

LUNG CANCER

LINK

UW MULTIDISCIPLINARY CANCER TEAM

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In 1971, President Nixon and Congress declared war on cancer with the passage of the National Cancer Act. At that time, lung cancer was the leading cause of cancer death and the overall 5-year survival rate was 12%. 40 years later, lung cancer is still the leading cancer killer and the overall survival rate is only 15%. In addition to the obvious lethality of this disease, patients with lung cancer experience a range of mild to severe symptoms which negatively impact on the quality, and length, of their lives. Dr. Hopwood and colleagues showed that patients with advanced lung cancer experienced an average of 14 and 17 symptoms in NSCLC and SCLC respectively. A study by Dr. Temel published in the New England Journal of Medicine last year demonstrated that early, and integrated, palliative care (PC) improved overall survival for patients in the intervention arm from 8.9 months to 11.6 months ($p = 0.02$). In addition, patients in the early palliative care arm had improved quality of life across multiple measurement tools as well as less depressive symptoms. Patients in the early PC group were also more likely to have a resuscitation preference documented and have their end-of-life wishes followed and received less aggressive care at the end of life.

At the University of Wisconsin Carbone Cancer Center we believe that early palliative care for our lung cancer population improves the quality of their care and their quality of life. We offer outpatient palliative care consultation daily through

a variety of palliative care providers including myself as a part of the multidisciplinary lung cancer clinic. The following model demonstrates the integrative potential for palliative care in lung cancer care.

Most of the treatment early on is directed towards traditional oncologic treatment but the proportion of care which is primarily symptom relieving escalates as the patient progresses through the illness. The goals of early palliative care include quality symptom management, care discussions, end-of-life planning, and smoothing the transitions between traditional oncologic care and hospice and end-of-life.

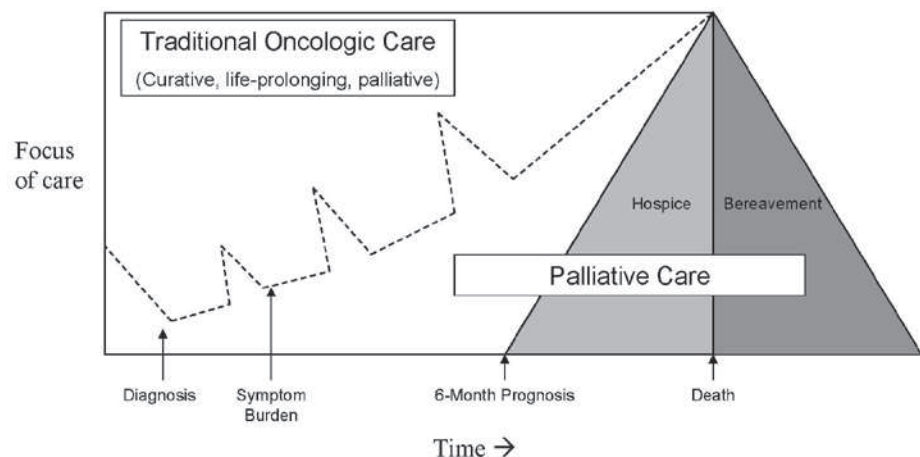
We look forward to working with you in the care of our patients and pushing the frontier of great clinical care through basic science research, clinical and translational research, and clinical improvements including early palliative care.

I invite you to review this newsletter which contains updates and highlights of our ongoing research initiatives.

Sincerely,
Toby Campbell, MD
Palliative Care Fellowship Director



Toby Campbell, MD



OUR FEATURED PROTOCOLS

NSCLC: A Randomized Phase 2 Study of Imetelstat as Maintenance Therapy after Initial Induction Chemotherapy for Advanced Non-small Cell Lung Cancer

Upregulation of telomerase is necessary for most cancer cells to replicate indefinitely. Inhibiting telomerase activity should result in telomere shortening which may cause cancer cell death or inhibit cancer cell's ability to be immortal. Because telomerase is expressed at very low levels, if at all, in most normal cells, toxicity with this approach is better than with cytotoxic chemotherapy. Imetelstat is an oligonucleotide enzyme inhibitor which targets the active site of telomerase. Imetelstat has highly potent telomerase inhibitory activity.

Study Design

This is a multicenter, randomized phase 2 study designed to evaluate the safety and efficacy of Imetelstat (GRN 163L) as maintenance therapy after a response or stable disease to front-line platinum based chemotherapy in non small cell lung cancer. Eligible patients will receive either Imetelstat 9.4mg/kg monotherapy (patients receiving bevacizumab prior to randomization will continue to receive it in combination with Imetelstat) or standard care (observation or bevacizumab for patients already on bevacizumab regimens), given IV over 2 hours on day 1 and 8 of a 21 day cycle until disease progression.

PROTOCOL ELIGIBILITY*

- *Histologically or cytologically confirmed advanced NSCLC.*
- *Have squamous or non-squamous cell histology type.*
- *Have completed 4-6 cycles of platinum based chemotherapy in the front-line setting and achieved at least stable disease. Patients who received bevacizumab as part of their front-line treatment will continue to receive bevacizumab.*
- *Have recovered from prior chemotherapy (ANC > 1500, Hgb >9, Plt > 75K)*
- *Creatinine clearance > 45ml/min or creatinine < 1.5 mg/dl.*
- *Patients need not have measurable disease (e.g. can have had a complete response)*
- *ECOG performance status of 0 or 1.*
- *Treated and stable CNS metastasis is allowed.*

***Select eligibility requirements**

LINK

<http://www.clinicaltrials.gov/ct2/show/study/NCT01137968?term=imetelstat&rank=1#locn>

Phase 3, Randomized, Open-Label Study of the Efficacy and Safety of Crizotinib Versus Pemetrexed/Cisplatin or Pemetrexed/Carboplatin in Previously Untreated Patients with Non-Squamous Carcinoma of the Lung Harboring a Translocation or Inversion Event Involving the Anaplastic Lymphoma Kinase (ALK) Gene Locus

The EML4 (echinoderm microtubule-associated protein-like 4)-ALK (anaplastic lymphoma kinase) fusion-type tyrosine kinase, resulted from a small inversion in the short arm of chromosome 2, is an oncoprotein found in 4 to 5% of NSCLC. Through constitutive dimerization and activation, EML4-ALK plays an essential role in lung cancer development.

Crizotinib is a potent small molecule inhibitor of ALK and its fusion proteins (EML4-ALK), as well as c-Met/ Hepatocyte Growth Factor Receptor. A phase I study in which 82 patients with advanced ALK-positive NSCLC received single agent crizotinib demonstrated a promising anti-tumor activity of this agent. The overall response rate was 57% and disease control rate (CR/PR and SD) was 90%. The estimated probability of 6-month progression free survival was 72%, with no median survival reached at the time of report.

Study Design

This is a global, multicenter, randomized phase 3 study designed to demonstrate the superiority of crizotinib over first-line chemotherapy of pemetrexed/cisplatin or pemetrexed/carboplatin in prolonging PFS in patients with advanced non-squamous NSCLC whose tumors harbor a translocation or inversion in ALK gene locus. A total of 334 eligible patients will be randomized 1:1 to either Arm A: crizotinib 250 mg PO BID, until progression; or Arm B: pemetrexed 500 mg/m² in combination with cisplatin 75 mg/m² or carboplatin AUC 5 or 6, every 3 week x 6 cycles. Arm B patients whose disease progresses may be allowed to cross-over to receive crizotinib.

PROTOCOL ELIGIBILITY*

- *Histologically or cytologically confirmed advanced non-squamous NSCLC (locally advanced disease not suitable for local treatment, or recurrent, or metastatic disease).*
- *Positive for translocation or inversion in ALK gene locus (eg, resulting in EML4-ALK fusion) determined by FISH. Archived tumor samples will be sent to a central lab for testing to determine eligibility.*
- *No prior systemic treatment for locally advanced or metastatic disease Exception: Prior adjuvant chemotherapy for stage I-III or combined chemoradiation for locally advanced disease allowed if completed > 12 months prior to randomization.*
- *Measurable disease as per RECIST 1.1.*
- *ECOG performance status of 0-2.*
- *Adequate organ function.*
- *Treated and stable brain metastasis is allowed.*

***Select eligibility requirements**

LINK

<http://clinicaltrials.gov/ct2/show/NCT01154140>

OUR CURRENT PROTOCOLS

Chemotherapy Protocols - Non-Small Cell Lung Cancer

Non-Small Cell Lung Cancer (NSCLC)

- A Phase I, Inpatient Dose-Escalation Study of Sorafenib in Advanced or Relapsed NSCLC
- A Randomized Phase II Study of LY2181308 in Combination with Docetaxel versus Docetaxel in Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer who Were Previously Treated with First-Line Chemotherapy
- A Randomized Phase II Study of Imetelstat as Maintenance Therapy After Initial Induction Chemotherapy for Advanced Non Small Cell Lung Cancer
- A Randomized Phase II Study of a Human Anti-PDGFR Monoclonal Antibody (IMC-3G3) with Paclitaxel/Carboplatin or Paclitaxel/Carboplatin Alone in Previously Untreated Patients with Locally Advanced or Metastatic Non-Small Cell Lung Cancer
- A Randomized, Double-Blind, Phase III Study of Docetaxel and Ramucirumab versus Docetaxel and Placebo in the Treatment of Stage IV Non-Small Cell Lung Cancer Following Disease Progression after One Prior Platinum-Based Therapy
- A Double-Blind, Randomized, Placebo-Controlled Phase III Study to Assess the Efficacy of recMAGE-A3 + AS15 Antigen-Specific Cancer Immunotherapeutic as Adjuvant Therapy in Patients with Resectable MAGE-A3-Positive NSCLC
- ECOG 1505: Phase III Randomized Trial of Adjuvant Chemotherapy With or Without Bevacizumab for Patients With Completely Resected Stage IB (≥ 4 cm)-IIIA Non-Small Cell Lung Cancer

Radiation Protocols

- Phase I Study of Image Guided Stereotactic Body Radiotherapy for Small Lung Malignancies
- Phase I Study Evaluation of the Safety, Tolerability and Pharmacokinetics of ABT-888 in Combination with Whole Brain Radiation Therapy in Subjects with Brain Metastases
- Randomized, Phase III, Open Label Study of Oral Topotecan plus Whole-Brain Radiation Therapy (WBRT) Alone in Patients with Brain Metastases from NSCLC
- A Randomized Phase III Comparison of Standard-dose (60Gy) versus High-dose (74Gy) Conformal Radiotherapy with Concurrent and Consolidation Carboplatin/Paclitaxel in Patients with Stage IIIA/IIIB Non-small Cell Lung Cancer

Other Protocols

- Molecular Markers for Non-Small Cell Lung Cancer Susceptibility

LINK > A complete listing of all clinical trials at the UW Carbone Cancer Center is also available on our website: <http://www.uwhealth.org/cancer>

For more information about referring patients to the UW Carbone Cancer Center, please contact Cancer Connect at (800) 622-8922 or (608) 262-5223.

TOGETHER WE CAN SAVE LIVES

Learn More About UW Multidisciplinary Lung Cancer Team

LUNG CANCER LINK

DID YOU KNOW?

The UW Carbone Cancer Center has a web site dedicated to cancer education and fund-raising events. Many of these events directly support lung cancer research programs. We encourage patients, families, friends and staff to bookmark this page and check it often for events in your area: www.uwhealth.org/cancer

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SAVE THE DATE:

Refer to the UW Carbone Cancer Center website: www.uwhealth.org/cancer for more information on the following:

June 20, 2011:

Drive for Hope Golf Tournament - La Crosse, WI
Sponsored by Gundersen Lutheran, Inc.
La Crosse Country Club

For more information and registration details visit gundluth.org/partners

August 8, 2011:

Drive for Hope Golf Tournament - Madison, WI
Maple Bluff Country Club in Madison, WI
For more information and registration details visit: www.driveforhopeuwhealth.org

Our Current List of Open Protocols
Gene Locus
Anaplastic Lymphoma Kinase (ALK)
Inversion Event Involving the Lung Harboring a Translocation or Non-Squamous Carcinoma of the
Previously Untreated Patients with Cisplatin or Pemetrexed/Carboplatin
Crizotinib Versus Pemetrexed/
Phase 3, Randomized, Open-Label Study of the Efficacy and Safety of

Featured Protocols
A Randomized Phase 2 Study of Imetelstat as Maintenance Therapy after Initial Induction Chemotherapy for Advanced Non-small Cell Lung Cancer (NSCLC)

A Letter from Toby Campbell, MD

INSIDE THIS ISSUE:



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