Welcome to the Winter 2017 issue of the Stanford Cancer Institute Clinical Research Newsletter. This quarterly publication is designed to inform our colleagues in the medical community, and especially physicians who are considering treatment options for their patients with cancer, about current clinical trials available at the Stanford Cancer Institute, a National Cancer Institute designated Comprehensive Cancer Center. Many of these trials provide access to novel therapies including new “targeted” agents, often not available in the community.

As leaders of the Stanford Head and Neck Cancer Care Program, we are delighted to introduce this edition of the newsletter, as it focuses on our Neuro-Oncology, Thoracic Oncology, and Developmental Therapeutics programs. Each of these programs offers cutting-edge clinical trials for patients with tumors that can be challenging to treat with current routine care. Weekly multidisciplinary tumor boards are available for each program. The articles on each program will introduce you to our programs, faculty researchers, and currently available clinical trials.

The Thoracic Oncology Program features a wide number of clinical trials for both early- and advanced-stage lung cancer, including clinical trials focused on individualized treatment based on the molecular characteristics of tumors, overcoming drug resistance, and employing immunotherapeutics. The program now offers interventional pulmonology (IP) modalities, including navigational bronchoscopy for biopsy of lung nodules. IP is an emerging field that uses minimally invasive diagnostic and staging techniques for potential lung cancers.

The Head and Neck Oncology Program’s research studies and protocols include treatment of intermediate and advanced disease as well as hypoxia imaging. A breadth of treatment options are available including minimally invasive surgery, robotic surgery, stereotactic radiosurgery such as CyberKnife®, microvascular reconstruction, intraoperative radiation therapy (IORT), along with new chemotherapy trials.

The Stanford Cancer Institute Neuro-Oncology Program offers Phase I through III trials as well as multidisciplinary, collaborative evaluation and treatment of patients with tumors of the nervous system. This includes, but is not restricted to; brain metastases, leptomeningeal cancer, glioblastomas and less aggressive gliomas, benign brain and spinal tumors, and base of brain neoplasms including pituitary disorders. Clinical trials have focused on vaccine therapy, antibody therapy, novel chemotherapy agents, radiation sensitizers, novel radiation therapy, and radiosurgery techniques.

The Developmental Therapeutics Program conducts pharmacokinetic and pharmacodynamic driven first-in-human trials tailored to make early, informed decisions regarding the suitability of novel molecular agents for further clinical investigation.

We hope that you will consider referring your patients to Stanford for one of our many clinical trials.

Chris Holsinger, MD
Professor of Otolaryngology – Head and Neck Surgery
Director, Head and Neck Cancer Care Program

Quynh Le, MD, FACR, FASTRO
Katherine Dexter McCormick and Stanley McCormick Memorial Professor and Professor, by courtesy, of Otolaryngology – Head and Neck Surgery

Dimitri Colevas, MD
Professor of Medicine (Oncology) and, by courtesy, of Otolaryngology – Head and Neck Surgery
The Stanford Head & Neck Oncology Program (HNOP) provides leading-edge multi-disciplinary, collaborative and integrated treatment and evaluation for patients with head and neck cancer. World-renowned specialists in each discipline (surgery, radiation oncology, medical oncology, and speech and swallowing rehabilitation) lead and participate in both national and Stanford-initiated clinical trials. Physician and surgeon-scientists at Stanford bring the latest discoveries in basic and translational science to the bedside and clinic.

HNOP is a pioneer of major scientific breakthroughs that help patients through:

- Organ preservation approaches to head and neck cancer, using minimally invasive surgery and state-of-the-art radiation.

- New drugs and immunotherapy for head and neck squamous cell carcinoma (HNSCC) and innovative uses of existing drugs to HNSCC.

- Advanced radiation therapy techniques that limit toxicity and improve outcomes.

- A cutting edge method to synthesize novel tracers for hypoxia imaging.

- Robotic head and neck surgery, using transoral minimally invasive techniques to preserve speech and swallowing function.

- Bench to bedside approaches such as a Phase 1 dichloroacetate (DCA) study on modulating tumor cell metabolic activity.

- Pioneering laboratory research that demonstrated the existence of “cancer stem cells” in HNSCC that correlated with worse prognosis.

- Identification of adult salivary gland stem cells and their governing pathways that can be manipulated for preservation and/or restoration of salivary function from radiation damage.

- Collaboration with the Stanford Clinical Laboratory to harmonize biomarker measurement for biomarker driven trials to test treatment intensification or de-intensification such as the use of circulating EBV DNA in nasopharyngeal carcinoma.

- Genetic sequencing to identify a key driver mutation in ameloblastoma, leading to a clinical trial targeting BRAF in these tumors.
• Developing novel imaging approaches for intraoperative assessment of tumor margins to maximize tumor resection and organ preservation.

• Collaboration with basic scientists to define the best combination of immunotherapy in head and neck cancer.

FEATURES AT THE HNOP INCLUDE

• Close working relationships with:
  — Neurosurgery, Interventional Radiology, and Neuroradiology, which are critical for complex open and endonasal endoscopic skull base surgery.
  — Endocrinology in the treatment of thyroid cancer.
  — Dermatology and Cutaneous Oncology in the treatment of advanced skin cancers, including melanoma, basal cell carcinoma, and cutaneous squamous cell carcinoma.

• Leadership in the head and neck disease site committee of the NRG Oncology Group to develop new nationwide clinical trials in head and neck cancer.

• Biomarker studies to identify novel circulating biomarkers for prognostication and post-treatment surveillance in head and neck cancer.

• Strong links to the Stanford Developmental Therapeutics Program for testing new agents to treat cancer.

• Provision of a full range of treatment options that include minimally invasive surgery, robotic surgery, stereotactic radiosurgery such as CyberKnife, microvascular reconstruction, intraoperative radiation therapy (IORT), and new chemotherapy trials.

• Innovative research by physicians now at Stanford that demonstrates the utility of the Mobetron® for intraoperative radiation therapy.

CURRENTLY OPEN SELECTED TRIALS

Minimally Invasive Surgery (Transoral Robotic Surgery)

• Randomized Trial of Transoral Surgery Followed by Low-dose or Standard-dose IMRT in Resectable p16+ Oropharynx Cancer (ECOG3311)

This national clinical trial evaluates whether or not minimally invasive surgery can reduce the intensity of treatment for HPV-associated throat cancer.

Chemotherapy, Radiation Therapy, and Chemoradiation

• A Phase 2 Study of Sequential and Concurrent Chemoradiation for Patients with Advanced Nasopharyngeal Carcinoma (NPC) (ENT0025)

This protocol is for patients with high risk locally advanced NPC or metastatic disease at presentation who may benefit from an initial approach of chemotherapy followed by chemoradiation.

  PI: Dimitrios Colevas, MD

• A Randomized Phase 2 Trial for Patients with p16 Positive, Non-Smoking Associated, Locoregionally Advanced Oropharyngeal Cancer (NRGHN002)

This trial represents an innovative patient-specific approach to overall treatment reduction, by either using accelerated radiation techniques or lower chemotherapy doses for patients with very good prognosis HPV related cancer.

  PI: Quynh Le, MD

• A Randomized Study of Individualized Treatment for Nasopharyngeal Carcinoma Based on Epstein Barr Virus (EBV) Deoxyribonucleic Acid (DNA) (NRGHN001)

This trial, the largest ever conducted in NPC, will both explore whether a patient specific biomarker can help select patients who will not benefit from adjuvant chemotherapy and whether an alternative chemotherapy will benefit patients at highest risk of relapse. Dr. Quynh Le is the...
translational science co-chair and Dr. Dimitrios Colevas is the medical oncology co-chair of this collaborative international trial.

**PI:** Dimitrios Colevas, MD

### Advanced Disease

- **A Randomized Study of Topical Dilute Hypochlorite (Modified Dakin’s Solution) Treatment for the Prevention of Radiation Dermatitis in Head and Neck Cancer (ENT0042)**

  **PI:** Wendy Hara, MD

- **A Randomized Phase 2 Trial of Neoadjuvant and Adjuvant Therapy with the IRX-2 Regimen in Patients with Newly Diagnosed Stage III or IVA Squamous Cell Carcinoma of the Oral Cavity (ENT0045)**

  **PI:** Michael J. Kaplan, MD

- **Phase Ib/II Trial of IPH2201 and Cetuximab in Patients with HPV (+) and HPV (-) Recurrent or Metastatic Squamous Cell Carcinoma of the Head and Neck (ENT0052)**

  **PI:** Dimitrios Colevas, MD

### Diagnostic

- **NBI to Characterize Patterns of Vascular Supply within Lymphoepithelial Mucosa in Oropharyngeal Cancer (ENT0044)**

  The purpose of this study is to characterize the blood supply at the base of the tongue and within the tonsil region. We hypothesize that high-resolution Narrow Band Imaging (NBI) will improve the diagnosis of oropharyngeal carcinoma (OPC). The goal is to provide better tumor assessment, thus providing better preoperative expectations to patients with OPC or tumor extent prior to radiation therapy.

  **PI:** Chris Holsinger, MD

- **Clinical Validation of ThyroidPrint: A Gene Expression Signature for Diagnosis of Indeterminate Thyroid Nodules (END0019)**

  This study is a prospective evaluation of a novel thyroid molecular diagnostic assay.

  **PI:** Chris Holsinger, MD

- **Phase I, Open-label Study Evaluating the Safety and Pharmacokinetics of Escalating Doses of Cetuximab-IRDye800 as an Optical Imaging Agent to Detect Cancer During Surgical Procedures (ENT0049)**

  The investigators are evaluating whether or not the use of the study drug along with the special camera will better identify the cancer while patients are in the operating room.

  **PI:** Eben Rosenthal, MD; Dimitrios Colevas, MD

- **Phase I, Open-label Study Evaluating the Safety and Pharmacokinetics of Escalating Doses of Panitumumab-IRDye800 as an Optical Imaging Agent to Detect Head and Neck Cancer During Surgical Procedures (ENT0050)**

  The purpose of this study is to evaluate the safety of escalating dose levels of conjugated panitumumab-IRDye800 in subjects with head and neck squamous cell carcinoma (HNSCC) that undergo surgery with curative intent.

  **PI:** Eben Rosenthal, MD; Dimitrios Colevas, MD

### Observational

- **Human Salivary Gland Disposition of Alda-341 in Patients Undergoing Salivary Gland Surgery (ENT0051)**

  This is a 2-week, open-label, disposition study of Alda-341 (d-limonene) given orally to subjects who have elected to undergo surgery for a recent diagnosis of parotid or submandibular tumors.

  **PI:** Quynh-Thu Le, MD; Davud Sirjani, MD

- **Identification and Characterization of Novel Proteins and Genes in Head and Neck Cancer (ENT0008)**

  Through this study, we hope to learn more about the mechanisms that may contribute to development and progression of head and neck cancer. The long-term goal of this study is to develop new strategies and drugs for the diagnosis and treatment of head and neck cancer.

  **PI:** Quynh-Thu Le, MD

- **highlighted studies are Stanford investigator initiated**
Stanford Cancer Center’s Developmental Therapeutics (DT) Program, led by director Shivaani Kummar, MD, offers Phase 1 and 2 clinical trials designed to evaluate new treatments for cancer. Other faculty participating in this effort include Drs. Heather Wakelee and Joel Neal (lung cancers), A. Dimitrios Colevas (head and neck cancers), George Fisher and Pamela Kunz (GI cancers), George Sledge, Suleiman Massarweh, Mark Pegram and Melinda Telli (breast cancers), Sunil Reddy (melanoma), Ranjana Advani (lymphomas), and Branimir I. Sikic.

DT Program Director Dr. Kummar is a Professor of Medicine in the Stanford Division of Oncology and former leader of the National Cancer Institute’s Developmental Therapeutics Clinic and Early Clinical Trials Development Program. Her research interests focus on developing novel therapies for cancer. Dr. Kummar specializes in conducting pharmacokinetic and pharmacodynamic driven first-in-human trials tailored to make early informed decisions regarding the suitability of novel molecular agents for further clinical investigation. Her studies integrate genomics and laboratory correlates into early phase trials, establishing the proof of mechanism and proof of concept in these trials. Dr. Kummar has published numerous articles in medical journals and serves on a number of national and international scientific committees.

As a translational clinical studies program, Developmental Therapeutics brings together outstanding physicians with internationally regarded scientists to develop novel therapies and diagnostic modalities that utilize cutting-edge science and technologies. The program offers the opportunity for patients to enroll in clinical trials evaluating novel anticancer therapies. The overall goal of the program is to facilitate the development of promising, new treatments for cancer while ensuring the highest standards of patient safety.

Following is a sampling of currently available Phase 1 and 2 studies.

### FEATURED PHASE 1 AND 2 STUDIES

#### Multiple Solid Tumor Sites

- A Phase 1b/2, Open-label, Multicenter, Dose-escalation Trial of Intratumoral Injections of SD-101 in Combination with Pembrolizumab in Patients with Metastatic Melanoma (METS0003)

- A Phase 1/2 Dose Escalation and Cohort Expansion Study of the Safety and Tolerability of Urelumab Administered in Combination with Nivolumab in Advanced/Metastatic Solid Tumors and B Cell Non-Hodgkins Lymphoma (VAR0126)

- Phase 1/2, First-in-Human, Dose-Escalation Study of X-396 in Patients with Advanced Solid Tumors and Expansion Phase in Patients with ALK+ Non-Small Cell Lung Cancer (VAR0098)

- A First-in-Human Phase 1, Dose Escalation, Safety and Pharmacokinetic Study of PF-06647020 in Adult Patients with Advanced Solid Tumors (VAR0130)

- A Phase 2 Basket Study of the Oral TRK Inhibitor LOXO-101 in Subjects with NTRK Fusion-Positive Tumors (VAR0136)

- A Phase 1/1b, Open-Label, Multicenter, Repeat-Dose, Dose-Selection Study of CPI-444 as Single Agent and in Combination with Atezolizumab in Patients with Selected Incurable Cancers (VAR0141)

- NCI 9938: Phase 1 Clinical Trial of VX-970 in Combination with the Topoisomerase I Inhibitor Irinotecan in Patients with Advanced Solid Tumors (VAR0144)

- Phase 1/2 Multicenter Trial of ICOS Agonist Monoclonal Antibody (mAb) JTX-2011 Alone or in Combination With Nivolumab in Adult Subjects with Advanced Refractory Solid Tumor Malignancies (VAR0143)

- An open-label Phase I dose-escalation study to evaluate the safety, tolerability, maximum tolerated dose, pharmacokinetics, and pharmacodynamics of the anti-C4.4a antibody drug conjugate BAY 1129980 in subjects with advanced solid tumors known to express C4.4a (VAR0146)
The Stanford Thoracic Oncology Program features a variety of clinical trials incorporating novel treatments for both early and advanced stage non-small cell lung cancer and for other thoracic malignancies. In addition, the group provides high quality standard-of-care surgical, oncological, and radiotherapeutic approaches for lung cancer patients.

**THORACIC ONCOLOGY PROGRAM UPDATES/HIGHLIGHTS**

- Leah Backhus, MD, thoracic surgeon, has been appointed Associate Professor of Cardiothoracic Surgery. She comes to Stanford from the University of Washington and has particular expertise in VATS (thoracoscopic) lobectomy for lung cancer and surgical therapy for malignant mesothelioma.

- Joseph Shrager, MD, is the National Principal Investigator of a new, multicenter, international randomized study testing a modified type of “PleurX” catheter vs. the original device, to treat malignant pleural effusions. The study hypothesizes that the new catheter will achieve a more rapid pleurodesis than the older catheter, and that it likely will become the new standard of care.

- We continue to see more tumors on the “adenocarcinoma-in situ” spectrum more likely than any other center in the United States, due partly to our large population with Asian ancestry. In addition, the Program has published three articles and is in the process of carrying out several other research projects that seek to establish the standard of care approach to surgical therapy for these types of tumors.

- The Stanford Center for Minimally Invasive Thoracic Surgery (SMITS), co-directed by Drs. Mark Berry and Joseph Shrager, continues to push the envelope, carrying out an increasing number of our anatomic lung resections through minimally invasive methods. This includes initiating a program in robotic lobectomy. This Center solidifies Stanford’s leadership in minimally invasive approaches to all thoracic problems.

- Our group remains in the top quartile in all outcome measures in the Society of Thoracic Surgeon’s national database — a group that includes only the top institutions doing thoracic surgery in the country. In the most recent data collection covering three years, Stanford had not a single death after more than 100 esophagectomies — an operation that nationally has an approximately 5 percent death rate.
Our interventional pulmonology (IP) program continues to expand, with new faculty, delivering expertise in a number of fully endoscopic approaches to lung cancer. Among the modalities offered is navigational bronchoscopy for biopsy of lung nodules, endobronchial ultrasound with needle biopsy of mediastinal and hilar lymph nodes, bronchoscopic approaches such as cryotherapy and laser therapy for endobronchial disease, and endobronchial valves for the treatment of emphysema. Stanford’s lead interventional pulmonologist is Arthur Sung, MD, Clinical Associate Professor, Medicine – Pulmonary & Critical Care Medicine. The program has hired two additional IP experts, Drs. Meghan Ramsey and Harmeet Bedi.

INNOVATIVE RESEARCH INCLUDES

- Molecular Profiling of Lung Cancer: Stanford Cancer Institute investigators use minute quantities of tumor tissue to tailor personalized drug therapy against certain tumors, particularly non-small cell tumors with oncogenic driver mutations in EGFR, ALK, ROS1, BRAF, HER2, KRAS, MET and multiple others.

- Cancer Immunotherapy: Stanford is at the forefront of discoveries in cancer immunotherapy, yielding exciting prospects of re-training the immune system to fight cancer. Stanford investigators were involved in research with pembrolizumab, nivolumab and atezolizumab, all now approved to treat metastatic lung cancer. Trials ongoing and in development are 1) exploring novel strategies for knowing which patients are most likely to benefit from this class of drugs and 2) looking at novel combination regimens.

- Imaging: Stanford has advanced imaging capabilities, including radiation planning with PET/CT scans and clinical trials with novel PET tracers. Stanford has an established CT-screening program for patients at high risk for developing lung cancer.

CURRENT RESEARCH FEATURES

Early stage therapy for patients with EGFR and ALK positive NSCLC

- Adjuvant therapy options following surgery (Adjuvant afatinib and the ALCHEMIST trial with adjuvant erlotinib or crizotinib)
- The RTOG 1306 trial, nationally chaired by Dr. Bill Loo, using neoadjuvant erlotinib or crizotinib prior to chemotherapy and radiation for stage III NSCLC.

Adjuvant immunotherapy for patients with resected early stage NSCLC

- Adjuvant therapy following surgery for those without EGFR mutated or ALK+ NSCLC include nivolumab on the ALCHEMIST trial or the recently opened IMPOWER010 trial, nationally chaired by Dr. Heather Wakelee, looking at the newly approved PD-L1 agent atezolizumab after chemotherapy for patients who have undergone surgery.

Advanced stage lung cancer clinical trials focused on individualized treatment based on the molecular characteristics of tumors and overcoming drug resistance

- Patients with acquired resistance to the EGFR inhibitor erlotinib or afatinib may consider the avitinib clinical trial to overcome resistance.
- Patients with acquired resistance to the ALK inhibitor crizotinib and/or alectinib may also have a clinical trial option with the agent X-396.
- Depending on line of therapy and tumor histology, patients may consider immunotherapeutic strategies to target advanced non-small cell lung cancer with anti-PDL1 and anti-PD1 drugs alone or in combination with other immune modifying agents.
Thoracic Oncology Program, continued

Studies to identify tumor cells or tumor DNA circulating in the blood
In collaboration with basic science colleagues, members of the Thoracic Oncology Program are participating in innovative studies to identify circulating tumor factors in the blood. In the future, the ability to identify circulating tumor cells and DNA may:

- Reduce the need for invasive biopsies for patients with the disease, and
- Allow for cutting edge molecular testing, bringing Stanford closer to providing truly personalized treatments for lung cancer.

Phase II study of using SABR (stereotactic ablative radiation) as a therapy for end-stage emphysema
Many patients do not qualify for surgical lung volume reduction surgery (LVRS). So, based on encouraging preliminary retrospective data from patients who have emphysema and received SABR for lung cancer, we have initiated a trial intentionally treating emphysema with SABR.

CLINICAL OUTCOMES RESEARCH
Stanford thoracic surgeons, radiation oncologists and oncologists are continuously reviewing their results with current and past patients to gather information that will help future patients. One such study, for example, has shown that Stanford’s novel approach to patients with multifocal adenocarcinoma in situ (formerly termed bronchioloalveolar carcinoma, or “BAC”) — consisting of surgical resection of the dominant tumor and close monitoring of other smaller tumors — appears to be highly successful. Other work in collaboration with the Cancer Prevention Institute of California (CPIC) is focused on trying to identify why patients who have never smoked develop lung cancer.

ADVANCED TECHNIQUES FOR RESECTABLE LUNG CANCER
When a lung cancer is resectable, the thoracic surgery team offers advanced and minimally invasive techniques that are available in only a few centers in the United States. These methods allow resection of the smallest amount of lung tissue that will provide the optimal chance of cure, with the least risk. They include:

- VATS (thoracoscopic) lobectomy (and VATS segmentectomy for small Stage I tumors)
- Sleeve resections to avoid pneumonectomy for centrally located tumors
- Anterior, smaller-incision-based approaches to Pancoast tumors
- Endobronchial Ultrasound for biopsy of hilar and mediastinal lymph nodes
- Stereotactic Ablative Radiotherapy (SABR) for stage I lung cancers in surgically ineligible or high-risk surgical patients

All patients who have a question about whether surgery or radiation therapy would be best for them are encouraged to be seen by the multidisciplinary tumor board, which meets weekly.

CURRENTLY OPEN STUDIES INCLUDE
Stage I-III NSCLC

- Phase 2 Trial of Individualized Lung Tumor Stereotactic Ablative Radiotherapy (iSABR) (LUN0048)
- EF5-PET for Imaging of Tumor Hypoxia in Early Stage Lung Cancer Treated with SABR
- A Randomized Phase 2 Study Comparing Concise (3 months) versus Prolonged (2 years) Afatinib as Adjuvant Therapy for Patients with Resected Stage I-III NSCLC with EGFR Mutation (LUN0058)
- Fresolimumab and Stereotactic Ablative Radiotherapy in Early Stage Non-Small Cell Lung Cancer (LUN0071)
- Phase 1/2, First-in-Human, Dose-Escalation Study of X-396 in Patients with Advanced Solid Tumors and Expansion Phase in Patients with ALK+ Non-Small Cell Lung Cancer (VAR0098)
• Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients with Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant Non-small Cell Lung Cancer (NSCLC) (ECOGA081105)

• A Phase 3, Open-Label, Randomized Study to Investigate the Efficacy and Safety of Atezolizumab (Anti-PD-L1 Antibody) Compared with Best Supportive Care Following Adjuvant Cisplatin Based Chemotherapy in PD-L1-Selected Patients with Completely Resected Stage IB-IIIA Non-Small Cell Lung Cancer - GO29527 (LUN0076)

• Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trial (ALCHEMIST) (ECOGA151216)

• Randomized Phase 2 Trial of Individualized Adaptive Radiotherapy Using During-Treatment FDG-PET/CT and Modern Technology in Locally Advanced Non-Small Cell Lung Cancer (NSCLC) (RTOG1106)

• A Randomized Phase 2 Study of Individualized Combined Modality Therapy for Stage III Non-Small Cell Lung Cancer (NSCLC) (RTOG1306)

Stage III-IV NSCLC

• A Biomarker-Driven Master Protocol for Previously Treated Squamous Cell Lung Cancer (Lung-MAP) (ECOGS1400)

• A Multi-Center Study of the Bruton’s Tyrosine Kinase (BTK) Inhibitor, Ibrutinib, in Combination with Durvalumab (MEDI4736), in Subjects with Relapsed or Refractory Solid Tumors (VAR0127)

• A Phase 2, Multi-Center, Open-Label, Five-Arm Study to Evaluate the Efficacy and Safety of Oral Ceritinib Treatment for Patients with ALK-Positive Non-Small Cell Lung Cancer (NSCLC) Metastatic to the Brain and/or to Leptomeninges (METS0002)

• A Pivotal Multi-Center, Randomized, Controlled, Single-Blinded Study Comparing the Silver Nitrate-Coated Indwelling Pleural Catheter (SNCIPC) to the Uncoated PleurX Pleural Catheter for the Management of Symptomatic, Recurrent, Malignant Pleural Effusions (LUN0073)

• A Phase 1/2, Multicenter, Open-label Safety, Pharmacokinetic and Preliminary Efficacy Study of Wild-type Sparing EGFR Inhibitor, AC0010MA, in Adult Patients with Previously Treated EGFRmut and Acquired T790M Mutation Non-Small Cell Lung Cancer (NSCLC) (LUN0083)

• A Phase 1/2 Study of the Safety, Pharmacokinetics, and Anti-Tumor Activity of the Oral EGFR/HER2 Inhibitor AP32788 in Non-Small Cell Lung Cancer (LUN0082)

Stage III-IV NSCLC Well Differentiated Carcinoid

• A Phase 3, Prospective, Randomized, Double-Blind, Multi-Center, Study of the Efficacy and Safety of Lanreotide Autogel/ Depot 120 mg Plus vs. Placebo Plus BSC for Tumor Control in Subjects with Well Differentiated, Metastatic and/or Unresectable Typical or Atypical Lung Neuroendocrine Tumors (NET0022)

Small Cell

• Phase 3 Comparison of Thoracic Radiotherapy Regimens in Patients with Limited Small Cell Lung Cancer also Receiving Cisplatin and Etoposide (RTOG0538-CALGB30610)

Emphysema

• Lung Function Improvement After Bronchoscopic Lung Volume Reduction With Pulmonx Endobronchial Valves Used in Treatment of Emphysema – LIBERATE Trial

• Phase 2 Study of Using SABR (stereotactic ablative radiation) as a Therapy for End-stage Emphysema

[highlighted studies are Stanford investigator initiated]
The Stanford Cancer Institute Neuro-Oncology Program runs national and Stanford-originated clinical trials and offers multidisciplinary, collaborative evaluation and treatment of patients with tumors of the nervous system. This includes but is not restricted to brain metastases, leptomeningeal cancer, glioblastomas and less aggressive gliomas, benign brain and spinal tumors, and base of brain neoplasms including pituitary disorders.

The Neuro-Oncology medical team also treats neurological complications of cancer including chemotherapy and radiation complications that affect the nervous system as well as cancer-related immune diseases (paraneoplastic syndromes). The participating faculty includes representatives from the Departments of Neurosurgery, Radiation Oncology, Neurology, Radiology, and Pathology.

**CLINICAL TRIALS HAVE FOCUSED ON**

- vaccine therapy
- antibody therapy
- novel chemotherapy agents
- radiation sensitizers
- novel radiation therapy and radiosurgery techniques

**FEATURES OF THE ADULT NEURO-ONCOLOGY SERVICE INCLUDE**

- Weekly Multidisciplinary Tumor Boards.
- CyberKnife stereotactic radiosurgery.
- Advanced radiation techniques such as Intensity Modulated Radiotherapy (IMRT) and Rapid Arc® Volumetric Modulated Arc Therapy (VMAT).
Adult Neuro-Oncology Program
Multidisciplinary, Collaborative Evaluation and Treatment of Nervous System Tumors

• Expertise in base of brain surgery for tumors such as pituitary adenomas, meningiomas, acoustic neuromas, chordomas, and chondrosarcomas.

• Close working relationships between center members as well as other physicians and services within the Stanford Cancer Institute.

• Strong links to developmental therapeutics scientists within Stanford that facilitate advancement of new treatment strategies.

• Full range of treatment options including minimally invasive surgery, CyberKnife stereotactic radiosurgery, and individualized immunotherapy and chemotherapy based on molecular analysis of tumor in the Tumor Tissue Bank.

• Coordination of patient care for medical, social, and referral needs.

CURRENTLY OPEN STUDIES INCLUDE

• A Comparison of Overall Survival Post-CyberKnife Radiosurgery Treatment of Patients with 1-3 Versus 4 or More Brain Metastases (BRN0022)

• A Phase 1/2 Study of Local Field Irradiation and Temozolomide Followed by Continuous Infusion Plerixafor as an Upfront Therapy for Newly Diagnosed Glioblastoma GBM (BRN0023)

• A Multi-Center Phase 2 Open-Label Study to Evaluate Safety and Efficacy in Subjects with Melanoma Metastatic to the Brain treated with Nivolumab in Combination with Ipilimumab Followed by Nivolumab Monotherapy (BRN0027)

• A Phase 2/3 Randomized, Open-Label Study of Toca 511, a Retroviral Replicating Vector, Combined With Toca FC versus Standard of Care in Subjects Undergoing Planned Resection for Recurrent Glioblastoma or Anaplastic Astrocytoma (BRN0029)

• A Phase 3 Randomized Double-Blind, Controlled Study of ICT-107 with Maintenance Temozolomide (TMZ) in Newly Diagnosed Glioblastoma Following Resection and Concomitant TMZ Chemoradiotherapy (STING (STudy of Immunotherapy in Newly Diagnosed Glioblastoma)) (BRN0030)

• A Phase 1b/2, Multicenter, Open-label Study of ACP-196 in Subjects with Recurrent Glioblastoma Multiforme (GBM) (BRN0031)

• A First-In-Human Study of Repeat Dosing with REGN2810, a Monoclonal, Fully Human Antibody to Programmed Death-1 (PD-1), as Single Therapy and in Combination with Other Anti-Cancer Therapies, In Patients with Advanced Malignancies (BRN0032)

• MR Imaging of Inflammatory Responses in the Central Nervous System with Ferumoxytol-enhanced MRI (BRNCNS0007)

• A Phase 2 Study of Etirinotecan Pegol (NKTR 102) in Patients with Refractory Brain Metastases and Advanced Lung Cancer or Metastatic Breast Cancer (MBC) (LUN0067)

• A Phase 2, Multi-Center, Open-Label, Five-Arm Study to Evaluate the Efficacy and Safety of Oral Ceritinib Treatment for Patients with ALK-Positive Non-Small Cell Lung Cancer (NSCLC) Metastatic to the Brain and/or to Leptomeninges (METS0002)

• Randomized Phase 3 Trial of Memantine and Whole-Brain Radiotherapy with or without Hippocampal Avoidance in Patients with Brain Metastases (NRGCC001)

• Highlighted studies are Stanford investigator initiated
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