ST. LUKE'S® Cancer Center

ONKOS

Third Quarter 2013

St. Luke's in the Texas Medical Center was recognized as on of America's Best Hospitals.

The Texas Heart® Institute at St. Luke's ranked in the top 10 for Cardiology & Heart Surgery for the 23rd consecutive year.

In its annual survey *U.S. News & World Report* also ranked St. Luke's among the nation's designated high-performing in the areas of **Cancer, Ear, Nose & Throat**, **Geriatrics**, **Gynecology**, **Nephrology**, **Neurology** & **Neurosurgery**, **Orthopedics** and **Urology**.

For more information about the rankings, visit *U.S. News* at usnews.com/best-hospitals.

Community Outreach Events

Walk or run with fellow Houstonians for a great cause! St. Luke's Health System Team will be showing their spirit in the fight against breast cancer on Saturday, October 5, at the Susan G. Komen Houston Race for The Cure in Downtown Houston.

To be a part of the St. Luke's Team, sign-up today! The online registration deadline is noon on Friday, September 27. To register:

- Click on "Join a Team" via the Komen homepage at komen-houston.org
- In the "Team Name:" box, type "St. Luke's Health System"

For more information, registration fees, race day events and much more, visit komen-houston.org.

Attention all Nurses!

The Cancer Center at St. Luke's needs RN to volunteers for the Medical Triage Team at the Komen Houston Race for The Cure on October 5. Headed by Joe Chorley, MD. who will organize teams and position them around the race route. Team members will carry a backpack with first aid supplies provided by the Cancer Center. If interested in volunteering, contact Marisol Belmares at mbelmares@sleh.com or 832-355-3490 before September 13.

TIVANTINIB (ARQ 197) vs PLACEBO as 2nd Line Therapy for Patients with MET Diagnostic-High Inoperable Hepatocellular Carcinoma (HCC)

TIVANTINIB is a non-ATP-competitive small molecule inhibitor of the tyrosine kinase c-Met. The c-Met receptor tyrosine kinase is the only known high-affinity receptor for hepatocyte growth factor (HGF)

Liver Cancer is the sixth most common cancer and the third leading cause of cancer related deaths. Advanced hepatocellular carcinoma patients are in need of more therapies to prolong their life expectancy and improve their quality of life. Expression of c-Met in tumors correlates with aggressive HCC features. Overexpression of the receptor is related to higher recurrence rate after surgery for HCC, while high c-Met expression correlates with shorter survival of patients diagnosed with HCC.

This phase 3 study evaluates the role of Tivantinib as a possible treatment option for patients with MET Diagnostic-High inoperable hepatocellular carcinoma (HCC) which have been previously treated with one prior therapy containing sorafenib.

SORAFENIB + VT-122 vs SORAFENIB + PLACEBO for Patients with Hepato-cellular Carcinoma and Systemic Inflammation at Risk for Cachexia

VT-122 is a combination of propranolol and etodolac, which synergistically targets systemic inflammation and key cell signaling pathways in the tumor, liver and immune system

The metabolic response associated with systemic inflammation is exacerbated in patients with HCC because of liver inflammation from the cancer and metabolic response to stress. VT-122 has mechanisms of action that attenuate the inflammatory and autonomic stress signaling. Propranolol is a non-selective beta adrenergic receptor blocker that inhibits beta adrenergic receptors 1, 2 and 3. Etodolac, a COX-2 inhibitor, was approved by the FDA as a nonsteroidal antiinflammatory drug (NSAID). The ability of propranolol and etodolac to target multiple signal transduction pathways in HCC may enhance the effect of sorafenib, the current standard of care therapy for patients with liver cancer.

This phase 2 study evaluates the clinical benefit of VT-122 in patients receiving sorafenib for the treatment of hepatocellular carcinoma.

Research

Randomized, Phase II Study of Lambrolizumab versus Chemotherapy in Patients with Advanced Melanoma.

Lambrolizumab (previously known as MK-3475) is a potent and highly selective humanized mAb of the IgG4/kappa isotype designed to directly block the interaction between PD-1 and its ligands, PD-L1 and PD-L2.

The programmed cell death 1 (PD-1) pathway represents a major immune control switch which may be engaged by tumor cells to overcome active T-cell immune surveillance. The ligands for PD-1 (PD-L1 and PD-L2) are constitutively expressed or can be induced in various tumors. High expression of PD-L1 on tumor cells (and to a lesser extent of PD-L2) has been found to correlate with poor prognosis and survival in various cancer types, including renal cell carcinoma (RCC), MEL, pancreatic carcinoma, hepatocellular carcinoma, and ovarian carcinoma. Furthermore, PD-1 has been suggested to regulate tumor-specific T-cell expansion in patients with malignant MEL.

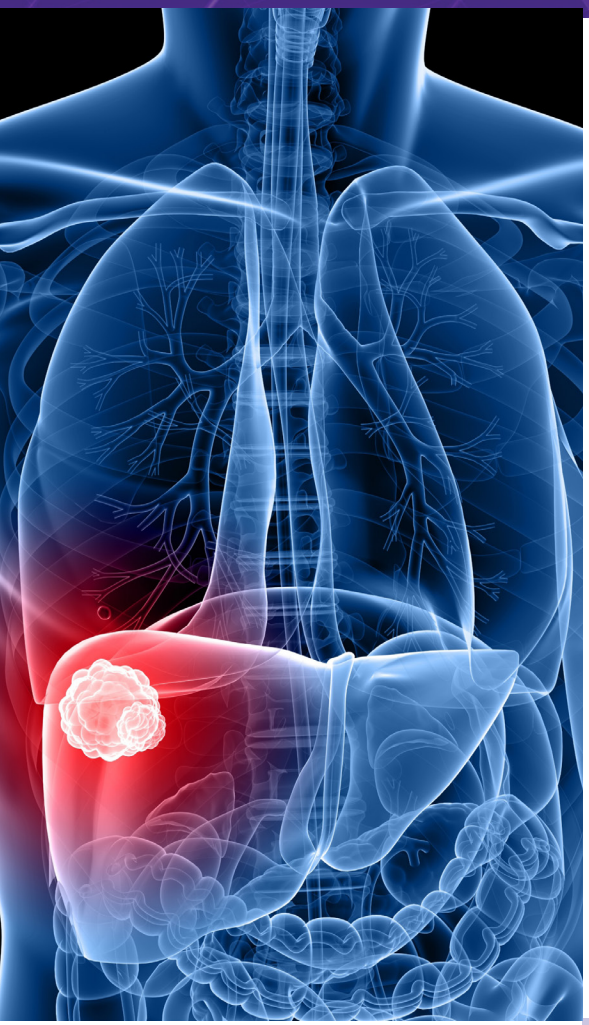
This study will be conducted as a phase 2 randomized trial. Participants will be randomized to receive either low dose Lambrolizumab, higher dose Lambrolizumab, or Investigator-choice chemotherapy. The two Lambrolizumab arms are double-blinded to Investigator and patients, while the control arm is open label. The five standard chemotherapy choices are carboplatin + paclitaxel, carboplatin alone, paclitaxel alone, dacarbazine, or temozolomide.

A Phase 3, Randomized, Placebo-controlled, Parallel group, Multicenter, Double-blind Study to Evaluate the Efficacy and Safety of Telotristat Etiprate (LX1606) in Patients with Carcinoid Syndrome Refractory to Somatostatin Analog (SSA) Therapy

Telotristat Etiprate is an orally-delivered small molecule that acts by inhibiting the enzyme tryptophan hydroxylase (TPH), the rate-limiting enzyme responsible for serotonin production.

Carcinoid Tumors are a type of nueroendocrine tumor that may come from multiple different organs systems, including small bowel, appendix, rectum, stomach and lung, which often produces and releases large amounts of serotonin (5-HT). Likewise, Carcinoid syndrome is a combination of symptoms, including severe diarrhea, bronchial restriction, facial flushing and rapid heartbeat, caused by the release of excessive serotonin and other substances into the blood stream from metastatic carcinoid tumors. Telotristat Etiprate is currently being evaluated as potential treatment for carcinoid syndrome.

This study will be conducted as a phase 3 randomized, placebo-controlled, parallel-group, multicenter, double-blind study in patients with CS refractory to SSA therapy to evaluate 2 oral doses levels of telotristat etiprate, 250 or 500 mg tid versus placebo.



Cancer Center at St. Luke's Announces the Neuroendocrine Tumor Program

St. Luke's Neuroendocrine Tumor Program is dedicated to providing the best quality outcomes through a collaborative care process.

Neuroendocrine tumors are a heterogeneous group of solid tumors that originate from neuroendocrine cells found throughout the body including the gastrointestinal tract, lungs, thymus, thyroid, adrenal glands, central nervous system (CNS) and pancreas. Management of neuroendocrine tumors depends on tumor size, grade and location. Due to the complexity of these tumors and that there are numerous therapeutic options available for patients with neuroendocrine tumors, the Neuroendocrine Tumor Program adapted a multidisciplinary team approach for the management of these tumors. After initial patient consultation, the cases are presented before a Multidisciplinary Neuroendocrine Tumor Board, consisting of medical and surgical oncologists, endocrinologists, radiologists, nuclear medicine, pathologists and gastroenterologists who coordinate the contributions of their areas of expertise to provide a personalized treatment plan for each patient. St. Luke's is dedicated to caring for its patients and their families—body, mind and spirit.

For more information about St. Luke's Neuroendocrine Tumor Program or to schedule an appointment today, call 832-355-3627.

The St. Luke's Radiation Therapy and Cyberknife center now offers special package pricing for patients without insurance for prostate cancer treatment using CyberKnife® or IMRT!

Depending on the clinical assessment, the location, and the size of the tumor, our physicians will determine the best modality for the individual patient. Pricing for CyberKnife® or IMRT is equivalent. The package pricing includes consultation with the radiation oncologist, an MRI procedure, and radiation treatments. For more information or to schedule an appointment, please contact the St. Luke's Radiation Therapy and CyberKnife® Center at 832-355-7118.

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For more information contact Marisol Belmares, Cancer Program Coordinator, at 832-355-3490.

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