Clinical Trial Review Guide

Site Study ID: **LU208944**	Protocol ID: **S1404**	Version: **1-19-2017**
Title: A Phase III Randomized Trial Comparing Physician/ Patient choice of Either High Dose Interferon or Ipilimumab to MK-3475 (Pembrolizumab) in Patients with High Risk Resected Melanoma		

This guide was developed in collaboration with the SWOG ORP Liaison Committee and the SWOG Protocol Coordinators Operations Office.
The purpose of the guide is to facilitate a thorough review of a NCI NCTN Group Clinical Trial for the following purposes; determining site feasibility, protocol implementation planning and a study aide for research staff training.

Suggested documents to include during the clinical trial review: Study protocol. Consent, Funding memorandum, National coverage analysis, Local Coverage Analysis, Data collection forms and other trial related documents as needed.

To ensure accurate and current information, update this form with new protocol amendments as needed and include the specific section or page of the protocol for a quick reference.

Intervention / Therapeutic ☒	**Non-Interventional** ☐	**NCT#: 02506153**
NCI Anticipated Accrual: 1378	**NCTN Group credit assignment(s):** 1 group or split between the following: ☒ SWOG ☐ Alliance ☐ NRG ☐ ECOG ☐ CCTG	
Site Reimbursement Considerations:	**Base Award**: Standard/ High Performing funds with additional funds for specimen processing, PRO administration, image submission and additional audits. **Credits**: As above **See attached funding memo for specific reimbursement**	
Participating Site(s): Loyola University Chicago		

National CA Available? Version 4-1-2015, no update with protocol revision 1-19-2017	☒ Yes ☐ No	**Are there any special billing or contractual considerations?** **Local CA considerations**: Triglyceride levels at any time point is not a billable event (NCD 190.23) **Patient billing contact**: Click or tap here to enter text.
Is this an FDA Registration Trial?	☒ Yes ☐ No	**What is the monitoring plan?** 1st onsite visit within 6 months of 1st patient randomization. (Section 18.6)
Are there additional regulatory requirements? (i.e., Master Trial File) ☒ Yes ☐ No		Master Trial File and Study Specific Site Training Requited

Study Objectives

Provide a clear statement of study objectives with specific reference to all study modalities and type of data needed to correlate with objectives: (i.e., survival, disease response, disease-free interval)

Primary:

1) To compare overall survival (OS) of patients with resected Stage III and IV melanoma treated with physician/patient choice of either high dose interferon alfa-2b or ipilimumab versus MK-3475 (pembrolizumab)2) Among patients who are PD-L1 positive, to compare OS of patients with resected Stage III and IV melanoma treated with physician/patient choice of either high dose interferon alfa-2b or ipilimumab versus MK-3475 (pembrolizumab).
3) To compare relapse-free survival (RFS) of patients with resected Stage III and IV melanoma treated with physician/patient choice of either high dose interferon alfa-2b or ipilimumab to MK-3475 (pembrolizumab).

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4) Among patients who are PD-L1 positive, to compare RFS of patients with resected Stage III and IV melanoma treated with physician/patient choice of either high dose interferon alfa-2b or ipilimumab to MK-3475 (pembrolizumab

Secondary:

1)To estimate OS and RFS for patients who are PD-L1 negative or PD-L1 indeterminate in this population.
2)To compare OS and RFS of patients between the two arms within PD-L1 positive and negative subgroups and to look at the interaction between PD-L1 (positive versus negative) and treatment arm.
3) To assess the safety and tolerability of the regimens.

Additional:

1)To bank tissue and whole blood in anticipation of future correlative studies in this patient population.
2) To evaluate PD-L1 expression through immunohistochemistry assay.
3) To evaluate the effect of treatment-related side effects that may have an impact on the health-related domains of quality of life (QOL) using the FACT-BRM and EQ-5D-3L between patients treated with physician/patient choice of either high dose interferon alfa-2b or ipilimumab and MK-3475 (pembrolizumab).
4)Pharmacokinetic (PK) and anti-drug antibody (ADA) testing will be performed on all patients receiving MK-3475 (pembrolizumab). These analyses will evaluate: exposure-response analyses for activity and efficacy, potential pharmacodynamics biomarkers, and the safety of MK-3475 (pembrolizumab).

Background

Provide rationale for doing the study. Should include history of toxicities from previous studies to allow some assessment of expected toxicities and severity. This will provide a reference point for development of study parameters, case report forms and eligibility. (For protocol development reviewer: Are the references applicable for the patient population?)

Notes:

Comparing approved drugs for adjuvant treatment with Pembrolizumab (MK-3475). Interferon have known toxicities in this patient population. Pembrolizumab in an adjuvant setting is not approved. Assess the toxicity profile and RFS rate of Pembrolizumab to the standard approved drugs. Does PDL1 testing in melanoma predict the outcome in this patient population?
Patients will be randomized between Arm 1 and Arm 2 in a 1:1 fashion.
Stratification is based on:
1)Surgically resected AJCC stage IIIA (N2a) versus IIIB versus IIIC versus IV
2)PD-L1 status positive versus negative versus indeterminate (Institutions will be blinded to the patient's PD-L1 status)
3)Planned control arm regimen IFN vs. Ipilimumab

For Non-Treatment Studies Only: Schema and / or Plan **Protocol Section:** 7.0

Guide Questions	Review	Site Implementation Plan / Considerations
How will patients be identified and screened for this study?	N/a	Click or tap here to enter text.
What if any departments need to be involved in conducting the trial?	N/a	Click or tap here to enter text.

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Are there any supplies or equipment provided for this study?	N/a	Click or tap here to enter text.
Required training?	N/a	Click or tap here to enter text.

Study Participant Selection (eligibility, staging, stratification) **Protocol Section:** 5.0 , 6.0

What are the histological classifications and staging?

Refer to Section 5.0 in SWOG protocol.
Stage IIIA (N2a), IIIB, IIIC or Stage IV completely resected melanoma Patients with mucosal or other non-cutaneous origin are eligible. Patients with brain metastasis or ocular melanoma are not eligible.
Patients must be registered within 98 days of the last surgery performed to render the patient free of disease.
Reference materials:
AJCC staging version _7th edition, 2010_____

Are there any compatible trials for this patient population that are appropriate for co-enrolling? **If yes, list protocol number: : Blood and Tumor banking consent**	☒ Yes ☐ No

Treatment Plan and Schedule of Events (study calendar) **Protocol Section:** 7.0,9.0

Guide Questions	Site Implementation Plan / Considerations
Treatment setting (outpatient, inpatient, home)	Outpatient Infusion Home injections for IFN
Overall duration of study:	IFN- 52 weeks of active treatment Ipilimumab- 4 doses every 3 weeks and maintenance up to 3 years Pembrolizumab- 49 weeks or 12 doses (6 cycles). Follow up- see footnotes on calendar pages for schedule for non-relapse and relapse follow up (10 years or until death)
Are there provisions for missed study events and scheduling issues?	See Section 8.2 Interferon See Section 8.3 Ipilimumab See Section 8.4 MK3475 (missed doses should be made up)
Duration of each treatment dose for scheduling purposes.	Arm 1 HDI interferon alfa 2a (Intron-A) IV, M-F for 4 weeks 20 minute infusion and then subcutaneous 3x/week for 48 weeks Or Ipilimumab 10mg/kg IV every 3 weeks for 4 doses and the IV every 12 weeks for a total of 3 years. 90 minute infusion. Arm 2: MK-3475 (Pembrolizumab) IV every 3 weeks for 18 doses. 30 minute infusion.
Concurrent administration of agents, timing of pre-meds and hydration.	Premedication for the management of Infusion reactions associated with MK-3475 administration. Grade 1 no premeds, Grade 2 pre-medicate 1.5 hours prior to the infusion of MK-3475 with Diphenhydramine 50mg PO and Acetaminophen 500-1000mg PO.

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	See section 8.4 for specifics. Grade 4 do not administer MK-3475.
Is sequencing of therapies routine if multiple agents, is sequencing of agents clearly specified and whether there needs to be rest period between administration?	N/A
Are supportive therapies specified in the protocol? Are they non-routine?	Steroids for immune mediated side effects. Infliximab for severe immune mediated side effects.
Are any medications contraindicated with this treatment?	1). Any chemotherapy or biologic therapy (investigational or not), live vaccines, radiation therapy, glucocorticoids for any purpose other than to modulate symptoms from an event of immunologic etiology 2). Replacement corticosteroids are permitted, however consultation is required for doses greater than 10mg prednisone. 3). Due to the possible effect of treatment with ipilimumab on the immunologic response to infectious disease vaccines, patients must not have had any infectious disease vaccination (e.g., standard influenza, H1N1 influenza, pneumococcal, meningococcal, tetanus toxoid) 4 weeks before or after any dose of ipilimumab.
Are guidelines for dose calculations / rounding / capping (i.e., maximum BSA, Cr Cl estimation, actual weight vs ideal weight vs adjusted weight) provided?	Dose calculations will be based on actual weight.
Administrative considerations, central vs peripheral venous access.	Peripheral access
If drug is available via PO/IV, and there is institutional standard, does the protocol specify whether one route or other is required?	Ipilimumab, Pembrolizumab and HD Interferon are given IV and Interferon (Intron A) is given subcutaneous.
Are there special considerations for patients to manage during their treatment?	Education for Interferon self- injection and specific self-monitoring for side effects with ipilimumab and MK3475
What type of staff education is needed for administering treatment?	Approved drugs. MK3475 is approved for advanced melanoma and other diseases and has been given in our day hospital setting.
What type of patient education is needed?	Self-injection and side effect monitoring.
Is drug administration congruent with known site institutional standards/package insert? If deviation, please comment / or specify.	Ipilimumab will be given at 10mg/kg which is the approved dose for adjuvant, but not for the metastatic population.
Are treatment plan order sets needed / study aides	Beacon order sets Immune mediated checklist to be used prior to treatment

Registration Section: 13.0

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Guide Questions	Site Implementation Plan / Considerations
Are the pre-study testing requirements routine? (refer to Coverage Analysis) ☐ Yes ☐ No If not, is there funding identified to cover, and is this adequately addressed in the cost of the funding memorandum? Refer to funding memo and coverage analysis.	See Section 9.0 version 1-19-17 Added ECG, Echo, CPK and Troponins at baseline for patients with history of CHF or known underlying cardiovascular disease and are at risk for exposure to cardiotoxic drugs. Pts with evidence at baseline should have a cardiologist consult. No
Patient Registration: System used: OPEN ☒ or Other ☐ Click or tap here to enter text.	
Is there more than 1 registration step? ☒ Yes ☐ No **If yes, what are the time frames?**	Step 1- Screening registration. Must be registered within 3 business days prior to submission of tissue sample PDL-1 and 98 days to the last surgery. Step 2- Randomization must register with 7 days of receipt of email results of PDL-1 testing.
Time frame from registration to treatment and / or drug delivery.	No more than 5 working days prior to the start of treatment. Ipilimumab and Interferon are commercially available. Pembrolizumab can be obtained 24-48 hours following randomization of patient.
How will patients be identified and screened for this study.	Patients will be referred internally from the surgical oncology team and externally from referrals.

Site Credentialing Requirements: **Protocol Section:** Click here to enter text. **Note: for SWOG, this may also be included / addressed in Section 13 or 15 of the protocol.**	
Are there site certifications requirements for certain modalities?	Site Specific training required – see SWOG website
Radiology **Credentialing** ☐ Yes ☒ No **Protocol training** ☒ Yes ☐ No **Phantom scans required** ☒ No ☐ Yes When: Click or tap here to enter text. **Central confirmatory review for imaging** ☒ Yes ☒ No **Site or Sponsor Contact:** Click or tap here to enter text.	Specific needs: 1)Imaging will be need to be uploaded to Triad. 2)PET-CT or CT chest/ABD/pelvis (or MRI) and Neck performed every 12 weeks. 3)During treatment a brain MR/ CT performed annually during treatment and follow up.

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Laboratory and Pathology **Site training required** ☐ Yes ☒ No **Central confirmatory review required** ☒ Yes ☐ No **Time point:** Prior to randomization **Clinical lab contact:** Click or tap here to enter text. **Pathology contact**: Routine procedure	Specific needs: Pathology slides for PDL1 expression. 5 unstained slides from primary, lymph node, or metastatic site within 7 days after registration. Slides should be sent within 20 days of cutting. Identify the sample with MK3475-053 when submitting the sample. Tissue should be reviewed by a local pathologist to ensure sufficient tumor cells are present in the sample. Shipment should be entered into the SWOG
Surgical **Credentialing** ☐ Yes ☒ No **Surgical contact**: Click or tap here to enter text.	Specific needs: N/A
Radiation Therapy **Credentialing** ☐ Yes ☒ No **Radiation contact**: Click or tap here to enter text.	Specific needs: N/A
Contacts from other departments that need to be involved.	Dr. GXXXX

Investigational Drug(s) Supply and Administration Information. Protocol Section: 7.0, 8.0, 3.0

Drug	Guide Review	
1. Interferon	**Drug formulation and administration requirements**	20 MU/m2/d days 1-5 IV for 4 weeks 10 MU/m2/d days 1,3,5 SC for 48 weeks
	Supportive drug administration requirements (ex. hydration, premeds, etc.)	See protocol
	Are drug self- administration diaries required or included?	Self-injection diary
	Duration of each treatment dose for scheduling purposes.	20 minute infusion. Subcutaneous self-injections 3x/week for 48 weeks.
Drug Supplier: **Sponsor NCI ☐ Commercial ☒**	**NCI supply procurement timelines.** **NCI investigational drug storage.**	N/A
	Commercial drug procurement local considerations. **Institutional Formulary**	**Specific needs**

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Drug Section Continued

	☒ Yes ☐ No **2. Specialty Pharmacy**: Click here to enter text.	Pre cert and NCCN compendium check. Specialty pharmacy to obtain self-injection IFN.
IND status: ☐ **Exempt** ☐ **Non-Exempt** ☒ N/A **If Non-Exempt, who sponsors the IND?** Click or tap here to enter text. **IND#**: Click or tap here to enter text. **If Exempt, do you need an exemption letter for your IRB?** ☐ Yes ☐ No ☐N/A		
2. Ipilimumab	**Drug formulation and administration requirements.**	10mg/kg every 3 weeks for 4 doses and then maintenance every 12 weeks for 3 years.
	Supportive drug administration requirements (ex. hydration, premeds, etc.)	See protocol
	Are drug self- administration diaries required or included?	N/A
	Drug formulation and administration requirements.	90 minute infusion
Drug Supplier: **Sponsor NCI** ☐ **Commercial** ☒	**NCI supply procurement timelines.** **NCI investigational drug storage.**	N/A
	Commercial drug procurement local considerations. **1.Institutional Formulary** ☒ Yes ☐ No **2.Specialty Pharmacy**: Click here to enter text.	**Specific Needs** Precert and NCCN compendium check
IND status: ☐ **Exempt** ☐ **Non-Exempt** ☒ N/A **If Non-Exempt, who sponsors the IND?** Click or tap here to enter text. **IND#**: Click or tap here to enter text. **If Exempt, do you need an exemption letter for your IRB?** ☐ Yes ☐ No ☒N/A		

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3. **MK-3475 (Pembrolizumab)**	**Drug formulation and administration requirements.**	200mg IV every 3 weeks for 18 doses.
	Supportive drug administration requirements (ex. hydration, premeds, etc.)	If prior infusion reaction. See section 8.4 for specifics.
	Are drug self- administration diaries required or included?	N/A
	Duration of each treatment dose for scheduling purposes.	30 Minute infusion
Drug Supplier: **Sponsor NCI** ☒ **Commercial** ☐	**NCI supply procurement timelines.** **NCI investigational drug storage.**	Pembrolizumab can be obtained 24-48 hours following randomization of patient.
	Commercial drug procurement local considerations. **1.Institutional Formulary** ☐ Yes ☐ No ☒ N/A **2.Specialty Pharmacy**: Click here to enter text.	**Specific Needs** Click or tap here to enter text.

IND status:

☐ **Exempt** ☒ **Non-Exempt** ☐ N/A

If Non-Exempt, who sponsors the IND? NCI **IND#**: 125133

If Exempt, do you need an exemption letter for your IRB? ☐ Yes ☐ No ☒ N/A

Local pharmacy contact information:	B MXXXX
Implementation considerations:	Build ERx for Pemrolizumab

Safety Monitoring and Dose Modifications. Protocol Section 7.0 ,8.0

CTCAE: ☒ Version Click here to enter text.

☐ Other: Click here to enter text.

Drug Toxicities: Refer to consent and protocol section: Click here to enter text.

Notes

1).Interferon side effects: Common (>20%): infection, diarrhea, nausea, vomiting, flu-like symptoms including fever, chills body aches, and muscle pain, fatigue, loss of appetite, disorder of taste, headache, confusion, depression, suicidal

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Safety Monitoring and Dose Modifications Continued

thoughts, alopecia, rash, and/or pain.
Less common (4 to ≤ 20%): cardiomyopathy, cirrhosis of liver, hepatotoxicity, thrombocytopenia, organ damage and/or failure, edema, injection site extravasation, erythema of injection site, generalized exfoliative dermatitis, Stevens-Johnson Syndrome, toxic epidermal necrolysis, transient ischemic attack (TIA), cerebral infarction, Cerebrovascular accident, and/or ischemic stroke.
Rare (≤ 3%), and serious: anemia, arrhythmias, ischemic heart disease, myocardial infarction, NSTEMI, hypersensitivity reaction, anaphylaxis.
2).Ipilimumab side effects: Adrenal insufficiency Other (hypopituitarism/hypophysitis) Other (testosterone deficiency)Hyperthyroidism, Hypothyroidism, Eye disorders, Abdominal pain, colitis, constipation, enterocolitis, esophagitis, colonic perforation, ileus, pancreatitis, vomiting, nausea, diarrhea, fatigue, chills, Fever.
3).MK-3475 (Pembrolizumab) side effects: Less likely: Anemia, lymph node pain, adrenal insufficiency, endocrine disorders, colitis, diarrhea, mucositis, nausea, pancreatitis, chills, fever, infusion related reaction, hepatobiliary (autoimmune hepatitis), elevated ALT, AST, Bili, CPK, arthralgia, arthritis, avascular necrosis, joint effusion, myalgia, pleuritic pain, pneumonitis, bullous dermatitis, erythredema, pruritus, rash, urticaria.Rare/Serious: Myocarditis, pericarditis, uveitis, anaphylaxis, cytokine release syndrome, immune system disorder, serum sickness, nervous system disorders, renal and urinary disorders, erythema multiforme, Stevens-Johnson syndrome, vasculitis.

Are dose modifications consistent with standard of care and known drug toxicities? Are dose mods clear and consistent throughout the sections? (e.g., if multiple agents, is it clear when to hold/re-start therapy with each agent?)

1).Ipilimumab No dose reductions for ipilimumab. The dose of ipilimumab will either be given or delayed/discontinued. Patients may develop study drug-related toxicities that may require skipping doses or dose discontinuation. See the specific criteria in section 8.3 for dose modifications, restarting or discontinuing treatment.
2).MK-3475 No dose modifications for MK-3475. Missed doses should be made up. See section 8.4 for specific guidelines for drug related adverse events and dosing.
3). Dose modifications for Interferon can be found in section 8.2b. If a patient experiences any of the toxicities listed below, the patient must have a dose modification as follows: treatment must be held until the toxicity returns to institution's normal limits, patient's baseline, or normal limits per CTCAE or as listed in the table under Section 8.2c, then reduced per above. A patient requiring dose modification(s) in the first 4 weeks will therefore commence Week 5 at full dose. Doses missed during treatment due to toxicity, patient compliance, holiday, etc. should not be made up.

Criteria for holding, re-instituting, discontinuing or escalating treatment clearly stated.

Ipilimumab may not be restarted while the patient is being treated with oral or intravenous corticosteroids for the management of immune related adverse events except for patients on stable doses of hormone replacement therapy for adrenal insufficiency such as hydrocortisone. In addition, patients must be off and have no requirement for oral/I.V. corticosteroids for at least 1 week and meet the other criteria for retreatment as outlined below. Also must not be receiving any immunomodulating drugs such as infliximab (Remicade) for immune related adverse events while receiving ipilimumab or MK3475. See Section 8.3 and 8.4 for restarting Ipilimumab and MK-3475.

Any special instructions for treating adverse events?

See commercial insert for management of IRAE's for Ipilimumab. See section 8.4b for management of AE's on MK-3475

Timeframe for reporting AEs and SAEs in relation to last dose.

Section 16.1 for Expedited reporting within 30 days of last administration of MK-3475. See chart for reporting timeframes. Specifically note all hospitalizations are reported and grade 3, 4 & 5 non-hospitalized. SPEER reporting see table 16.1 for MK-3475.See table 16.2 for reporting on IFN and Ipilimumab (commercial drug).

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Non-routine requirements for SAE reporting. Report routinely in medidata RAVE
Any special assessments and reporting for commercial drugs. See Section 16.2, Unexpected grade 4 and all grade 5
Other considerations, ex. documentation tools, etc. Online CTEP-AERs for all SAE reporting

Criteria for Evaluation and Endpoints **Protocol Section:** 10.0

Guide Questions	Site Implementation Plan / Considerations
Disease response criteria: ☒ RECIST ☐ Other: Click here to enter text.	Click or tap here to enter text.
Criteria for removal from study routine? **Protocol Section** Click here to enter text.	For removal see section 7.5
Procedure for discontinuing patient from study. Protocol Section Click here to enter text.	Follow for 30 days post treatment and complete off treatment information
Other:	Click or tap here to enter text.
Documentation considerations.	Click or tap here to enter text.

Data Submission Schedule and Considerations. **Protocol Section:** 14.0

Guide Questions	Site Implementation Plan / Considerations
Data capture system:	☒ RAVE Medidata ☐ Other (specify): Click here to enter text.
Is timeframe for data reporting routine? If not, then explain.	Timeframe for reporting data see section 14.0. Initial data forms are due within 7 days or registration step 1. Within 14 days of Step 2 Randomization, baseline laboratory values and submit IRCO via Triad. Within 14 days after each cycle of treatment submit, treatment form, adverse event form, lab values form, and concomitant med form. Follow up within 14 days of disease assessment submit until recurrence or 5 years after randomization submit radiology reports to Rave and IROC via Triad.
Data submission effort.	Additional requirements to redact, scan and upload.
Is additional data required that is not routine? (i.e., ECG monitoring.)	None identified

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Pathology submission requirements.	See below for correlative studies
Imaging:	☒ TRIAD: Click here to enter text. ☐ Other: Click here to enter text.
QOL / PRO submissions? ☒ Yes ☐No List Patient Report Outcomes FACT-BRM, EQ-5D-3L	Schedule of QOL: Baseline, wk 1, 4, then prior to Cycles 3, 4, 5, 6 and week 24 after date of last Tx, week 48 after date of last Tx. QOL- Provide a calendar with upcoming dates to make the patient aware of impending questionnaires. Patients who relapse before 48 after the last treatment will complete a questionnaire at relapse. Patients do not need to complete any further questionnaires after relapse. Patients who go off protocol therapy before Week 49 (cycle 6) without recurrence will complete the two post treatment questionnaires at week 24 and 48 form the last date of treatment. Cover sheet for QOL need to be completed with the set of completed forms for tracking purposes.
PRO surveys (effort involved, special arrangements: paper or electronic). Are there survey tools provided? If electronic, does special arrangements need to be made? **Who is the PRO contact for the study?**	PRO training recommended – training link on CRA home page, quicklinks Click or tap here to enter text.
Documentation considerations.	Click or tap here to enter text.

Correlative Studies **Protocol Section:** 15.0

Guide	Site Implementation Plan / Considerations
Biologic specimens.	Sent to multiple labs Lab #218 Lab Corp for PDL-1 Lab # 201 Nationwide for specimen banking Lab #219 Serum PK, ADA samples Initial pathology sample (fresh or archived) from primary, lymph node or metastatic site- 5 unstained slides on positively charged slide. Requesting that the local pathologist sign the S1404 local pathology review form. Slides must be shipped within 20 days of cutting the slides. See protocol for specific processing. Pathology for banking (optional): 10 unstained slides and 1 H&E from tumor at baseline / relapse.
Are kits provided? ☒ Yes ☐No	Order through specimen tracking on SWOG
Specimen processing, storage, shipping considerations.	Multiple blood draws

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Are there multiple time points for collections? Over what period of time?	Yes. Serum, Plasma, Buffy coat for banking (optional): 3 (10ml) SST, 3 (10ml) lavender at baseline, start of Cycle 3, 4 and removal from Tx or relapse. Draw labs based on schedule and not at rescheduled time points. K/ ADA samples for patients on MK3475. 1 (3ml) SST and 1 (8.5ml) serum at wk 1, 4, Cycle 2, 3, 4, 6 and 30 days after last infusion.
Resource studies – example: economic	N/A
Are any of these studies optional?	Banking study only

Recruitment and Marketing Strategies

Recruiting materials generally attached in the appendices (Section 18 of the protocol) Routine

Reviewer: Click or tap here to enter text.	**Date:** Click or tap here to enter text.

Implementation Plan and Effort Analysis

Study Team Click or tap here to enter text.

Clinical Departments that will be involved with this clinical trial:

Click or tap here to enter text.

Clinical Trial Acuity

Clinical Coordination Resources : High , additional funds for tissue and lab processing, QOL, refer to funding memo

Regulatory Management Resources: High, additional auditing requirements as recommended by FDA, 1K per audit

Data Management Resources: High, funds for additional image transfer requirements

Implementation Planning Notes:

Click or tap here to enter text.

Implementation Planning Notes:

Click or tap here to enter text.

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Additional Implementation Planning by Milestones (optional)

Study Milestones	Schedule of Events / Requirements	Implementation Plan	Comments
Start Up Considerations and Research Team Training Needs	1). TRIAD training needed for study team 2.PRO training 3). Online mandatory SWOG training	Schedule TRIAD training Schedule PRO training	Click or tap here to enter text.
Clinical Staff Study Training and Implementation Considerations	Routine trial education	Click or tap here to enter text.	Click or tap here to enter text.
Screening/eligibility	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Randomization	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Treatment period	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
AE reporting	Anticipate increase volume	Click or tap here to enter text.	Click or tap here to enter text.
Disease response	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Correlative studies	Pathology Requesting that the local pathologist sign the S1404 local pathology review form	Send protocol highlighting pathology section to path dept	Click or tap here to enter text.
End of treatment	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Follow up	Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Study Close Out			

Presentation