Study of Nivolumab in Combination With Ipilimumab or Standard of Care Chemotherapy Compared to the Standard of Care Chemotherapy Alone in Treatment of Participants With Untreated Inoperable or Metastatic Urothelial Cancer

CLINICALTRIALS.GOV IDENTIFIER	RECRUITMENT STATUS	FIRST POSTED	LAST UPDATE POSTED
NCT03036098	RECRUITING	JANUARY 30, 2017	JUNE 16, 2022

STUDY DESCRIPTION

Brief Summary

The purpose of this study is to determine whether an investigational immunotherapy nivolumab in combination with ipilimumab or in combination with standard of care chemotherapy is more effective than standard of care chemotherapy alone in treating participants with previously untreated inoperable or metastatic urothelial cancer.

Condition or Disease: Urothelial Cancer

Intervention/treatment: Biological: Nivolumab
Biological: Ipilimumab
Drug: Gemcitabine
Drug: Cisplatin
Drug: Carboplatin

Phase: Phase 3

DETAILED DESCRIPTION

N/A

STUDY DESIGN

Study Type: Interventional

Estimated Enrollment : 1307 participants

Intervention Model : Parallel Assignment

Masking: None (Open Label) ()

Primary Purpose: Treatment

Official Title: Study of Nivolumab in Combination With Ipilimumab or Standard of Care Chemotherapy Compared to the Standard of Care Chemotherapy Alone in Treatment of Participants With Untreated Inoperable or Metastatic Urothelial Cancer

Actual Study Start Date: March 2017

Estimated Primary Completion Date: November 2022

Estimated Study Completion Date: July 2025

ARMS AND INTERVENTIONS

Arm	Intervention/treatment
Experimental: Arm A: Investigational immunotherapy	Biological: Nivolumab Specified Dose on Specified Days Biological: Ipilimumab Specified Dose on Specified Days
Experimental: Arm C: Investigational immunotherapy	Biological: Nivolumab Specified Dose on Specified Days Drug: Gemcitabine Specified Dose on Specified Days Drug: Cisplatin Specified Dose on Specified Days
Active Comparator: Arm B: Standard of care chemotherapy	Drug: Gemcitabine Specified Dose on Specified Days Drug: Cisplatin Specified Dose on Specified Days Drug: Carboplatin Specified Dose on Specified Days
Active Comparator: Arm D: Standard of care chemotherapy	Drug: Gemcitabine Specified Dose on Specified Days Drug: Cisplatin Specified Dose on Specified Days

OUTCOME MEASURES

Primary Outcome Measures:
1. Overall survival (OS) in cisplatin-ineligible randomized participants [Time Frame: Up to 55 months]
2. Overall survival (OS) in PD-L1 positive (>=1%) randomized participants by immunohistochemistry (IHC) [Time Frame: Up to 52 months]
3. Progression-free survival (PFS) by blinded independent central review (BICR) (using RECIST 1.1) in cisplatin-eligible participants with previously untreated, unresectable or metastatic UC [Time Frame: Up to 64 months]
4. Overall survival (OS) in cisplatin-eligible participants with previously untreated, unresectable or metastatic UC [Time Frame: Up to 64 months]

Secondary Outcome Measures:
1. Overall survival (OS) in all randomized participants [Time Frame: Up to 55 months]
2. Progression-free survival (PFS) by blinded independent central review (BICR) (using Response Evaluation Criteria in Solid Tumors (RECIST) 1.1) in cisplatin-ineligible randomized participants [Time Frame: Up to 55 months]
3. Progression-free survival (PFS) by blinded independent central review (BICR) (using Response Evaluation Criteria in Solid Tumors (RECIST) 1.1) in PD-L1 positive (≥1%) randomized participants [Time Frame: Up to 55 months]
4. Progression-free survival (PFS) by blinded independent central review (BICR) (using Response Evaluation Criteria in Solid Tumors (RECIST) 1.1) in all randomized participants [Time Frame: Up to 55 months]
5. European Organisation for Research and Treatment of Care (EORTC) QLQ-C30 Global Health Status score in all randomized participants [Time Frame: Up to 55 months]
6. European Organisation for Research and Treatment of Care (EORTC) QLQ-C30 Global Health Status score in cisplatin eligible participants with previously untreated, unresectable or metastatic UC [Time Frame: Up to 64 months]
7. Progression-free survival (PFS) by BICR (using RECIST 1.1) by immunohistochemistry (IHC) [Time Frame: Up to 64 months]
8. Overall survival (OS) by PD-L1 expression at ≥ 1% expression by immunohistochemistry (IHC) [Time Frame: Up to 64 months]

ELIGIBILITY CRITERIA

Ages Eligible for Study: 18 Years and older (Adult, Older Adult)

Sexes Eligible for Study: All

Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
Histological or cytological evidence of metastatic or surgically inoperable transitional cell cancer (TCC) of the urothelium involving the renal pelvis, ureter, bladder or urethra No prior systemic chemotherapy for metastatic or surgically inoperable urothelial cancer (UC) Eastern Cooperative Oncology Group (ECOG) performance status (PS) 0 or 1 Women and men must agree to follow specific methods of contraception, if applicable
Exclusion Criteria:
Disease that is suitable for local therapy administered with curative intent Any serious or uncontrolled medical disorder in the opinion of the investigator that may increase the risk associated with study participation or study drug administration or interfere with the interpretation of study results Prior treatment with an anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-CTLA-4 antibody, or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways
Other protocol-defined inclusion/exclusion criteria apply

CONTACTS AND LOCATIONS

Contacts

Contact: BMS Study Connect Contact Center http://www.bmsstudyconnect.com/ 855-907-3286 Clinical.Trials@bms.com
Contact: First line of the email MUST contain NCT # and Site #.

Locations

United States, Alabama	Local Institution	Birmingham
United States, Alabama	Local Institution	Birmingham
United States, Alaska	Alaska Urological Institute dba Alaska Clinical Research Center	Anchorage
United States, Arkansas	Local Institution	Little Rock
United States, California	Local Institution - 0115	Fresno
United States, California	Local Institution	Santa Rosa
United States, Florida	Boca Raton Regional Hospital	Boca Raton
United States, Florida	Holy Cross Hospital	Fort Lauderdale
United States, Florida	Cancer Specialists of North FL	Jacksonville
United States, Georgia	University Cancer & Blood Center, LLC	Athens
United States, Georgia	Lewis Hall Singletary Oncology Center at John D. Archbold Memorial Hospital	Thomasville
United States, Illinois	University Of Illinois At Chicago	Chicago
United States, Iowa	Local Institution	Iowa City
United States, Louisiana	Local Institution - 0117	New Orleans
United States, Massachusetts	Dana Farber Cancer Institute	Boston

United States, Massachusetts	Local Institution - 0073	Boston
United States, Massachusetts	Milford Regional Medical Center	Boston
United States, Massachusetts	South Shore Hospital Cancer Center	Boston
United States, Michigan	St. Joseph Mercy Hospital	Ypsilanti
United States, Minnesota	Ridges Cancer Clinic	Burnsville
United States, Mississippi	Hattiesburg Clinic	Hattiesburg
United States, Missouri	Washington University School OF Medicine-Siteman Cancer Center	Saint Louis
United States, Nebraska	GU Research Network, LLC	Omaha
United States, New Hampshire	Local Institution - 0057	Manchester
United States, New Mexico	University Of New Mexico	Albuquerque
United States, New York	Roswell Park Cancer Institute	Buffalo
United States, New York	NYU Winthrop Hospital Dept of Oncology/Hematology	Mineola
United States, New York	Icahn School Of Medicine At Mount Sinai	New York
United States, New York	Local Institution	New York
United States, North Carolina	Local Institution - 0116	Durham
United States, Ohio	The Ohio State University	Columbus
United States, Oregon	Providence Portland Med Ctr	Portland
United States, Pennsylvania	St Lukes Hospital	Easton
United States, Pennsylvania	Allegheny General Hospital	Pittsburgh
United States, Texas	Local Institution	Houston
United States, Utah	Local Institution	Salt Lake City
United States, Washington	Seattle Cancer Care Alliance	Kirkland
United States, Wisconsin	Local Institution	Milwaukee
Argentina, Buenos Aires	Local Institution - 0005	Capital Federal
Argentina, Buenos Aires	Local Institution - 0007	Mar Del Plata
Argentina, RIO Negro	Local Institution - 0008	Viedma
Argentina	Local Institution - 0009	Buenos Aires
Argentina	Local Institution - 0134	Cordoba
Argentina	Local Institution - 0006	Cordoba
Australia, New South Wales	Local Institution	Darlinghurst
Australia, New South Wales	Local Institution - 0096	Waratah
Australia, New South Wales	Local Institution - 0099	Westmead
Australia, Queensland	Local Institution - 0188	South Brisbane
Australia, Queensland	Local Institution - 0120	Tugun
Australia, Victoria	Local Institution - 0101	Heidelberg
Australia, Western Australia	Local Institution	Doubleview
Brazil, Distrito Federal	Local Institution - 0017	Brasilia
Brazil, RIO Grande DO SUL	Local Institution - 0021	Ijui
Brazil, RIO Grande DO SUL	Local Institution - 0119	Passo Fundo
Brazil, RIO Grande DO SUL	Local Institution - 0020	Porto Alegre
Brazil, Santa Catarina	Local Institution - 0016	Florianopolis
Brazil, Sao Paulo	Local Institution - 0018	Barretos
Brazil, Sao Paulo	Local Institution - 0019	Sao Jose Do Rio Preto
Brazil	Local Institution	Sao Paulo
Canada, Nova Scotia	Local Institution - 0053	Halifax

Canada, Ontario	Local Institution - 0064	London
Canada, Quebec	Local Institution - 0052	Sherbrooke
Canada	Local Institution - 0054	Quebec
Chile, Metropolitana	Local Institution - 0010	Santiago
Chile, Metropolitana	Local Institution	Santiago
Chile, Valparaiso	Local Institution - 0012	Vina del Mar
Chile	Local Institution - 0106	Vitacura
China, Beijing	Local Institution - 0171	Beijing
China, Beijing	Local Institution - 0169	Beijing
China, Chongqing	Local Institution - 0182	Chongqing
China, Guizhou	Local Institution	Guiyang
China, Heilongjiang	Local Institution - 0219	Harbin
China, Hubei	Local Institution - 0180	Wuhan
China, Jiangsu	Local Institution - 0177	Nanjing
China, Jiangsu	Local Institution - 0176	Nanjing
China, Jiangsu	Local Institution - 0175	Nanjng
China, Jilin	Local Institution - 0186	Changchun
China, Shan1xi	Local Institution - 0220	Taiyuan
China, Shandong	Local Institution - 0216	Yantai
China, Shanghai	Local Institution - 0167	Shanghai
China, Shanghai	Local Institution - 0162	Shanghai
China, Shanghai	Local Institution - 0163	Shanghai
China, Shanghai	Local Institution	Shanghai
China, Sichuan	Local Institution - 0184	Chengdu
China, Zhejiang	Local Institution - 0174	Hangzhou
China, Zhejiang	Local Institution - 0172	Hangzhou
China, Zhejiang	Local Institution - 0173	Hangzhou
China	Local Institution - 0170	Beijing
China	Local Institution - 0164	Shanghai
Czechia	Local Institution - 0160	Brno
Czechia	Local Institution - 0152	Hradec Kralove
Denmark	Local Institution - 0190	Aalborg
Denmark	Local Institution - 0196	Herlev
Finland	Local Institution	Helsinki
France	Local Institution - 0089	Lille
France	Local Institution - 0088	Marseille Cedex 9
France	Local Institution - 0091	Nimes Cedex 09
France	Local Institution - 0090	St Priest En Jarez
France	Local Institution - 0092	Suresnes
France	Local Institution - 0093	Tours Cedex
France	Local Institution - 0094	Villejuif
Germany	Universitat Dresden	Dresden
Germany	Local Institution - 0048	Essen
Germany	Local Institution - 0047	Freiburg
Germany	Local Institution - 0049	Hamburg

Germany	Local Institution - 0037	Hannover
Germany	Local Institution - 0041	Jena
Germany	Local Institution - 0213	Mannheim
Germany	Local Institution	Muenchen
Germany	Local Institution - 0038	Nuernberg
Germany	Local Institution - 0040	Tuebingen
Germany	Local Institution - 0114	Weiden
Germany	Local Institution - 0039	Wuerzburg
Greece	Local Institution - 0102	Athens
Greece	Local Institution - 0103	Ioannina
Hungary	Local Institution	Budapest
Hungary	Local Institution	Budapest
Hungary	Local Institution	Budapest
Hungary	Local Institution	Debrecen
Hungary	Local Institution	Miskolc
Israel	Local Institution - 0199	Kfar Saba
Israel	Local Institution - 0198	Ramat Gan
Italy	Local Institution - 0108	Arezzo
Italy	Local Institution - 0197	Faenza
Italy	Local Institution - 0111	Forlì
Italy	Local Institution - 0109	Grosseto
Italy	Local Institution - 0107	Milano
Italy	Local Institution - 0110	Napoli
Japan, Aomori	Local Institution - 0136	Hirosaki-shi
Japan, Chiba	Local Institution - 0135	Chiba-shi
Japan, Ehime	Local Institution - 0147	Matsuyama-shi
Japan, Fukuoka	Local Institution - 0140	Fukuoka-shi
Japan, Hokkaido	Local Institution - 0146	Sapporo-city
Japan, Ibaraki	Local Institution - 0150	Tsukuba-shi
Japan, Iwate	Local Institution - 0214	Morioka-shi
Japan, Kagawa	Local Institution - 0137	Kita-Gun
Japan, Niigata	Local Institution - 0141	Niigata-shi
Japan, Okayama	Local Institution - 0143	Okayama-shi
Japan, Osaka	Local Institution - 0144	Osaka-shi
Japan, Osaka	Local Institution - 0139	Osakasayama
Japan, Osaka	Local Institution - 0145	Takatsuki-shi
Japan, Shizuoka	Local Institution - 0201	Hamamatasu
Japan, Tokyo	Local Institution - 0149	Arakawa-ku,tokyo
Japan, Tokyo	Local Institution - 0148	Bunkyo-ku
Japan, Tokyo	Local Institution - 0142	Bunkyo-ku
Japan, Tokyo	Local Institution - 0138	Shinjuku-Ku
Japan, Wakayama	Local Institution - 0215	Wakayama-shi
Japan, Yamaguchi	Local Institution	Ube City
Korea, Republic of	Local Institution - 0125	Goyang-si
Korea, Republic of	Local Institution - 0126	Seongnam-si

Korea, Republic of	Local Institution - 0124	Seoul
Korea, Republic of	Local Institution - 0151	Seoul
Korea, Republic of	Local Institution - 0128	Seoul
Korea, Republic of	Local Institution - 0127	Seoul
Mexico, Distrito Federal	Local Institution - 0129	Ciudad de Mexico
Mexico, Distrito Federal	Local Institution	Mexico City
Mexico, Distrito Federal	Local Institution - 0130	Tlalpan
Mexico, Nuevo Leon	Local Institution - 0131	Monterrey
Netherlands	Local Institution - 0022	Amsterdam
Netherlands	Local Institution	Enschede
Netherlands	Local Institution - 0024	Groningen
Netherlands	Local Institution - 0026	Leeuwarden
Norway	Local Institution	Bergen
Norway	Local Institution - 0081	Lorenskog
Peru	Local Institution - 0030	Lima
Peru	Local Institution - 0031	Lima
Poland	Local Institution - 0189	Bydgoszcz
Poland	Local Institution - 0205	Koszalin
Poland	Local Institution - 0202	Warszawa
Romania, Cluj	Local Institution - 0191	Cluj-Napoca
Romania	Local Institution - 0187	Craiova
Russian Federation	Local Institution	Moscow
Russian Federation	Local Institution	Moscow
Russian Federation	Local Institution	Moscow
Russian Federation	Local Institution	Novosibirsk
Russian Federation	Local Institution	St Petersburg
Singapore	Local Institution - 0192	Singapore
Spain	Local Institution - 0070	A Coruna
Spain	Local Institution - 0068	Barcelona
Spain	Local Institution - 0065	Madrid
Spain	Local Institution - 0066	Madrid
Spain	Local Institution - 0209	Santander
Spain	Local Institution - 0067	Sevilla
Spain	Local Institution - 0069	Valencia
Sweden	Local Institution - 0075	Jonkoping
Sweden	Local Institution	Linkoping
Sweden	Local Institution	Lund
Switzerland	Local Institution - 0061	Baden
Switzerland	Local Institution - 0042	Chur
Taiwan	Local Institution - 0156	Kaohsiung
Taiwan	Local Institution - 0159	Taichung
Taiwan	Local Institution - 0158	Taipei
Taiwan	Local Institution - 0155	Taipei
Taiwan	Local Institution - 0157	Taoyuan
Turkey	Local Institution - 0194	Ankara

Turkey	Local Institution - 0204	Istanbul
Turkey	Local Institution - 0193	Izmir

Sponsors and Collaborators

Bristol-Myers Squibb

Ono Pharmaceutical Co. Ltd

Investigator

Study Director :	Bristol-Myers Squibb	Bristol-Myers Squibb

MORE INFORMATION

Responsible Party :	Bristol-Myers Squibb
ClinicalTrials.gov Identifier :	NCT03036098
Other Study ID Numbers :	CA209-901, 2016-003881-14
First Posted :	January 30, 2017
Last Update Posted :	June 16, 2022
Last Verified :	June 2022
Studies a U.S. FDA-regulated Drug Product:	Yes
Studies a U.S. FDA-regulated Device Product:	No