July 10 2015 Date of analysis for the patent claim

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Phase 2 Study of MK-3

Latest

- A study version is represented by a ro
- Select two study versions to compare.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
- Click "Compare" to do the comparison and show the differences.
- Select a version's Submitted Date link to see a rendering of the study for that version.
- The yellow A/B choices in the table indicate the study versions currently compared below. A yellow table row indicates the study version currently being viewed.
- Hover over the "Recruitment Status" to see how the study's recruitment status changed.
- Study edits or deletions are displayed in ~~red~~.
- Study additions are displayed in green.

Study Record Versions

Version	A	B	Submitted Date	Changes
1	◉	◉	June 10, 2013	None (earliest Version on record)
2	○	○	June 12, 2013	Outcome Measures and Study Status
3	○	○	September 20, 2013	Recruitment Status, Study Status, Contacts/Locations and Oversight
4	○	○	May 21, 2014	Study Status and Conditions
5	○	○	June 25, 2014	Study Status, Contacts/Locations and Outcome Measures
6	○	○	September 15, 2014	Study Status and Contacts/Locations
7	○	○	December 26, 2014	Contacts/Locations and Study Status
8	○	○	January 29, 2015	Study Status and Contacts/Locations
9	○	○	February 26, 2015	Study Status and Contacts/Locations
10	○	○	April 15, 2015	Study Status, Contacts/Locations and Eligibility
11	○	○	June 9, 2015	Study Status, Eligibility and Study Design
12	○	○	January 4, 2016	Study Status and Eligibility

History of Changes for Study: NCT01876511

Phase 2 Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors

Latest version (submitted February 4, 2020) on ClinicalTrials.gov

- A study version is represented by a row in the table.
- Select two study versions to compare. One each from columns A and B.
- Choose either the "Merged" or "Side-by-Side" comparison format to specify how the two study versions are to be displayed. The Side-by-Side format only applies to the Protocol section of the study.
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12	○	○	January 4, 2016	Study Status and Eligibility

Version	A	B	Submitted Date	Changes
13	○	○	June 28, 2016	Study Status
14	○	○	November 10, 2016	Study Status
15	○	○	May 3, 2017	Study Status and Contacts/Locations
16	○	○	August 28, 2017	Study Status
17	○	○	October 5, 2017	Contacts/Locations, Arms and Interventions, Study Status, Eligibility, Outcome Measures, Conditions and Study Description
18	○	○	December 13, 2017	Study Status and Conditions
19	○	○	February 27, 2018	Contacts/Locations and Study Status
20	○	○	March 27, 2018	References, Study Status, Eligibility and Conditions
21	○	○	January 8, 2019	Study Status, Contacts/Locations and Eligibility
22	○	○	February 18, 2019	Contacts/Locations, Study Status, Eligibility and Conditions
23	○	○	February 18, 2019	Contacts/Locations and Study Status
24	○	○	March 4, 2019	Conditions, Study Status
			▶ Results Submission Events	
25	○	○	December 20, 2019	Recruitment Status, Study Status, Outcome Measures, Contacts/Locations, Arms and Interventions, Study Design, Conditions, Oversight, Study Identification, Document Section, Results, IPDSharing, Eligibility and Study Description
26	○	○	January 17, 2020	Study Status and Adverse Events
27	○	○	February 3, 2020	Study Status
28	○	○	February 4, 2020	Study Status

Compare

Comparison Format: ◉ Merged ○ Side-by-Side

Scroll up to access the controls

Study NCT01876511

Submitted Date: June 10, 2013 (v1)

▼ Study Identification

Unique Protocol ID: J1365

Brief Title: Phase 2 Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors

Official Title: Phase 2 Study of MK-3475 in Patients With Microsatellite Unstable (MSI) Tumors

Secondary IDs: MK-3475-016 [Merck]

NA_00085756 [JHMIRB]

Study Status

Record Verification:	June 2013
Overall Status:	Not yet recruiting
Study Start:	July 2013
Primary Completion:	June 2017 [Anticipated]
Study Completion:	
First Submitted:	June 10, 2013
First Submitted that Met QC Criteria:	June 10, 2013
First Posted:	June 12, 2013 [Estimate]
Last Update Submitted that Met QC Criteria:	June 10, 2013
Last Update Posted:	June 12, 2013 [Estimate]

Sponsor/Collaborators

Sponsor:	Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
Responsible Party:	Sponsor
Collaborators:	Merck Sharp & Dohme LLC

Oversight

U.S. FDA-regulated Drug:	
U.S. FDA-regulated Device:	
Data Monitoring:	Yes

Study Description

Brief Summary:	This study will be looking at whether MK-3475 (an antibody that blocks negative signals to T cells) is effective (anti-tumor activity) and safe in three different patient populations. These include: 1. patients with MSI positive colon cancer, 2. patients with MSI negative colon cancer, and 3. patients with other MSI positive cancers.
Detailed Description:	

Conditions

Conditions:	MSI Positive Colorectal Cancer MSI Negative Colorectal Cancer MSI Positive Non-Colorectal Cancers

Keywords:

Study Design

Study Type: Interventional

Primary Purpose: Treatment

Study Phase: Phase 2

Interventional Study Model: Parallel Assignment

Number of Arms: 3

Masking: None (Open Label)

Allocation: Non-Randomized

Enrollment: 71 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: MSI Positive Colorectal Cancer	Drug: MK-3475 MK-3475 10 mg/kg every 14 days
Experimental: MSI Negative Colorectal Cancer	Drug: MK-3475 MK-3475 10 mg/kg every 14 days
Experimental: MSI Positive Non-Colorectal Cancer	Drug: MK-3475 MK-3475 10 mg/kg every 14 days

Outcome Measures

Primary Outcome Measures:

1. Immune-related progression free survival (irPFS) rate at 20 weeks in patients with MSI positive and negative colorectal adenocarcinoma using immune related response criteria (irRC)
   [Time Frame: 4 years]

2. Objective response rate (irORR) at 20 weeks in patients with MSI positive and negative colorectal adenocarcinoma using immune related response criteria (irRC)
   [Time Frame: 4 years]

3. Immune-related progression free survival (irPFS) rate in patients with MSI positive non-colorectal adenocarcinoma using immune related response criteria (irRC) at 20 weeks
   [Time Frame: 4 years]

Secondary Outcome Measures:

1. Overall survival
   [Time Frame: 4 years]

2. irPFS and PFS in patients with MSI positive and negative tumors at 28 weeks using irRC and RECIST 1.1
   [Time Frame: 4 years]

3. Best overall response rate and disease control rate in patients with MSI positive and negative tumors
   [Time Frame: 4 years]

4. Number of participants experiencing immune-related toxicities (IRAEs)
   [Time Frame: Continuous]

5. Does MSI as a marker predict treatment response
   [Time Frame: 4 years]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: No

Criteria: Inclusion Criteria:

1. Arm 1 only: Patients with MSI positive colorectal cancer
2. Arm 2 only: Patients with MSI negative colorectal cancer
3. Arm 3 only: Patients with MSI positive non-colorectal cancer
4. Have measurable disease
5. ECOG Performance Status of 0 to 1
6. Adequate organ function as defined by study-specified laboratory tests
7. Must use acceptable form of birth control through the study and for 28 days after final dose of study drug
8. Signed informed consent form
9. Willing and able to comply with study procedures
10. Agree to have a biopsy of their cancer

Exclusion Criteria:

1. Currently have or have history of certain study-specified heart, liver, kidney, lung, neurological, immune or other medical conditions
2. Systemically active steroid use
3. Patients on home oxygen

4. Patients who have had prior treatment with anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, anti-OX-40, anti-CD40, or anti-CTLA-4 antibodies
5. Another investigational product within 28 days prior to receiving study drug
6. Pregnant or lactating
7. Conditions, including alcohol or drug dependence, or intercurrent illness that would affect the patient's ability to comply with study visits and procedures

Contacts/Locations

Study Officials: Dung Le, MD
Principal Investigator
Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins

Locations: **United States, Maryland**

Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins
Baltimore, Maryland, United States, 21231
Contact: Contact: Holly Kemberling, RN 443-287-5013 hkember1@jhmi.edu
Contact: Principal Investigator: Dung Le, MD

IPDSharing

Plan to Share IPD:

References

Links:

Available IPD/Information: