

Medical Research



Dr. André K.D. Liem

It is exciting to be involved in oncology these days. Numerous novel treatments, such as specially engineered molecules and antibodies, are being tested for a range of cancers. These new drugs work differently from chemotherapy; they trigger signals that interfere with cancer cell growth. Clinical trials bring about the medical studies needed to test the efficacy and safety of these new medications. Chemotherapy still plays a major role, but these medications certainly expand our options. Clinical research is an integral part of our clinical practice and I encourage people to ask their doctor about it.

Our Research Program Director, Dr. André K.D. Liem has been active in clinical research since joining Pacific Shores Medical Group in 1999. Since 2004 he has been overseeing the research program. Research meetings carried on twice a month are attended by oncologists as well as the entire research team. At the meetings the most recent findings and relevant information pertaining to the care of patients is presented and discussed in detail.

A list of the active clinical trials at Pacific Shores Medical Group is provided here.
For updated information please visit our website at www.pacshoresoncology.com

BONE METASTASES

- ◆ A Randomized, Active Controlled Study of AMG 162 in Subjects with Advanced Cancer Currently Being Treated with Intravenous Bisphosphonates

BREAST Adjuvant

- ◆ Neo-adjuvant Treatment and Molecular Characterization Of Locally Advanced Breast Cancer
- ◆ A Clinical Trial of Adjuvant Therapy Comparing Six Cycles of 5-fluorouracil, Epirubicin and Cyclophosphamide (FEC) to Four Cycles of Adriamycin and Cyclophosphamide (AC), in Patients with Node-Negative Breast Cancer
- ◆ A Phase III, Adjuvant Trial Comparing Three Chemotherapy Regimens In Women with Node-Positive Breast Cancer:

Docetaxel/Doxorubicin/Cyclophosphamide (TAC); Dose-Dense (DD) Doxorubicin/Cyclophosphamide Followed by DD Paclitaxel (DD AC±p); DD AC Followed by DD Paclitaxel Plus Gemcitabine (DD AC±PG)

BREAST First Line

- ◆ Phase I/II Combined Biological Therapy of Breast Cancer Using Monoclonal Antibodies directed against HER2/NEU Proto-Oncogene and Vascular Endothelial Growth Factor (VEGF)
- ◆ Phase II Randomized Trial of Faslodex and Herceptin, Alone and Combined, in the First-Line treatment of Hormone Receptor-Positive, HER-2/neu-Overexpressing Metastatic Breast Cancer
- ◆ Phase I/II Study of Herceptin Combined with OSI-774 in the First-Line Treatment of Metastatic Breast Cancer Associated with HER/neu Overexpression.
- ◆ A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase III Study Comparing GW572016 and Letrozole versus Letrozole in Subjects with Estrogen/Progesterone Receptor-Positive Advanced or Metastatic Breast Cancer
- ◆ A Phase II, Open-Label, Randomized, Multicenter Trial of GW786034 (Pazopanib) in Combination with Lapatinib (GW572016) Compared to Lapatinib Alone as First Line Therapy in Subjects with Advanced or Metastatic Breast Cancer with ErbB2 Fluorescence In Situ Hybridization (FISH) Positive Tumor
- ◆ A Multicenter, Phase III, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Bevacizumab in Combination with Chemotherapy Regimens in subjects with Previously UnTreated Metastatic Breast Cancer (Ribbon #1)

BREAST Second/Third Line

- ◆ A Phase III, Multicenter, Randomized, Placebo-Controlled Trial Evaluating the Efficacy and Safety of Bevacizumab in Combination with Chemotherapy Regimens in subjects with Previously Treated Metastatic Breast Cancer (Ribbon #2)
- ◆ Expanded Use Lapatinib, An Open-label Expanded Access Study of Lapatinib And Capecitabine Therapy in Subjects With ErbB2 Overexpressing Locally Advanced or Metastatic Breast Cancer.

COLON AND RECTAL Adjuvant

- ◆ A Randomized, Three-Arm Multinational Phase III Study to Investigate Bevacizumab (q3w or q2w) in Combination With Either Intermittent Capecitabine Plus Oxaliplatin (XELOX) (q3w) or Fluorouracil/Leucovorin With Oxaliplatin (FOLFOX-4) Versus FOLFOX-4 Regimen Alone as Adjuvant Chemotherapy in Colon Carcinoma
- ◆ A Phase III Clinical Trial Comparing Infusional 5-fluorouracil (5-FU), Leucovorin, and Oxaliplatin (mFOLFOX6) every two weeks with Bevacizumab to the same Regimen without Bevacizumab for the Treatment of Patients with Resected Stages II and III Carcinoma of the Colon

COLON AND RECTAL First Line

- ◆ A Randomized, Open-label, Controlled, Clinical Trial of Chemotherapy and Bevacizumab With and Without Panitumumab in the First-line Treatment of Subjects With Metastatic Colorectal Cancer
- ◆ A Phase II Trial to Evaluate the Efficacy and Safety of Bevacizumab in Combination with Capecitabine (XELODA) in Frail Patients with Untreated Metastatic Colorectal Cancer
- ◆ A Phase IV, Randomized, Prospective, Multicenter Comparison of an Intermittent schedule of Oxaliplatin (IO) Combined with 5-Fluorouracil/Leucovorin (FOLFOX) / Bevacizumab versus the Conventional (CO) Mode of Administration of FOLFOX/ Bevacizumab ± Neuroprophylaxis with Calcium/Magnesium for the Optimization of First-Line Therapy of Metastatic Colorectal Cancer

LUNG First Line

- ◆ A Phase 2 Randomized Study of Tarceva® (Erlotinib) as a single Agent or Intercalated with Combination Chemotherapy in Patients with Newly Diagnosed Advanced Non-small Cell Lung Cancer who have Tumors with EGFR Protein Overexpression and/or Increased EGFR Gene Copy Numbers
- ◆ Paclitaxel Poliglumex (CT-2103) vs. Paclitaxel for the Treatment of Women with Chemotherapy-Naïve Advanced Non-Small Cell Lung Cancer (NSCLC) who are performance Status

LUNG Second Line

- ◆ A Phase III, Randomized, Double-Blinded, Multi-Center Study to assess the Efficacy of Docetaxel (TAXOTERE™) in Combination with ZD6474 (ZACTIMA™) versus Docetaxel (TAXOTERE™) in combination with Placebo in Patients With Locally Advanced or Metastatic (Stage IIIb – IV) Non-small Cell Lung Cancer (NSCLC) after failure of 1st Line Anti-Cancer Therapy
- ◆ A multicenter, open-label, single-arm, two-stage Phase II study of efficacy and safety of AVE0005 (VEGF Trap) administered intravenously every 2 weeks in subjects with platinum-, and erlotinib-resistant locally advanced or metastatic non-small-cell lung adenocarcinoma

LYMPHOMA

- ◆ The National Lymphocare Study: An Observational Study of Treatment, Outcomes, and prognosis in patients with Follicular Non-Hodgkin's Lymphoma

MELANOMA First Line

- ◆ A Phase 3, Open Label, Randomized, Comparative Study of Ticilimumab and either Dacarbazine or Temozolomide in Patients with Advanced Melanoma

PROSTATE

- ◆ A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Phase 3 Study of Denosumab on Prolonging Bone Metastasis-Free Survival in Men with Hormone-Refractory Prostate Cancer
- ◆ A Randomized, Double-Blind, Multicenter Study of Denosumab Compared with Zoledronic Acid (Zometa®) in the Treatment of Bone Metastases in Men with Hormone-Refractory Prostate Cancer
- ◆ A Phase 3, Randomized, Open-Label Study Evaluating DN-101 in Combination with Docetaxel in Androgen-Independent Prostate Cancer (AIPC) (ASCENT-2)

SOLID TUMOR

- ◆ An Open Label Treatment Extension Study of AMG 706