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Society of Thoracic Surgeons

General Thoracic Surgery Database Neoadjuvant Therapy Module Webinar

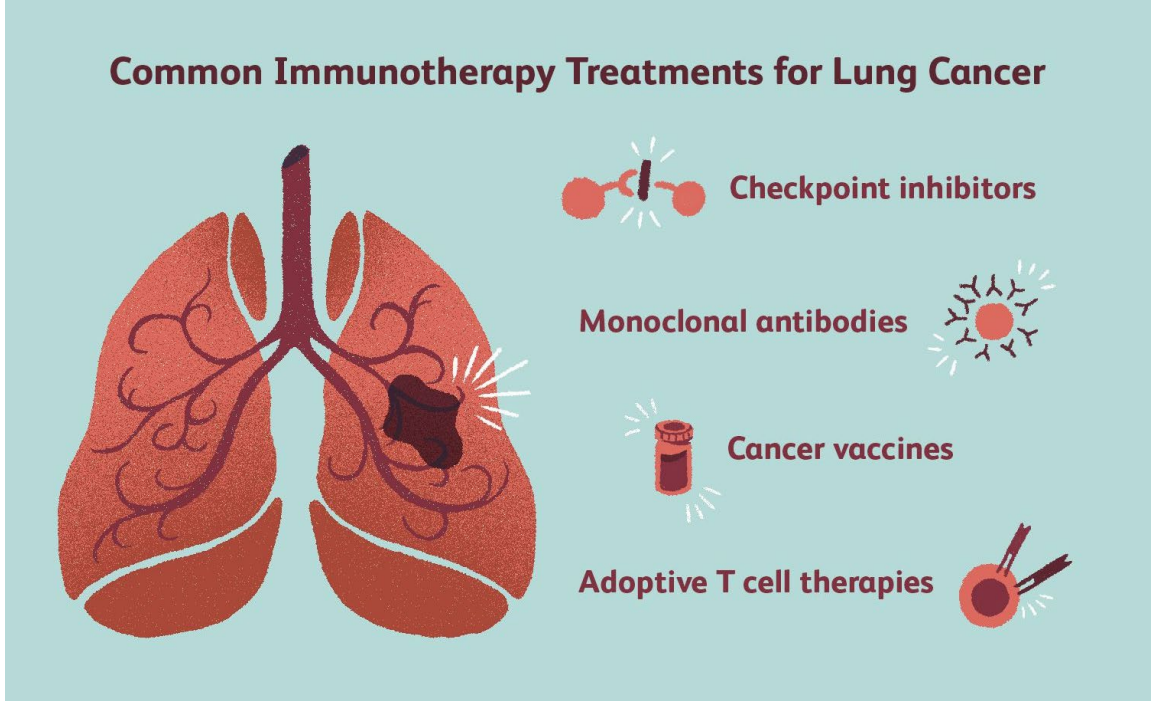
October 23, 2023

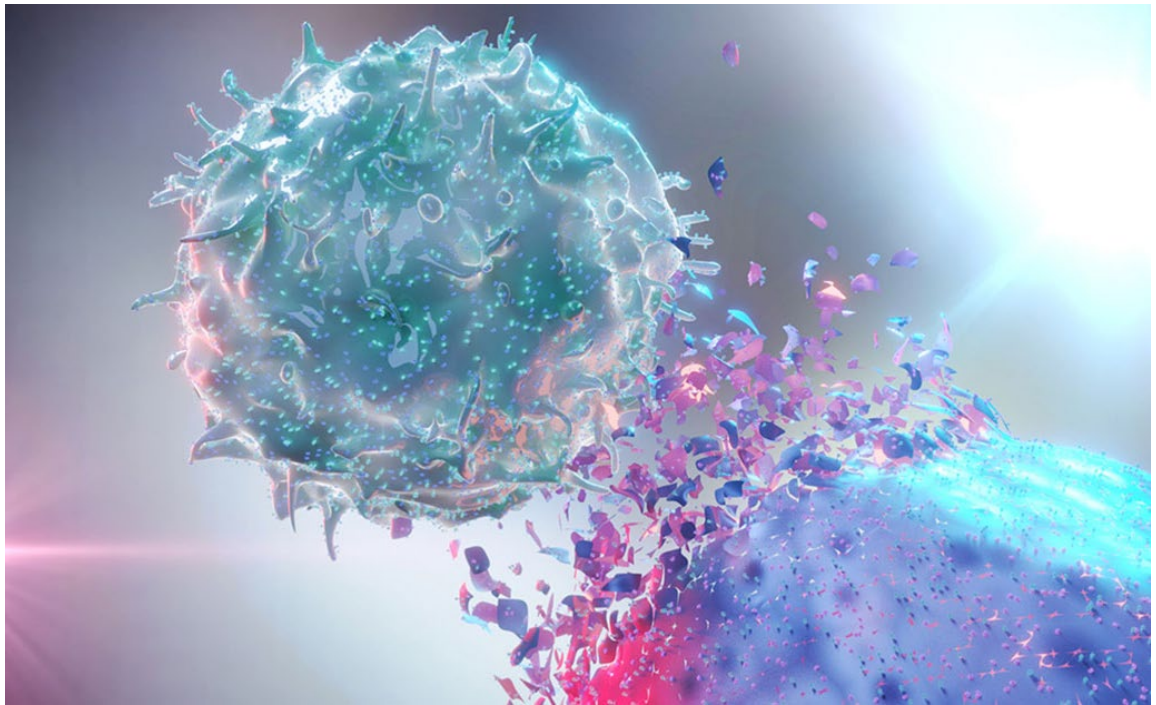
Agenda

- Welcome and Introduction
- Temporary Fields (Dr. Chris Seder)
- Neoadjuvant Therapy Module (Dr. Chris Seder and Dr. Stephen Broderick)
- Case Scenario (Ruth Raleigh, GTSD Clinical Consultant)
- Q&A

STS Temporary Fields

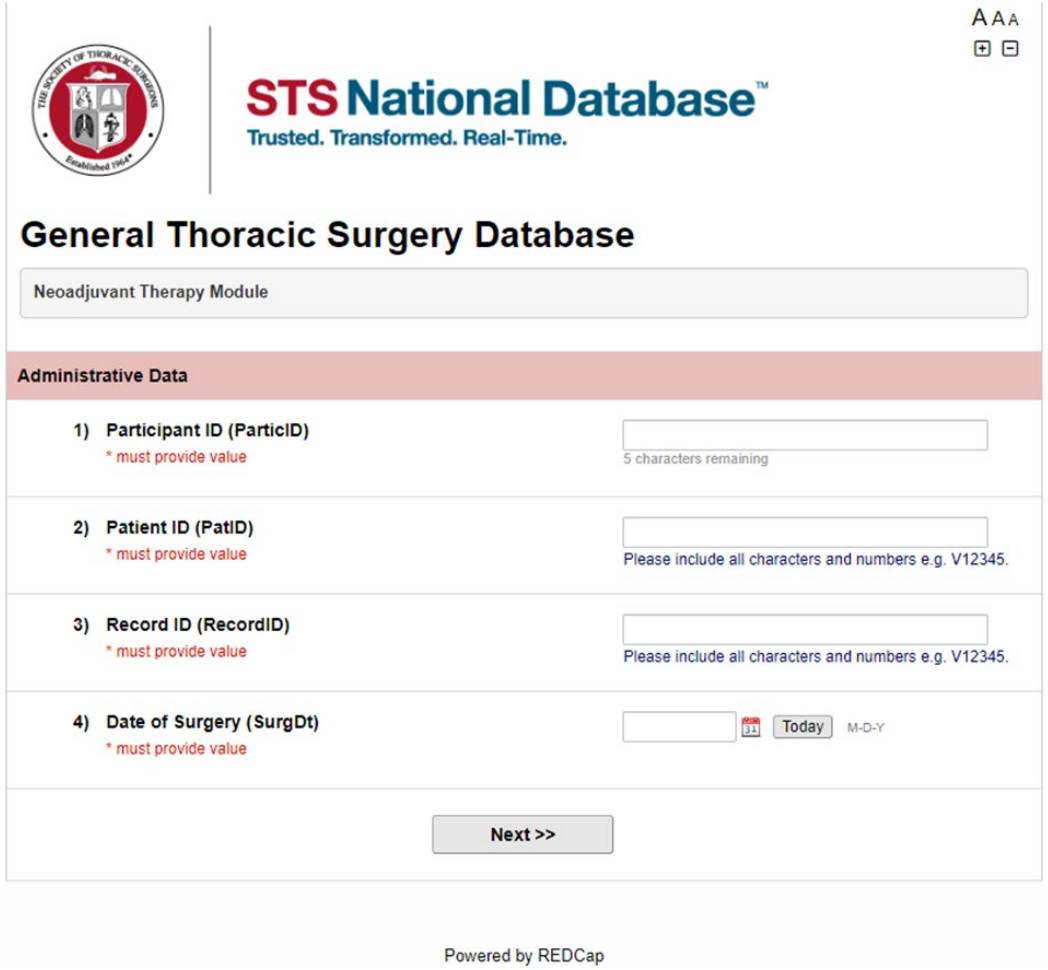
- Why are we activating these two fields?
- TempY/N1 (Seq. 4580) : Did the patient receive preoperative immunotherapy or a targeted agent directed at the lung cancer of interest?
- TempText (Seq.4620): If so, what agent?





GTSD Neoadjuvant Therapy Module

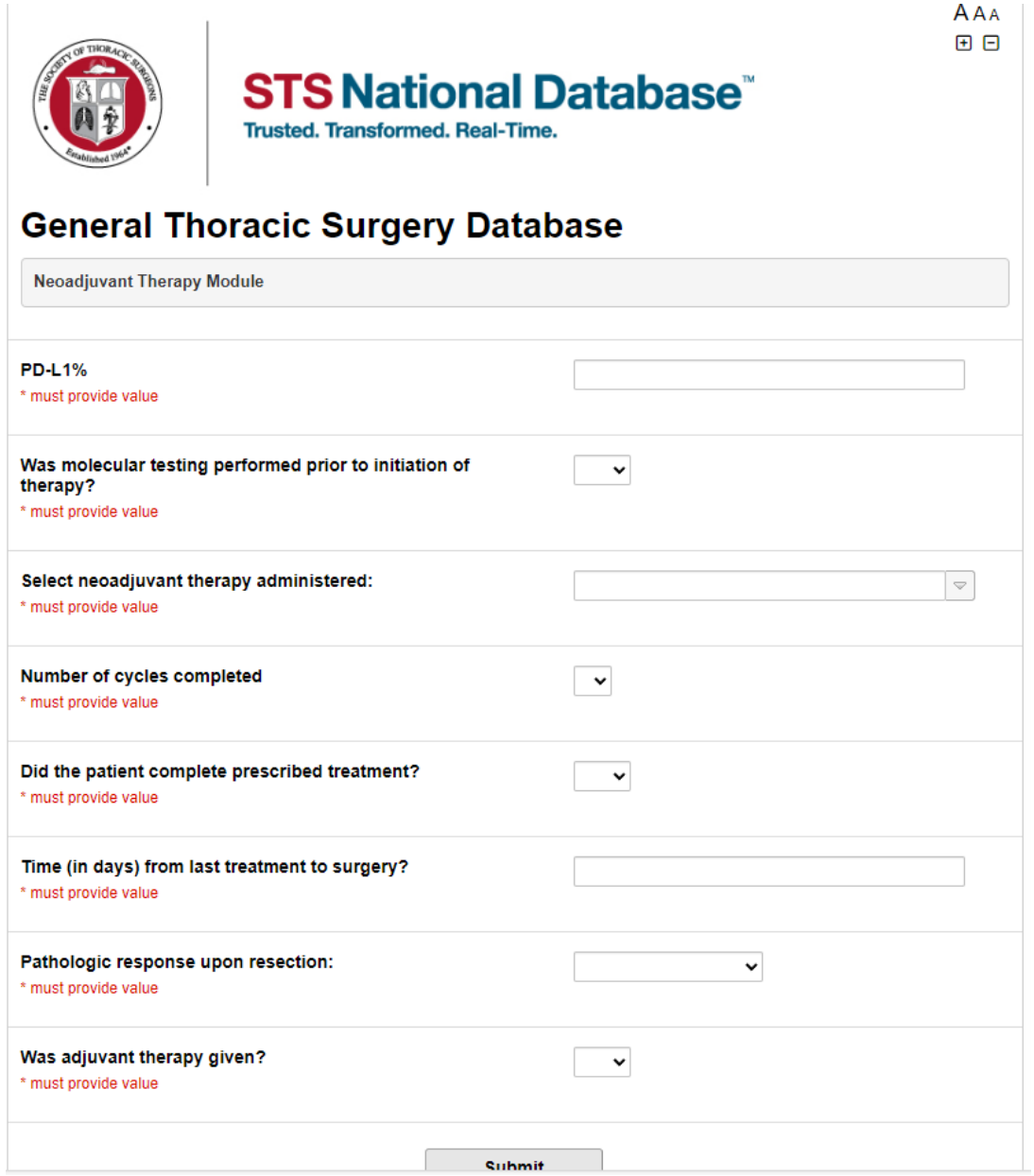
Administrative Data



GTSD Neoadjuvant Therapy Module

Medication Usage

*please note this version is not final



AAA

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General Thoracic Surgery Database

Neoadjuvant Therapy Module

PD-L1%
* must provide value

Was molecular testing performed prior to initiation of therapy?
* must provide value

Select neoadjuvant therapy administered:
* must provide value

Number of cycles completed
* must provide value

Did the patient complete prescribed treatment?
* must provide value

Time (in days) from last treatment to surgery?
* must provide value

Pathologic response upon resection:
* must provide value

Was adjuvant therapy given?
* must provide value

Submit

Case Scenario: GTSD Neoadjuvant Therapy Module

Ruth Raleigh BSN, RN

Clinical Consultant GTSD

October 23, 2023

What Are Driver Mutations?

Driver mutations are genetic changes that drive the development and progression of lung cancer.

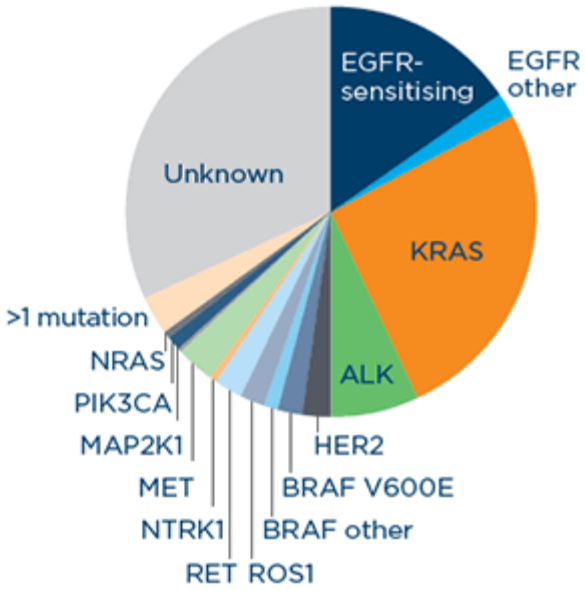
They often affect genes that encode for receptor tyrosine kinases (RTKs), such as EGFR, ERBB2, MET, RET, ALK, and ROS1.

These mutations can also influence the risk of brain metastasis, which is a common complication of lung cancer.

Therapies that target driver mutations can improve the survival and quality of life of lung cancer patients, but resistance can also emerge over time.

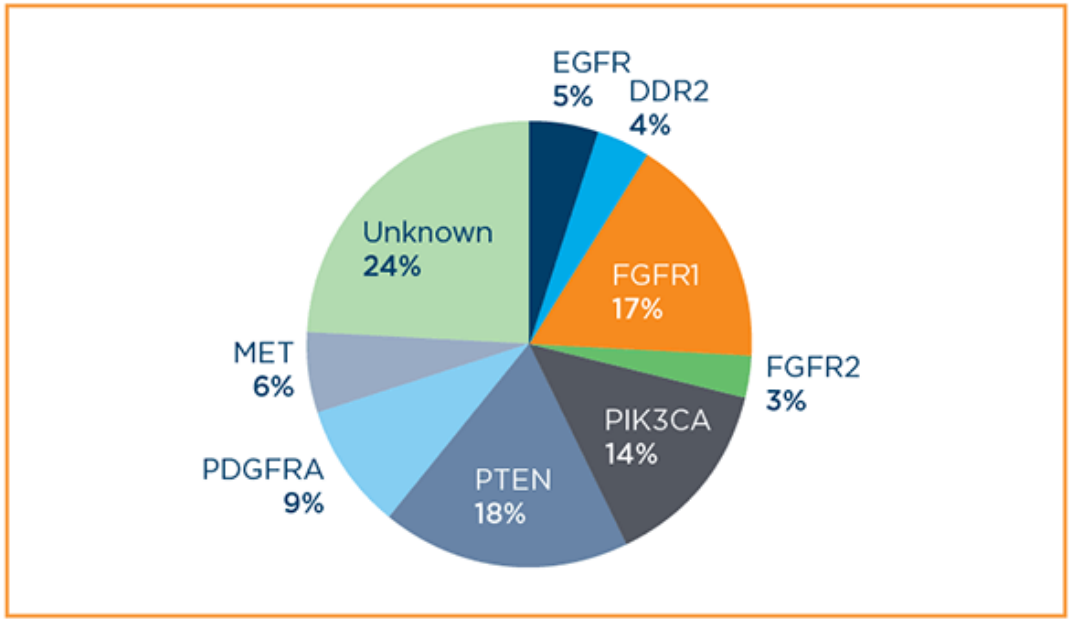
Genetic or Driver Mutations in Lung Cancer

DRIVER MUTATIONS IN LUNG ADENOCARCINOMA



Driver mutations in lung adenocarcinoma	
EGFR-sensitizing	15%
EGFR other	2%
KRAS	25%
ALK	7%
HER2	2%
BRAF V600E	2%
BRAF other	1%
ROS1	2%
RET	2%
NTRK1	0–5%
MET	3%
MAP2K1	0–5%
PIK3CA	1%
NRAS	0–5%
>1 mutation	3%
Unknown	31%

DRIVER MUTATIONS IN SQUAMOUS CELL LUNG CANCER



[Types of Lung Cancer | LUNGevity Foundation]

[Targeting mutations that drive lung cancer (nature.com)]

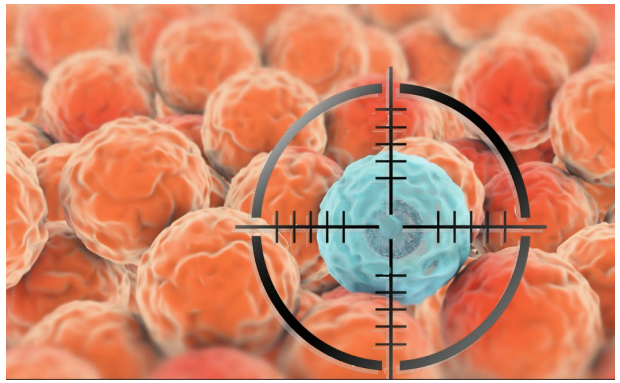
Common Targeted Therapies: ‘ib’s and ‘mab’s

There are two basic types of targeted therapies:

- **Small molecule drugs:** Small molecule drugs are able to travel to the inside of a cancer cell and target proteins involved in cell growth. They are then able to block the signals that tell the cells to divide and grow. These medications are identified by the suffix “ib” such as erlotinib.
- **Monoclonal antibodies:** Monoclonal antibodies are similar to the antibodies your body makes in response to exposure to viruses and bacteria. Unlike those antibodies, however, monoclonal antibodies are "man-made" antibodies. Instead of fighting off viruses and bacteria, they target a specific molecular target (proteins) on the surface of cancer cells. These medications carry a suffix “mab” such as bevacizumab.

https://www.verywellhealth.com/cancer-treatment-4014177

Common Targeted Therapies: ‘ib’s and ‘mab’s



- gefitinib (Iressa)
- afatinib (Giotrif)
- erlotinib (Tarceva)
- dactomitinib (Vizimpro)
- osimertinib (Tagrisso)
- amivantamab (Rybrevant)
- ceritinib (Zykadia)
- alectinib (Alecensaro)
- brigatinib (Alunbrig)
- lorlatinib (Lorbrena)
- entrectinib (Rozlytrek)
- crizotinib

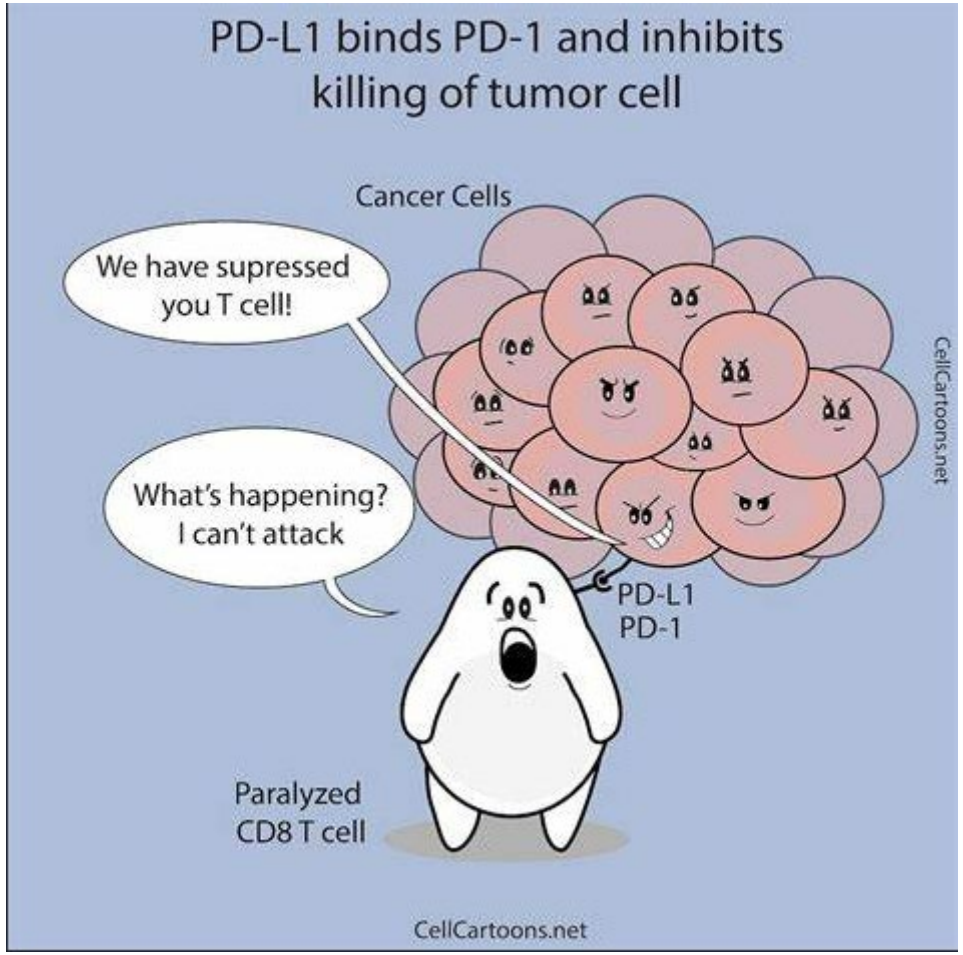
- sotorasib (Lumakras)
- dabrafenib (Tafinlar)
- trametinib (Mekinist)
- larotrectinib (Vitrakvi)
- tepotinib (Tepmetko)
- capmatinib (Tabrecta)
- pralsetinib (Gavreto)
- selpercatinib (Retevmo)
- bevacizumab (Avastin, Mvasi, Zirabev)
- ramucirumab (Cyramza)

Programmed Cell Death Ligand 1 aka PD-L1

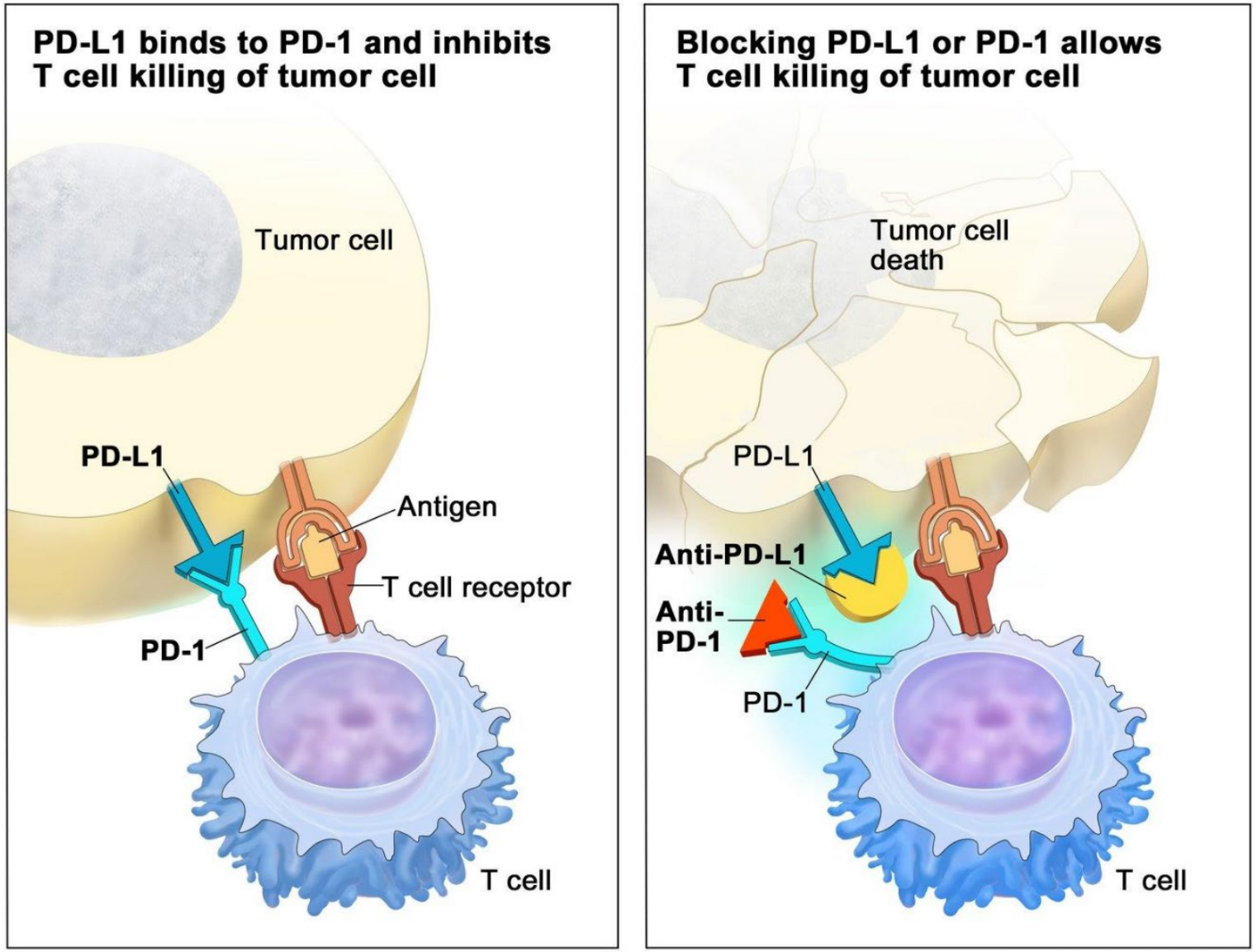
PD-L1 is a protein that plays a role in the body's immune system.

It can bind to another protein called PD-1.

When this happens, the two proteins block the immune system from killing cancer cells.



Roll of Immunotherapies



Common Immunotherpies: ‘mab’s

- atezolizumab (Tecentriq)
- cemiplimab (Libtayo)
- durvalumab (Imfinzi)
- ipilimumab (Yervoy)
- nivolumab (Opdivo)
- pembrolizumab (Keytruda)
- tremelimumab-actl (Imjudo)
- dostarlimab (Jemperli)

Pre-Operative Evaluation Note (Surgeon H&P)

Impression:

In summary, Vanna White is a pleasant 54 y.o. female recently former heavy smoker (quit 2 weeks ago) with HTN, HLD, PCKD, severe PAD s/p RLE stent and small infrarenal AAA with a clinical stage IIB (cT3 cN0 M0), 2 cm central/hilar left lower lobe squamous cell carcinoma and an additional FDG-avid approximate 7 mm LLL nodule also adjacent to thoracic aorta, suspicious for malignancy, s/p neoadjuvant chemoimmunotherapy per CheckMate-816 protocol. However only received 1 cycle of nivolumab due to a immunotherapy-related rash after cycle 1 of treated with Prednisone taper.

I reviewed and interpreted the images in detail of restaging CT on 9/19/2023 which showed partial treatment response with an interval decrease in size of the LLL juxta-aortic nodule, however there was interval development of multiple peripheral areas of abnormally increased density in the liver ranging in size up to 12 mm which could be related to regenerative nodules vs , metastases vs perfusion artifact.

Pre-Op Pathology Report

1 Result Note

Component

Addendum 2

Additional studies for PD-L1 were performed at Mayo Clinic (Rochester, MN), with the following findings:

PD-L1: 0% tumor cells positive for PD-L1.

The full reference lab report with specific details is available in Epic.

The archived slides and tissue block were obtained and reviewed for adequate neoplastic cellularity by the signing pathologist.

No change in diagnosis.

Addendum electronically signed by Matthew James Wasco, MD on 7/3/2023 at 1346

Addendum

Additional analysis was performed at Quest diagnostics, with results as follows:

EGFR mutation analysis: Negative (not detected)
ALK mutation: Negative (not detected).

The full reference lab reports will be scanned into epic. The archived slides and tissue block were obtained and reviewed for adequate neoplastic cellularity by the signing pathologist.

Addendum electronically signed by Matthew James Wasco, MD on 6/27/2023 at 1458

Final Diagnosis

Lung (left lower lobe): Squamous cell carcinoma

Electronically signed by Matthew James Wasco, MD on 6/6/2023 at 1228

Comment

Cellularity appears adequate for additional molecular testing, if indicated. Neoplasm is well differentiated and keratinizing.

Clinical Information

Lung mass

Gross Description

A. Lung, Left Lower Lobe, Core bx Mass:
Received in formalin is a 1.2 cm aggregate. All processed - 1 cassette.

Note, PD-L1 results lagged original final pathology by ~1 month. Your pathology department will have a ‘usual’ turnaround time for EGFR/ALK etc and PD-L1 testing to result.

Medical Oncology Progress Note

Impression:

#Stage IIB (cT3cN0,M0), non-small cell, squamous cell carcinoma of the lung

- 06/27/2023: EGFR and ALK mutation negative at Quest diagnostics.
- 07/03/2023: PD-L1 0% tumor cells positive for PD-L1.
- 07/24/2023: Cycle #1 carboplatin, paclitaxel, and nivolumab given in neoadjuvant setting with goal to complete 3 cycles followed by surgery
- 08/15/2023: Cycle #2 carboplatin, paclitaxel
- 09/06/2023: Cycle #3 carboplatin, paclitaxel
- 10/20/2023: Robotic Left Lower Lobectomy

#Rash, diffuse, initially papular, grade 2

-Developed following cycle 1, around 08/01/2023. Started on leg and then spread to back, abdomen, and arms. Associated itching which has been worsening.

- Rash significantly improved. Patient tapering off prednisone. Taper should be finished by next week.
- Pt was seen by dermatology who felt rash was due to nivolumab
- Rash did not become worse with cycle 2 of treatment (nivolumab held for cycle 2).

GTSD RedCap Survey Responses

General Thoracic Surgery Database

Neoadjuvant Therapy Module

PD-L1%
* must provide value
0

Was molecular testing performed prior to initiation of therapy?
* must provide value
Yes

If so, were mutations in any of the following genes identified?
* must provide value

Select neoadjuvant therapy administered:
* must provide value
Chemotherapy + Immunotherapy

Specific Chemotherapy + Immunotherapy used
* must provide value
Nivolumab+paclitaxel+carboplatin

Number of cycles completed
* must provide value
1

Did the patient complete prescribed treatment?
* must provide value
No

Time (in days) from last treatment to surgery?
* must provide value
44

Open Discussion

Please use the Q&A Function.

We will answer as many questions as possible.

We encourage your feedback and want to hear from you!

Upcoming GTSD Webinars

New Data Manager Webinar

- October 25 – @ 2pmCT

Monthly Webinar

- November 8 @ 1:30CT

Contact Information

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Clinical Support	• https://www.sts.org/sts-clinical-question-request-form
Helpdesk Support (Harvest Questions/Analysis Report Questions)	• STSDB_helpdesk@sts.org
Database Operational Questions (Database Participation, Contracts, etc.)	• STSDB@sts.org

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