation Oncology**
Radiation therapy, both standard (including intensity modulated radiation therapy) and investigational, for HNC cancers.

**Faculty:**
David Raben, M.D.
Changhu Chen, M.D.

**Referrals:** 720-848-0150 or fax to 720-848-0112

**Clinical Trial Contact:**
Robyn Swing 720-848-0607 or Robyn.Swing@ucdenver.edu

**ENT Surgical Oncology**
Operative approaches, both curative and palliative, in Head and Neck cancers.

**Faculty:**
John Song, M.D.
Julie Goddard, M.D.

**Referrals:** 720-848-2848

**Clinical Trial Contact:**
Ryan Helber 720-848-0736 or Ryan.Helber@ucdenver.edu
Head and Neck Cancer Clinical Trials

General Eligibility Criteria:
Biopsy-proven cancer. No chemotherapy or therapeutic radiotherapy 2-4 weeks prior to starting on study. Performance Status < 2 with life expectancy of > 12 weeks and adequate organ function. Some studies require PS < 1. No active brain metastasis (must have completed local therapy and be off steroids, anticonvulsants). 18 years or older, unless otherwise specified.

Squamous Head and Neck Cancer

10-0065
Title: A Phase II, Open-Label, 1:1 Randomized, Controlled Trial Exploring the Efficacy of EMD 1201081 in Combination with Cetuximab in Second-Line Cetuximab-Naïve Subjects with Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck.
The purpose of this study is to determine the efficacy of adding the immune mediator toll-like receptor agonist EMD 1201081 to the standard treatment of cetuximab which is safe and tolerable. The study will compare cetuximab alone with cetuximab plus EMD 1201081, and patients that have progression in the cetuximab arm are allowed to cross over and receive the investigational agent that promotes an immune response against cancer cells, which may make cetuximab more effective.

08-0552
Title: Head and Neck Squamous Cell Cancer Tissue Collection for Animal Xenograft Studies.
The purpose of this study is to collect tissue from patients undergoing standard of care surgical resection of a HNSCC. HNSCC tissue samples will be obtained from consenting patients at the University of Colorado Hospital and only tumor and normal tissue not required for histopathological analysis will be collected. Given the paucity of cell lines for some of the more rare locations in HNSCC, the need for xenografts is especially acute.

10-0206
Title: Comparison of biomarker modulation by inhibition of EGFR and/or src family kinases using erlotinib and dasatinib in head and neck cancers.
Patients are randomized preoperatively to short administration of erlotinib, dasatinib, the combination of both, or placebo. The central hypothesis to be tested in this study is that dual blockade of EGFR and Src, individually and in combination, will modulate expression of specific proteins compared to inhibition of either kinase alone in head and neck and lung cancers. To determine if the biomarkers are tumor-specific, skin biopsies will also be performed. The primary scientific objective is to determine the modulation of biomarkers by EGFR and/or Src targeting in head and neck and lung cancers. The secondary objective is to determine if biomarker modulation is correlated with reduction of tumor volume and/or evidence of histologic response in the tumor (e.g., decreased proliferation and/or decreased apoptosis).

10-0095
Title: RTOG 0920A Phase III Study of Postoperative Radiation Therapy (IMRT) +/- Cetuximab for Locally-Advanced Resected Head and Neck Cancer.
The overall goal of this study is to test whether the addition of cetuximab to radiation therapy will improve overall survival (OS) in postoperative patients with intermediate risk following surgery.

07-0633
Title: RTOG 0514 Establishment of Head and Neck Cancer Tissue/Specimen Bank.
The purpose is to establish a repository to serve as a resource for current and future scientific studies. Eligibility criteria include but are not limited to 18 years or older with head and neck cancer or tissue that is suspected of being cancerous. There are no therapeutic interventions associated with this study.

11-0109
Title: A Pilot Study of Cetuximab and the Hedgehog Inhibitor IPI-926 in Recurrent Head and Neck Cancer: a Rational anti-Cancer Stem Cell Combination.
The purpose of this study is to determine the dose-limiting toxicities and the recommended dose for phase II evaluation of the combination of IPI-926 and cetuximab in patients with advanced head and neck cancer. The secondary objective is to evaluate the clinical activity of the combination of IPI-926 and cetuximab in patients with advanced head and neck cancer and to characterize the pharmacodynamic effects of cetuximab alone and of the combination of IPI-926 and cetuximab in tumor tissue, in terms of cancer stem cell (CSC) subpopulation distribution, epithelial to mesenchymal transition (EMT) markers, and hedgehog pathway expression and signaling.
10-1479

Title: A Phase I/II Study of PX-866 and Cetuximab.
In the Phase I setting the purpose of this study is to determine the maximum tolerated dose (MTD) or recommended Phase II dose (RD) of PX-866 to be administered orally once per day in combination with cetuximab in patients with incurable metastatic colorectal carcinoma (CRC) or incurable progressive, recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN). The secondary objectives of this study in the phase I setting are to evaluate the preliminary antitumor activity of PX-866 administered in combination cetuximab. In the Phase II setting the primary objective of the study is to evaluate the antitumor effects of PX-866 administered in combination with cetuximab versus cetuximab alone in patients with incurable CRC or incurable progressive, recurrent or metastatic SCCHN. In the phase II setting prior cetuximab treatment is not allowed.

11-XXXX

Title: A Phase I Dose Escalation Study to Investigate the Safety and Pharmacokinetics of Intravenous CUDC-101 with Concurrent Cisplatin and Radiation Therapy in Subjects with Locally Advanced Human Papillomavirus Negative Head and Neck Cancer
The primary purpose of this study is to establish the safety, tolerability and maximum tolerated dose (MTD) of CUDC-101 when administered in combination with concurrent cisplatin and radiation in subjects with locally advanced human papillomavirus (HPV) negative head and neck cancers. The secondary objective of this study is to evaluate the efficacy of CUDC-101 in combination with cisplatin and radiation therapy in subjects with locally advanced HPV.

Thyroid Cancer

11-0042

Title: A Phase II Study of GW786034 (Pazopanib) in Advanced Thyroid Cancer
The purpose of this study is to establish the safety and efficacy of GW786034 as a therapeutic in patients afflicted with differentiated and medullary thyroid cancers. GW786034 is a VEGF inhibitor. Patients will take 800 mg daily of GW786034 until unacceptable toxicity, disease progression, patient refusal or at the physician's discretion.

Phase I

10-0961

Title: A Phase I/II Study of PX-866 and Docetaxel.
In the Phase I setting the purpose of this study is to determine the maximum tolerated dose (MTD) or recommended Phase II dose (RD) of PX-866 to be administered orally once per day in combination with docetaxel in incurable patients with diseases where docetaxel is indicated, like head and neck cancer. The secondary objectives of this study in the phase I setting are to evaluate the preliminary antitumor activity of PX-866 administered in combination cetuximab. A Phase 2 study specifically in patients with incurable progressive, recurrent or metastatic squamous cell carcinoma of the head and neck (SCCHN) will be launched in the summer of 2011. Prior docetaxel treatment is not allowed.

09-0065

Title: A Phase I, Multiple-Dose Escalation Study of the Safety and Tolerability of REGN421 in Patients with Advanced Solid Malignancies.
Clinical trial of investigational drug REGN421 (a notch inhibitor) given intravenously. Eligible patients will receive both study drugs as there is no placebo. Eligibility: Patients with recurrent or metastatic cancer.
**Faculty and Research Groups**

**Medical Oncology**

**Antonio Jimeno, MD, PhD**  
(Associate Professor, Director of the Developmental Therapeutics/Pharmacodynamic Laboratory; Director of Head and Neck Cancer Medical Oncology Program) obtained his MD from the University of Valladolid Spain, trained in Madrid and Johns Hopkins University in Medical Oncology and Drug Development. His clinical interest is squamous cell cancer of the head and neck and Phase 1 trials, and his research interest is cancer stem cells and novel therapeutic approaches in head and neck cancer.  
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**Madeleine Kane, MD, PhD**  
(Professor; Director, Clinical Investigations Core) got her MD from the University of Miami and her PhD in Biochemistry from the University of Maryland. She joined the UCCC faculty in 1985 and specializes in Thyroid and Head and Neck Cancers. Dr. Kane serves as the Director of the Clinical Investigations Core at UCCC.  
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**David Raben, MD**  
(Professor) received his medical degree from The Bowman Gray School of Medicine, Wake Forest University, Winston Salem, North Carolina, and completed his residency in Radiation Oncology at Johns Hopkins University, Baltimore, Maryland. Dr. Raben is internationally known and has established himself in the area of translational research combining radiation with biologic agents that alter the cancer cell growth cycle to enhance the effectiveness of radiation therapy for head and neck cancer. He serves on various local, national and international committees including the head and neck Steering Committee of the Radiation Therapy Oncology Group.  
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**Radiation Oncology**

**Changhu Chen, MD**  
(Associate Professor) is a radiation oncologist specialized in head and neck cancer radiation therapy. His clinical focus is utilizing Intensity-Modulated Radiation Therapy (IMRT) technique to maximize the chance of cure and minimize side effects in patients with a head and neck cancer. His research interest is on combining chemoradiation with biologic targeting agents for patients with a newly diagnosed head and neck cancer, and re-irradiation for patients who recurred after prior radiation therapy.  
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**Endocrinology**

**Joshua Klopper, MD**  
(Assistant Professor of Medicine) obtained his MD from Emory University School of Medicine in Atlanta, GA in 1999. He relocated to Colorado in 1999 where he completed his internship and residency in internal medicine at the University of Colorado Denver in 2002. Dr. Klopper then did a postdoctoral research fellowship in the Endocrinology Division from 2002-2003 prior to starting his endocrinology fellowship at UCD which he completed in June 2006. Dr. Klopper's research interests are in the treatment of poorly differentiated thyroid cancer by the investigation of molecular targets in the nuclear hormone receptor superfamily. Specifically he is investigating the activation of retinoid, PPARγ and Vitamin D receptors to inhibit cell growth and potentially induce redifferentiation in aggressive thyroid cancers.  
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**Surgical Oncology**

**John Song, MD**  
(Associate Professor) Department of Otolaryngology at the University of Colorado Denver School of Medicine and the Director of head and neck oncologic surgery at the University of Colorado Hospital. He also serves as chief of otolaryngology at the Denver VA Hospital. Dr. Song is a board-certified otolaryngologist and he specializes in head and neck, skull base, thyroid and parathyroid surgery, swallowing disorders, and rehabilitation after head and neck cancer. He received his medical degree from New York University School of Medicine, completed his residency at University of California Los Angeles Medical Center, and completed a fellowship in head and neck surgery and skull base surgery at the University of Pittsburgh Medical Center. His research interests include targeted therapies in head and neck cancer.  
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Bryan R. Haugen, MD  
(Professor of Medicine and Pathology at the University of Colorado Denver) He is Chief of the division of Endocrinology, Metabolism & Diabetes and Director of the Thyroid Tumor Program which monitors and manages more than 2000 patients with thyroid cancer. He currently holds the Marry Rossick Kern and Jerome H Kern Chair in Endocrine Neoplasms Research. Dr Haugen received is BA degree in Chemistry from Saint Olaf College and medical degree from the Mayo Medical School in 1987. Internship, medical residency and endocrine fellowship were completed at the University of Colorado Health Sciences Center. Dr Haugen is a Fellow in the American College of Physicians, and member of the American Thyroid Association, the Endocrine Society, the American Association of Clinical Endocrinologists and the American Society for Biochemistry and Molecular Biology. His current clinical interests include thyroid neoplasms, advanced thyroid cancer, thyroid dysfunction and other endocrine tumors (parathyroid, adrenal, carcinoid). Dr Haugen's research interests include molecular studies of thyroid neoplasm diagnosis and pathophysiology as well as the study of molecular therapeutic targets. Specific areas of research include nuclear hormone receptors (RXR, TR, PPAR) and kinase signaling pathways as therapeutic targets in thyroid cancer, as well as proteomic approaches to molecular markers in thyroid neoplasms. bryan.haugen@ucdenver.edu

Clinical Trial Coordination Team

Medical Oncology

Team Leader: Ryan Helber, Ph: 720-848-0736, Ryan.Helber@ucdenver.edu  
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Radiation Oncology

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Thyroid Medical Oncology

CRC: Jessica McDonald, Ph: 720-848-0630, Jessica.McDonald@ucdenver.edu