ADVANCED MALIGNENCIES

BOSTON BIOMEDICAL – BBI608-201  A Phase Ib/II Clinical Study of BBI608 Administered with Paclitaxel in Adult Patients with Advanced Malignancies as described below. (Coordinator – Carrie Palmer, RN)

Tumor-type specifics:

1. Epithelial Ovarian, Fallopian tube, or primary peritoneal
2. Breast
3. NSCLC
4. Melanoma
5. Prostate
6. Mesothelioma, HCC
7. Head & Neck
8. Small Cell Lung

BREAST

Novartis (MONALEESA-7)  A Phase III study of LEE011 in combination with tamoxifen and goserelin or a nonsteroidal aromatase inhibitor (NSAI) and goserelin for the treatment of premenopausal women with advanced breast cancer (Coordinator Kacee French, RN)

CLEE011F2301 (MONALEESA-3)  A randomized double-blind, placebocontrolled study of ribociclib in combination with fulvestrant for the treatment of postmenopausal women with hormone receptor positive, HER2-negative, advanced breast cancer who have received no or only one line of prior endocrine treatment (Coordinator Kacee French, RN)

Gastrointestinal: COLON, RECTAL, STOMACH, HEPATOCELLULAR

Colorectal
None

Adjuvant colorectal cancer
None

HCC

SILLAJEN Jx594-HEP024  A Phase 3 Randomized, Open-Label Study Comparing Pexa-Vec (Vaccinia GM CSF / Thymidine Kinase-Deactivated Virus) Followed by Sorafenib Versus Sorafenib in Patients with Advanced Hepatocellular Carcinoma (HCC) Without Prior Systemic Therapy (Coordinator Kacee French, RN)

Cholangio carcinoma
None
GENITOURINARY

**Renal Adjuvant.**

**ECOG 2810**  Phase III Study of Pazopanib vs. Placebo in Patients with Metastatic Renal Cell Carcinoma Who Have No Evidence of Disease Following Metastatectomy (Coordinator – Carrie Palmer, RN)

**SWOG S0931**  EVEREST: Everolimus for Renal Cancer Ensuing Surgical Therapy, A Phase III Study (Coordinator – Carrie Palmer, RN)

**Prostate Cancer – metastatic**

None

BRAIN

**ALLIANCE A071102**  A Phase II/III Trial of Veliparib or Placebo in Combination with Adjuvant Temozolomide in Newly Diagnosed Glioblastoma (Coordinator – Kacee French, RN)

**ImmunoCellular ICT-107-301**  STING (Study of Immunotherapy in Newly Diagnosed Glioblastoma: A Phase III randomized double-blind, controlled study of ICT-107 with maintenance temozolomide (TMZ) in newly diagnosed glioblastoma following resection and concomitant TMZ chemoradiotherapy (Coordinator Kacee French, RN)

GYNECOLOGIC

**GOG-0225**  Can Diet and Physical Activity Modulate Ovarian Fallopian Tube and Primary Peritoneal Cancer Progression-Free Survival (Coordinator Carrie Palmer, RN)

**GOG-0238**  A Trial of Pelvic Irradiation with or without Concurrent Weekly Cisplatin in Patients with Pelvic-only Recurrence of Carcinoma of the Uterine Corpus (Coordinator – Carrie Palmer, RN)

**MORPHOTEK**  A Phase 2 Study to Assess the Efficacy and Safety of Farletuzumab (MORAb-003) in Combination with Carboplatin plus Paclitaxel or Carboplatin plus Pegylated Liposomal Doxorubicin (PLD) in Subjects with Recurrent Ovarian Cancer (Coordinator – Carrie Palmer, RN)

**SOLO3 (AstraZeneca)**  A Phase III study to assess the efficacy and safety of Olaparib Monotherapy versus Physician’s Choice Single Agent Chemotherapy in the Treatment of Ovarian Cancer (Coordinator – Carrie Palmer, RN)

HEAD and NECK

**Galera GT-201**  A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Trial of the Effects of Intravenous GC4419 on the Incidence and Duration of Severe Oral Mucositis (OM) in Patients Receiving Post-Operative or Definitive Therapy with Single-Agent Cisplatin plus IMRT for Locally Advanced, Non-Metastatic Squamous Cell Carcinoma of the Oral Cavity or Oropharynx (Coordinator Carrie Palmer, RN)

LEUKEMIA/ LYMPHOMA/ MULTIPLE MYELOMA

**Lymphoma**

**NCI 9177**  Phase II Study of Dose-Adjusted EPOCH +/- Rituximab in Adults with Untreated Burkitt Lymphoma, Large B-Cell Lymphoma and Plasmablastic Lymphoma (Coordinator – Kacee French, RN)
**Pfizer Follicular Lymphoma**  
**B3281006** A Phase 3 study of PF-05280586 versus Rituximab for the treatment of patients with Follicular Lymphoma (Coordinator - Kacee French, RN)

**Multiple Myeloma**

**ECOG E3A06** Phase III Trial of Lenalidomide Versus Observation Alone in Patients with Smoldering Multiple Myeloma (Coordinator – Kacee French, RN)

**BMS CA204143** An Expanded Access Program for Elotuzumab in Combination with Lenalidomide plus Dexamethasone in Patients with Relapsed or Refractory Multiple Myeloma (Coordinator Carrie Palmer, RN)

**LUNG**

**Amgen** A Study to Evaluate the Long-Term Safety and Efficacy of Darbepoetin Alfa Administered at 500 mcg Once Every 3 Weeks in Anemic Subjects with Advanced Stage NSCLC Receiving Multi-Cycle Chemotherapy (Coordinator – Kacee French, RN)

**NewLink Genetics – NLG-0301** A Phase IIb/III Active Control Study of Second-line HyperAcute-Lung (tergenpumatucel-L) Immunotherapy versus Doxetaxel in Non-Small Cell Lung Cancer (Coordinator – Kacee French, RN)

**Lilly I4Y-MC-JFCP** A Single-Arm, Multicenter, Open-Label, Phase 2 Study of nab®-Paclitaxel (Abraxane®) and Carboplatin Chemotherapy plus Necitumumab (LY3012211) in the First-Line Treatment of Patients with Stage IV Squamous Non-Small Cell Lung Cancer (NSCLC) (Coordinator – Carrie Palmer, RN)

**MELANOMA**

**NewLink Genetics NLG0304** A Phase IIB Study of Ipilimumab with or without HyperAcute®-Melanoma Immunotherapy for Stage IV Melanoma Patients (Coordinator-Kacee French, RN)

**Polynoma 103A-301** A Multicenter, Double-blind, Placebo-controlled, Adaptive Phase 3 Trial of POL-103A Polyvalent Melanoma Vaccine in Post-resection Melanoma Patients with a High Risk of Recurrence (Coordinator – Kacee French, RN)

**PANCREATIC**

**Boston Biomedical - BBI608-118** A Phase Ib Clinical Study of BBI608 in Combination with Gemcitabine and nab-Paclitaxel in Adult Patients with Metastatic Pancreatic Adenocarcinoma (Coordinator Carrie Palmer, RN)

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**QUESTIONS REGARDING PROTOCOLS**  
Call the Office of Clinical Trials at (865) 305-9773