

## *Oncology Clinical Trial List*

### *November 2017*

#### Lung Cancer Screening (nodule 0.5 cm to 3 cm), or untreated NSCLC

A study to evaluate a panel of blood biomarkers  
for use in patients undergoing evaluation for lung cancer, ONC-LN-04.  
**OncoCyte PRO068**

#### Solid Tumors and SCCHN (dose escalation); (NSCLC or SCCHN dose expansion - not open)

An Open Label, Phase Ia/Ib Trial of the DNA-PK Inhibitor MSC2490484A in Combination with Radiotherapy in Patients with  
Advanced Solid Tumors.  
**EMR 100036-002**

**Dose escalation:** *Advanced solid tumors or metastasis (incl. lymphoma) located in the head, neck or thoracic region amenable to  
palliative radiation, SCCHN 1L with curative intent.*

#### Precision Medicine Basket Trials

See last page for  
list of mutations\*

Molecular Analysis for Therapy Choice (**NCI - MATCH**)  
**ECOG-ACRIN EAY131 (mutations on last page)**  
*After all approved treatments with overall survival have been exhausted*

NTRK1/2/3  
  
ROS1  
  
ALK

**Basket study for any solid tumor, including large cohorts for CRC or NSCLC**  
An Open-Label, Multicenter, Global Phase 2 Basket Study of Entrectinib for the Treatment of Patients with  
Locally Advanced or Metastatic Solid Tumors that Harbor NTRK1/2/3, ROS1, or ALK Gene Rearrangements.  
  
**RXDX-101-02 (STARTRK-2)**  
*Provides Ignyta assay for NTRK, ROS1 and ALK mutations*

#### Breast

Her-2 negative

A Randomized Phase III Double-Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node  
Positive HER2 Negative Breast Cancer: The ABC Trial  
**Alliance A011502**

HR-positive  
  
Her-2 negative

A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate Efficacy and Safety  
of Ribociclib With Endocrine Therapy as an Adjuvant Treatment in Patients With Hormone Receptor-positive,  
HER2-negative, High Risk Early Breast Cancer

**Novartis CLEE011G2301 (EarLEE-1)**

## Breast (con't)

HR-positive Her-2 negative	<p>A Phase III, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate Efficacy and Safety of Ribociclib With Endocrine Therapy as an Adjuvant Treatment in Patients With Hormone Receptor-positive, HER2-negative, Intermediate Risk Early Breast Cancer</p> <p style="text-align: center;"><b>Novartis CLEE011H2301 (EarLEE-2)</b></p> <div style="text-align: right; border: 1px solid #0070C0; border-radius: 10px; padding: 5px; background-color: #0070C0; color: white; display: inline-block;"> <b>Sponsor has study on hold</b> </div>
ER-positive Her-2 negative	<p>An Open-Label Phase 2 Study of MLN0128 (A TORC1/2 Inhibitor) in Combination With Fulvestrant in Women With ER-Positive/HER2-Negative Advanced or Metastatic Breast Cancer That Has Progressed During or After Aromatase Inhibitor Therapy</p> <p style="text-align: center;"><b>Millennium C31006</b></p>

### ASBrS Nipple Sparing Mastectomy Registry

### CALLER Registry: Collaborative Attempt to Lower Lumpectomy Re-excision Rates

## Non-small Cell Lung Cancer

Hyaluronan-high Adeno or squamous	<p>A Phase 1b Open-Label Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) Combined with Pembrolizumab in Subjects with Selected Hyaluronan-High Solid Tumors.</p> <p style="text-align: center;"><b>HALO-107-101</b></p>
No PD-1 positive requirement	<p>A Phase III, Open-label, Randomized Study to Investigate the Efficacy and Safety of MPDL3280A (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 NSCLC</p> <p style="text-align: center;"><b>GO29527</b></p>
MET Exon14 skipping mutation	<p>A Phase II single-arm trial to investigate tepotinib in advanced (Stage IIIB/IV) non-small cell lung cancer with MET exon 14 (METex14) skipping alterations (VISION)</p> <p style="text-align: center;"><b>cMet MS200095-022</b></p> <p style="text-align: center;"><i>Provides Oncomine Focus Assay or Gardant Liquid Biopsy Report</i></p> <div style="border: 1px solid #0070C0; border-radius: 15px; padding: 5px; background-color: #0070C0; color: white; display: inline-block; margin-left: 10px;"> <b>Now accepts liquid biopsy</b> </div>
T790M	<p>An Open-label, Non-randomized, Prospective Biomarker Study to Assess Analytic Concordance and Clinical Validity Between Non-invasive Testing and Tissue Testing for EGFR T790M Mutation Detection in Patients with Non-Small Cell Lung Cancer</p> <p style="text-align: center;"><b>AstraZeneca D5160L00032 RADIANCE</b></p>
MET Amplification or mutation	<p>A phase II study to evaluate antitumor activity of oral cMET inhibitor Capmatinib (INC280) in adult patients with EGFR wild-type, advanced non-small cell lung cancer (NSCLC) after one or two prior lines of systemic therapy for advanced/metastatic disease as measured by overall response rate (ORR). The study will also evaluate safety and pharmacokinetics of INC280.</p> <p style="text-align: center;"><b>INC 280A2201</b></p> <p style="text-align: center;"><i>Novartis Rapid start-up trial; platinum doublet not required</i></p>

## Non-small Cell Lung Cancer (con't)

	<p>A Phase 1b/2, Open-Label, Randomized Study of Daratumumab Administered in Combination with Atezolizumab Compared with Atezolizumab Alone in Subjects with Previously Treated Advanced or Metastatic Non-Small Cell Lung Cancer</p> <p><b>Janssen 54767414LUC2001 (CALLISTO)</b></p>	<div style="background-color: #0070C0; color: white; padding: 5px; border-radius: 10px; display: inline-block;">Open to Accrual</div>
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	<p>Prospective <i>observational</i> multicenter study to evaluate the performance of Inivata liquid biopsy analysis compared with standard tissue biopsy analysis for detection of genomic alterations in patients with advanced non-small cell lung cancer.</p> <p><b>INI-001</b></p> <p><i>Chemo naive NSCLC: provides Caris Lifescience's Molecular Intelligence Report</i></p>
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## Small Cell Lung Cancer

	<p>Phase III Randomized Clinical Trial of Lurbinectedin (PM01183) /Doxorubicin (DOX) versus Cyclophosphamide (CTX), Doxorubicin (DOX) and Vincristine (VCR) (CAV) or Topotecan as Treatment in Patients with Small-Cell Lung Cancer (SCLC) Who Failed One Prior Platinum-containing Line.</p> <p><b>PM1183-C-003-14 (ATLANTIS)</b></p>
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	<p>Phase 3 Placebo Controlled Study of Rovalpituzumab Tesirine as Maintenance Therapy Following First-Line Platinum-Based Chemotherapy in Subjects with Extensive Stage Small Cell Lung Cancer.</p> <p><b>Abbvie M16-298 (MERU)</b></p>
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## Renal Cell Cancer

	<p>A Phase 3 Randomized Study Comparing PERIoperative Nivolumab Vs Observation in Patients with Localized Renal Cell Carcinoma Undergoing Nephrectomy</p> <p><b>ECOG EA8143 (PROSPER-RCC)</b></p>	<div style="background-color: #0070C0; color: white; padding: 5px; border-radius: 10px; display: inline-block;">Open to Accrual</div>
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## Brain - Glioblastoma

EGFR amplification	<p>Phase 2b/3 Placebo Controlled Study of ABT-414 with Concurrent Chemoradiation and Adjuvant Temozolomide in Subjects with Newly Diagnosed Glioblastoma (GBM) with Epidermal Growth Factor Receptor (EGFR) Amplification</p> <p><b>AbbVie M13-813</b></p>
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## Gastrointestinal Cancer

Gastric  GEJ	<p>A Phase 1b Open-Label Study of PEGylated Recombinant Human Hyaluronidase (PEGPH20) Combined with Pembrolizumab in Subjects with Selected Hyaluronan-High Solid Tumors.</p> <p><b>HALO-107-101</b></p>
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## Urothelial

No PD-1 positive requirement	<p>A Phase 3, Open-label, Randomized Study of Nivolumab Combined With Ipilimumab Versus Standard of Care Chemotherapy in Participants With Previously Untreated Unresectable or Metastatic Urothelial Cancer</p> <p><b>BMS CA209-901</b></p>
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## Iron Deficiency Anemia

Phase III Comparative Safety and Efficacy Trial of Intravenous Iron Isomaltoide (Monofer®) and Iron Sucrose in Subjects With Iron Deficiency Anemia (Ferwon IDA)  
**IDA-03**

## MDS, AML, or ICUS

The Myelodysplastic Syndromes (MDS) and Acute Myeloid Leukemia (AML) Disease Registry  
**Connect® MDS and AML**  
*MDS, AML, Idiopathic cytopenia of unknown significance*

## Cancer Patients and Their Relatives

Molecular Genetics Studies of Cancer Patients and Their Relatives  
**CITY OF HOPE**

## CONTACT

**For a Physician Appointment Call:**  
954-267-7700

Leonard Seigel, M.D.  
Ena Segota, M.D.  
David Drew, M.D.  
Omar Rashid, M.D.  
Daniel Dammrich, M.D.  
Georges Azzi, M.D.  
Delia Constanza Guaqueta, M.D.

**For Research Information Call:**  
954-267-7788

Luke Beeler, Pharm. D. 954-267-7750  
Eileen Georgi, RN 954-267-7748  
Mariana Lykoudis, IMG 954-267-7792  
Kathy McTague, RN 954-267-7718

## NCI-Match Sub-protocols\*

Arm	Target	-	Drug
A	EGFR mut	-	Afatinib
C1	MET amp	-	Crizotinib
C2	MET ex 14 sk	-	Crizotinib
E	EGFR T790M	-	AZD9291
F	ALK transloc	-	Crizotinib
G	ROS1 transloc	-	Crizotinib
H	BRAF V600	-	Dabrafenib+trametinib
L	mTOR mut	-	TAK-228 (formerly MLN0128)
M	TSC1 or TSC2 mut	-	TAK-228 (formerly MLN0128)
S2	GNAQ/GNA11	-	Trametinib
T	SMO/PTCH1	-	Vismodegib
U	NF2 loss	-	Defactinib
V	cKIT mut	-	Sunitinib
X	DDR2 mut	-	Dasatinib
Z1B	CCND1,2,3 amp	-	Palbociclib
Z1C	CDK4 or CDK6 amp	-	Palbociclib
Z1E	NTRK fusions	-	Larotectinib (LOXO-101)