

# Observational study to evaluate PD-L1 protein expression in Chinese patients with advanced esophageal cancers and head and neck squamous cell carcinoma

<b>Submission date</b> 02/12/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/04/2021	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 16/11/2023	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Esophageal (food pipe) cancer (EC) and head and neck squamous cell carcinoma (HNSCC) are common cancers with high rates of incidence and mortality (death) in China. However, the levels of PD-L1 protein in Chinese patients with advanced EC and HNSCC are largely unknown. The aim of this study is to determine the prevalence of PD-L1 high expression in Chinese patients with advanced EC and HNSCC.

### Who can participate?

Patients aged 18 or older with advanced EC or HNSCC and an available tumor tissue sample

### What does the study involve?

PD-L1 protein expression levels are measured from tumor tissue samples.

### What are the possible benefits and risks of participating?

Since this study does not provide treatment, there is no direct benefit to the participant. Information learned from the study may help other people in the future.

### Where is the study run from?

Merck Sharp and Dohme (China)

### When is the study starting and how long is it expected to run for?

November 2020 to December 2022

### Who is funding the study?

Merck Sharp and Dohme (China)

Who is the main contact?  
Wenmin Tang  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**Protocol serial number**  
8746

## Study information

**Scientific Title**  
A multi-center retrospective observational study to evaluate PD-L1 protein expression in Chinese patients with advanced esophageal cancers and head and neck squamous cell carcinoma

**Acronym**  
Exceed

**Study objectives**  
To determine the prevalence of PD-L1 high expression (determined by CPS  $\geq$ 10 for EC, CPS  $\geq$ 20 for HNSCC) in Chinese patients with advanced esophageal cancers (EC) and head and neck squamous cell carcinoma (HNSCC).

**Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 23/11/2020, National Cancer Center/Cancer Hospital, Chinese Academy of Medical Sciences and Peking Union Medical College; National GCP Center for Anticancer Drugs, The independent Ethics Committee (No.17 Panjiayuan Nanli, Chaoyang District, Beijing P.R. China; +86 (0)8610 87788495; cancergcp@163.com), ref: 20/377-2573

### **Study design**

Multi-center retrospective observational study

### **Primary study design**

Observational

### **Study type(s)**

Other

### **Health condition(s) or problem(s) studied**

Esophageal cancer and head and neck squamous cell carcinoma

### **Interventions**

This is a multi-center retrospective non-interventional study designed to examine PD-L1 protein expression among 920 patients diagnosed with advanced EC and HNSCC at seven participating centers in China. Eligible patients should be 18 years of age or older and able to provide a representative tissue block for PD-L1 analysis.

In all study centers, PD-L1 expression will be determined locally by a pathologist in all samples using the PD-L1 IHC 22C3 pharmDx kit and described in prevalence of CPS  $\geq 10$  for EC, CPS  $\geq 20$ , CPS  $\geq 1$  for HNSCC and by key baseline demographic, clinicopathologic parameters, treatment status and other biomarkers.

Sample processing and analysis is estimated to last for 18 months. An interim analysis is planned when 640 samples (two-thirds of the overall sample required) have been analyzed.

### **Intervention Type**

Other

### **Primary outcome(s)**

PD-L1 expression determined using the PD-L1 IHC 22C3 pharmDx kit at baseline; this is a qualitative IHC assay using monoclonal mouse Anti-PD-L1, clone 22C3 intended for detection of PD-L1 protein in FFPE tissues using the EnVision FLEX visualization system on Autostainer Link 48. PD-L1 protein expression is determined by using Combined Positive Score (CPS), which is the number of PD-L1 staining cells (tumor cells, lymphocytes, macrophages) divided by the total number of viable tumor cells, multiplied by 100. CPS is defined as follows:  $CPS = \frac{\# \text{ PD-L1 staining cells (tumor cells, lymphocytes, macrophages)}}{\text{Total \# of viable tumor cells}} \times 100$

### **Key secondary outcome(s)**

Collected at baseline from each center's electronic medical record (EMR) system or by chart review if no EMR exists:

1. Key demographic characteristics (e.g. age at diagnosis, gender, family history of studied disease, history of tobacco use)

2. Clinicopathological parameters (e.g. primary tumor site, tumor stage, histology and grade, metastatic location and number, site and type of tumor tissue sample)
3. Treatment status (e.g. previous lines of therapy, prior curative treatments)
4. Other available biomarkers (e.g. HER2 for EC and HPV status for HNSCC)

**Completion date**

30/12/2022

## Eligibility

**Key inclusion criteria**

General criteria:

1. Patient must have informed consent form (ICF) signed previously, which gives consent for his /her sample to be used in a future study, unless the patient is under conditions accepted by IRB /ERC to waive ICF. Otherwise, the patient must provide a specific written informed consent for this study
2. Patient is 18 years of age or older at diagnosis

Criteria for EC:

1. Patient has histologically or cytologically confirmed diagnosis of adenocarcinoma or squamous cell carcinoma of the esophagus or Siewert type I adenocarcinoma of the EGJ (defined as adenocarcinomas of the lower esophagus with the center located within 1 cm to 5 cm above the anatomic EGJ)
2. Patient has metastatic disease or locally advanced, unresectable disease
3. Patient must have an available FFPE tumor specimen obtained with resection, core needle biopsy or endoscopic biopsy
  - 3.1. Newly-obtained specimen (collected up to 6 weeks prior to the start of PD-L1 IHC test) is preferred to archived one
  - 3.2. Archival tissue block should be no older than 1 year
  - 3.3. Tumor specimen collected from the primary site is preferred to that from the metastatic site

Criteria for HNSCC:

1. Patient has histologically or cytologically confirmed diagnosis of recurrent or metastatic HNSCC that is considered incurable by local therapies. The patient may not have a primary tumor site of nasopharynx (any histology)
2. Patient must have an available FFPE tumor specimen obtained with core or excisional biopsy
  - 2.1. Newly-obtained biopsy specimen (within 90 days prior to start of PD-L1 IHC test) is preferred to an archived one
  - 2.2. Archival tissue block should be no older than 2 years
  - 2.3. Tumor specimen collected from the primary site is preferred to that from the metastatic site
  - 2.4. Decalcified bony specimen is not accepted

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

Patient has only a specimen obtained with fine needle aspirate (FNA) or cytologic specimen

**Date of first enrolment**

05/01/2021

**Date of final enrolment**

01/05/2021

**Locations****Countries of recruitment**

China

**Study participating centre**

**The Cancer Institute and Hospital, Chinese Academy of Medical Sciences (CAMS)**

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**Study participating centre**

**West China School of Medicine and West China Hospital, Sichuan University**

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**Study participating centre**

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**Study participating centre**  
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**Study participating centre**  
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## **Sponsor information**

**Organisation**  
Merck Sharp and Dohme (China)

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Merck Sharp and Dohme

**Alternative Name(s)**

MSD United Kingdom, Merck Sharp & Dohme, Merck Sharp & Dohme Corp., MSD

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The participant-level data will be stored in a Merck internal website with a strict policy.

**IPD sharing plan summary**

Stored in repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		15/11/2023	16/11/2023	Yes	No