

Clinical Trials February 2018

	Protocol	Title	Study Site	PI Name
Breast	C-285 Alliance A011401 BWEL <i>HER2 negative</i> <i>Stage II/III</i>	Randomized Phase III Trial Evaluating the Role of Weight Loss in Adjuvant Treatment of Overweight and Obese Women with Early Breast Cancer https://www.clinicaltrials.gov/ct2/show/NCT02750826	Oncology Network	Dr. Cheryl Jones
	C-301 Novartis CLEE011G2301 EarLEE-1 <i>High-risk HER-2 negative, ER/PR+</i>	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 https://www.clinicaltrials.gov/ct2/show/NCT03078751	Oncology Network	Dr. Amelia Zelnak
	NSH1126 ECOG EA1131 <i>Post Neo-Adjuvant Triple Negative</i>	A Randomized Phase III Post-Operative Trial of Platinum Based Chemotherapy Vs. Capecitabine in Patients with Residual Triple-Negative Basal-Like Breast Cancer following Neoadjuvant Chemotherapy https://www.clinicaltrials.gov/ct2/show/NCT02445391	Oncology Network	Dr. Amelia Zelnak
	C-239 NRG BR003 <i>Adjuvant, Node + or High-Risk Node- TNBC</i>	A Randomized Phase III Trial of Adjuvant Therapy Comparing Doxorubicin Plus Cyclophosphamide Followed by Weekly Paclitaxel With or Without Carboplatin for Node-Positive or High-Risk Node-Negative Invasive TNBC https://www.clinicaltrials.gov/ct2/show/NCT02488967	Oncology Network	Dr. Amelia Zelnak
	C-295 SWOG S1418/BR006 <i>TNBC with residual disease</i>	A Randomized, Phase III Trial to Evaluate the Efficacy and Safety of MK-3475 (Pembrolizumab) as Adjuvant Therapy for Triple Receptor-Negative Breast Cancer With ≥ 1 CM Residual Invasive Cancer or Positive Lymph Nodes (ypN+) After Neoadjuvant Chemotherapy https://clinicaltrials.gov/ct2/show/NCT02954874	Oncology Network	Dr. Amelia Zelnak
	C-197 NSABP-B-55 <i>Adjuvant , BRAC 1/2 + HER2 negative ER/PR +/-</i>	A Randomized, Double-Blind, Parallel Group, Placebo-Controlled Multi-Centre Phase III Study to Assess the Efficacy and Safety of Olaparib Versus Placebo as Adjuvant Treatment in Patients with Germline BRCA1/2 Mutations and High Risk HER2 Negative Primary Breast Cancer Who Have Completed Definitive Local Treatment and Neoadjuvant or Adjuvant Chemotherapy https://www.clinicaltrials.gov/ct2/show/NCT02032823	Oncology Network	Dr. Cheryl Jones
	C-294 Alliance A011502 The ABC Trial <i>HER2 negative</i>	A Randomized Phase III Double Blinded Placebo Controlled Trial of Aspirin as Adjuvant Therapy for Node Positive HER2 Negative Breast Cancer: The ABC Trial https://www.clinicaltrials.gov/ct2/show/NCT02927249	Oncology Network	Dr. Gena Volas-Redd

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Breast	C-266 ONT-380-206 <i>Metastatic, HER2+ with prior Taxane, Trast, Pertuzumab & TDM1</i>	Phase 2 Randomized, Double-Blinded, Controlled Study of ONT-380 vs Placebo in Combination With Capecitabine and Trastuzumab in Patients With Pretreated Unresectable Locally Advanced or Metastatic HER2+ Breast Carcinoma https://www.clinicaltrials.gov/ct2/show/NCT02614794	Oncology Network	Dr. Amelia Zelnak
	C-259 I3Y-MC-JPBZ monarchHER <i>2nd/3rd line HER2+, HR+ Unresectable Locally Adv/ Metastatic, Prior taxane, TDM1</i>	A Phase 2, Randomized, Multicenter, 3-Arm, Open-Label Study to Compare the Efficacy of Abemaciclib plus Trastuzumab with or without Fulvestrant to Standard-of-Care Chemotherapy of Physician's Choice plus Trastuzumab in Women with HR+, HER2+ Locally Advanced or Metastatic Breast Cancer https://www.clinicaltrials.gov/ct2/show/NCT02675231	Oncology Network	Dr. Amelia Zelnak
	C-276 CLEE011XUS29 TRINITI-1 <i>HER2 negative, HR+ 1st or 2nd line adv/ metastatic</i>	A Phase I/II, Single Arm, Open-label Study of Ribociclib in Combination With Everolimus + Exemestane in the Treatment of Men and Postmenopausal Women With HR+, HER2- Locally Advanced or Metastatic Breast Cancer Following Progression on a CDK 4/6 Inhibitor https://www.clinicaltrials.gov/ct2/show/NCT02732119	Oncology Network	Dr. Amelia Zelnak
	C-247 REP0114; FRIDA <i>1st line Metastatic TNBC Post Adjuvant Therapy</i>	A Randomized, Double-blind, Placebo-controlled Phase 2 Study of Paclitaxel in Combination With Reparixin Compared to Paclitaxel Alone as Front-line Therapy for Metastatic Triple- Negative Breast Cancer https://www.clinicaltrials.gov/ct2/show/NCT02370238	Oncology Network	Dr. Amelia Zelnak
	C-311 IMMU-132-05 <i>2nd line Metastatic TNBC</i>	An International, Multi-Center, Open-Label, Randomized, Phase III Trial of Sacituzumab Govitecan versus Treatment of Physician Choice in Patients with Metastatic Triple-Negative Breast Cancer Who Received at Least Two Prior Treatments https://www.clinicaltrials.gov/ct2/show/NCT02574455	Oncology Network	Dr. Amelia Zelnak
	C-287 A5481074 MADELINE <i>Advanced/ metastatic breast cancer 1st/2nd/3rd Line</i>	Prospective Observational Study of Mobile App-Based Patient-Reported Outcomes in Advanced Breast Cancer	Oncology Network	Dr. Cheryl Jones

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GYN	C-258 GOG 3012; PR-30-5017-C <i>Ovarian ≥ 4 cycles of platinum chemo</i>	A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of Niraparib Maintenance Treatment in Patients with HRD-Positive Advanced Ovarian Cancer Following Response on Front-Line Platinum-Based Chemotherapy https://www.clinicaltrials.gov/ct2/show/NCT02655016	GYN Onc	Dr. Stephanie Yap
	NSH1083 GOG 0281 <i>Ovarian Recurrent/Progressive</i>	A Randomized Phase II/III Study to Assess the Efficacy of Trametinib (GSK 1120212) in Patients With Recurrent or Progressive Low-Grade Serous Ovarian Cancer or Peritoneal Cancer https://www.clinicaltrials.gov/ct2/show/NCT02101788	GYN Onc	Dr. Guilherme Cantuaria
	NSH998 GOG 0225 <i>Ovarian 1st complete remission</i>	Can Diet and Physical Activity Modulate Ovarian or Primary Peritoneal Cancer Progression-Free Survival? https://www.clinicaltrials.gov/ct2/show/NCT00719303	GYN Onc & Macon	Dr. Guilherme Cantuaria
	NSH1025 GOG 0264 <i>Ovarian 1st line stromal</i>	A Randomized Phase II Trial of Paclitaxel and Carboplatin vs. Bleomycin, Etoposide, and Cisplatin for Newly Diagnosed Advanced State and Recurrent Chemo-naïve Sex Cord-Stromal Tumors of the Ovary https://www.clinicaltrials.gov/ct2/show/NCT01042522	GYN Onc & Macon	Dr. Guilherme Cantuaria
	C-304 VX-EC-2-01 <i>Endometrial advanced/ metastatic, 1st/2nd line</i>	A Phase 2, Single Arm, Two Period Study of Sodium Cridanimod in Conjunction with Progestin Therapy in Patients with Endometrial Carcinoma https://www.clinicaltrials.gov/ct2/show/NCT03077698	GYN Onc	Dr. Meaghan Tenney
Heme Malignancies	NSH1145 14-174 Precursor Heme	Study of Precursor Hematological Malignancies to Assess the Relationship between Molecular Events of Progression and Clinical Outcome https://www.clinicaltrials.gov/ct2/show/NCT02269592	Oncology Network	Dr. Sreekanth Reddy
	C-093 GCS1209; SGN35-015 <i>Hodgkin's Lymphoma</i>	A phase 2 open-label study of brentuximab vedotin in front-line therapy of Hodgkin lymphoma (HL) in adults age 60 and above https://www.clinicaltrials.gov/ct2/show/NCT01716806	Oncology Network	Dr. Rodolfo Bordoni
	C-195 ECOG E1A11 ENDURANCE <i>Newly diagnosed multiple myeloma</i>	Randomized Phase III Trial of Bortezomib, Lenalidomide and Dexamethasone (VRd) Versus Carfilzomib, Lenalidomide and Dexamethasone (CRd) Followed by Limited or Indefinite Duration Lenalidomide Maintenance in Patients with Newly Diagnosed Symptomatic Multiple Myeloma https://www.clinicaltrials.gov/ct2/show/NCT01863550	Oncology Network	Dr. Kathleen Lambert

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Lung	C-190 Alliance A151216 ALCHEMIST screening trial <i>Adjuvant Stage I-III A</i>	Adjuvant Lung Cancer Enrichment Marker Identification and Sequencing Trials https://www.clinicaltrials.gov/ct2/show/NCT02194738	Oncology Network	Dr. Sreekanth Reddy
	C-191 Alliance A081105 <i>EGFR mutation</i>	Randomized Double Blind Placebo Controlled Study of Erlotinib or Placebo in Patients With Completely Resected Epidermal Growth Factor Receptor (EGFR) Mutant NSCLC https://www.clinicaltrials.gov/ct2/show/NCT02193282	Oncology Network	Dr. Sreekanth Reddy
	C-192 ECOG E4512 <i>ALK fusion</i>	A Phase III Double-Blind Trial for Surgically Resected Early Stage Non-Small Cell Lung Cancer: Crizotinib versus Placebo for Patients with Tumors Harboring the Anaplastic Lymphoma Kinase (ALK) Fusion Protein https://www.clinicaltrials.gov/ct2/show/NCT02201992	Oncology Network	Dr. Sreekanth Reddy
	C-280 ECOG EA5142 ANVIL <i>Non-match</i>	Adjuvant Nivolumab in Resected Lung Cancers (ANVIL): A Randomized Phase III Study of Nivolumab After Surgical Resection and Adjuvant Chemotherapy in NSCLC https://www.clinicaltrials.gov/ct2/show/NCT02595944	Oncology Network	Dr. Sreekanth Reddy
	C-163 SWOG S1400 LungMAP <i>2nd line Metastatic Squamous Sub-studies S1400F, S1400G, S1400I open</i>	Phase II/III Biomarker-Driven Master Protocol for Second Line Therapy of Squamous Cell Lung Cancer https://www.clinicaltrials.gov/ct2/show/NCT02154490	Oncology Network	Dr. Sreekanth Reddy
	C-233 G1T28-03 <i>2nd Line+ SCLC</i>	Phase 1b/2a Safety and Pharmacokinetic Study of G1T28 in Patients With Previously Treated Extensive Stage Small Cell Lung Cancer (SCLC) Receiving Topotecan Chemotherapy https://www.clinicaltrials.gov/ct2/show/NCT02514447	Center Pointe	Dr. Sreekanth Reddy
	C-305 M16-289 TAHOE <i>2nd Line DLL3high SCLC</i>	A Randomized, Open-Label, Multicenter, Phase 3 Study of Rovalpituzumab Tesirine Compared with Topotecan for Subjects with Advanced or Metastatic DLL3high SCLC who have First Disease Progression During or Following Front-Line Platinum-Based Chemotherapy (TAHOE) https://www.clinicaltrials.gov/ct2/show/NCT03061812	Center Pointe, Cumming, Kennestone	Dr. Sreekanth Reddy
GU	C-306 CO39303 <i>1st Line mCRPC</i>	A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multicenter Trial Testing Ipatasertib Plus Abiraterone Plus Prednisone/Prednisolone, Relative to Placebo Plus Abiraterone Plus Prednisone/Prednisolone in Adult Male Patients With Asymptomatic or Mildly Symptomatic, Previously Untreated, Metastatic Castrate-Resistant Prostate Cancer https://www.clinicaltrials.gov/ct2/show/NCT03072238	Oncology Network	Dr. Crain Garrot

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Neuro	C-204 A071102 <i>Newly Diagnosed GBM</i>	A Phase II/III Randomized Trial of Veliparib or Placebo in Combination With Adjuvant Temozolomide in Newly Diagnosed Glioblastoma With MGMT Promoter Hypermethylation https://www.clinicaltrials.gov/ct2/show/NCT02152982	Oncology Network	Dr. Lijo Simpson
Melanoma	C-188 Elios 2014-1932 <i>Stage III or IV Resected NED</i>	A Prospective, Randomized, Blinded, Placebo-controlled, Phase IIb Trial of an Autologous Tumor Lysate (TL) + Yeast Cell Wall Particles (YCWP) + Dendritic Cells (DC) Vaccine vs Unloaded YCWP + DC and Embedded Phase I/IIa Trial With Tumor Lysate Particle Only (TLPO) Vaccine in Stage III and Stage IV (Resected) Melanoma to Prevent Recurrence https://www.clinicaltrials.gov/ct2/show/NCT02301611	Oncology Network	Dr. Ronald Steis
	C-267 Elios vaccine 2015-2397 <i>Stable/ Slowly Progressive Dz</i>	Multi-center phase I/IIa trial of an autologous tumor lysate (TL) + yeast cell wall particles (YCWP) + dendritic cells (DC) vaccine in addition to standard of care checkpoint inhibitor of choice in metastatic melanoma patients with stable or slowly progressing disease https://www.clinicaltrials.gov/ct2/show/NCT02678741	Oncology Network	Dr. Aaron Alizadeh
	C-207 CDX011-05 <i>Stage III or IV Unresected</i>	A Phase II Study of Glematumumab Vedotin, an Anti-gpNMB Antibody-Drug Conjugate, in Patients with Advanced Melanoma https://www.clinicaltrials.gov/ct2/show/NCT02302339	Oncology Network	Dr. Aaron Alizadeh
	C-281 DV3-MEL-01 <i>Stage III or IV 1st or 2nd Line</i>	A Phase 1b/2, Open-label, Multicenter, Dose-escalation and Expansion Trial of Intratumoral SD-101 in Combination With Pembrolizumab in Patients With Metastatic Melanoma https://www.clinicaltrials.gov/ct2/show/NCT02521870	Alpharetta & Stemmer	Dr. Aaron Alizadeh
	C-293 ECOG EA6134 <i>Advanced BRAFV600</i>	A Randomized Phase III trial of Dabrafenib + Trametinib followed by Ipilimumab + Nivolumab at Progression vs. Ipilimumab + Nivolumab followed by Dabrafenib + Trametinib at Progression in Patients With Advanced BRAFV600 Mutant Melanoma https://www.clinicaltrials.gov/ct2/show/NCT02224781	Oncology Network	Dr. Ronald Steis
Sarcoma	C-275 I5B-MC-JGDL	A Phase 1b (Open-Label) / Phase 2 (Randomized, Double-Blinded) Study Evaluating Gemcitabine and Docetaxel With or Without Olaratumab in the Treatment of Advanced Soft Tissue Sarcoma https://www.clinicaltrials.gov/ct2/show/NCT02659020	Center Pointe	Dr. Gina D'Amato
	C-308 105SAR301 <i>Angiosarcoma</i>	A Randomized Phase 3 Trial of TRC105 and Pazopanib versus Pazopanib Alone in Patients with Advanced Angiosarcoma (TAPPAS) https://www.clinicaltrials.gov/ct2/show/NCT02979899	Center Pointe	Dr. Gina D'Amato
	C-314 Deciphera DCC-2618-03-001; INVICTUS	A Phase 3, INterVentional, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of DCC-2618 In Patients with AdvanCed Gastrointestinal Stromal	Center Pointe	Dr. Gina D'Amato

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	<i>GIST</i>	TUmorS who have Received Treatment with Prior Anticancer Therapies https://www.clinicaltrials.gov/ct2/show/NCT03353753		
Multiple Dz Sites / Phase I	C-297 BMS C017-003 <i>NSCLC, Melanoma, RCC cohorts</i>	A Phase 1/2a Study of BMS-986205 Administered in Combination with Nivolumab (BMS- 936558, anti-PD-1 Monoclonal Antibody) in Advanced Malignant Tumors https://www.clinicaltrials.gov/ct2/show/NCT02658890	Center Pointe	Dr. Gina D'Amato
	NSH1097 INCB52793-101 <i>No open cohorts AML, MDS cohorts on hold for DLT eval</i>	A Phase 1a/1b, Open-Label, Dose-Escalation, Safety and Tolerability Study of INCB052793 in Subjects With Advanced Malignancies https://www.clinicaltrials.gov/ct2/show/NCT02265510	Center Pointe	Dr. Gina D'Amato
	C-269 INCB24360-202 ECHO-202 <i>CRC (MSI High) & HCC cohorts</i>	A Phase 1/2 Study Exploring the Safety, Tolerability, and Efficacy of MK-3475 in Combination With INCB024360 in Subjects With Selected Cancers https://www.clinicaltrials.gov/ct2/show/NCT02178722	Oncology Network	Dr. Gina D'Amato
	C-228 ECOG EAY131 NCI MATCH <i>Targeted therapy</i>	Molecular Analysis for Therapy Choice (MATCH) https://www.clinicaltrials.gov/ct2/show/NCT02465060	Oncology Network	Dr. Amelia Zelnak
	C-265 DCP-001 <i>CCDR</i>	Use of a Clinical Trial Screening Tool to Address Cancer Health Disparities in the NCI Community Oncology Research Program (NCORP)	Oncology Network	Dr. Guilherme Cantuaria