U.S. FDA Approved Immune-Checkpoint Inhibitors[1-7]

Squamous Cell Head & Neck Cancer

Unresectable or Metastatic Melanoma

Merkel Cell Carcinoma
Cutaneous Squamous Cell Carcinoma

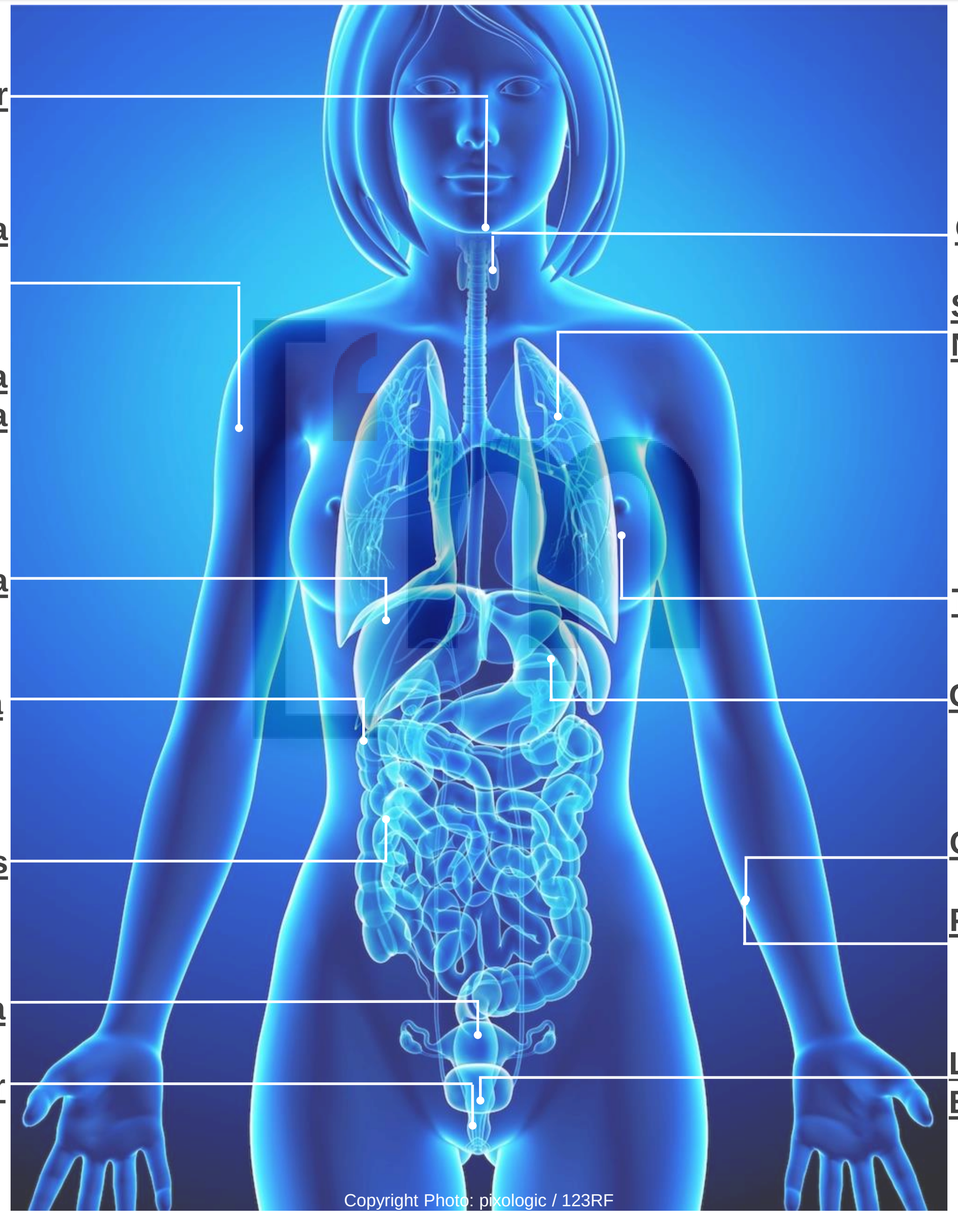
Hepatocellular Carcinoma

Renal Cell Carcinoma

Colorectal or MSI-H or dMMR Cancers

Endometrial Carcinoma

Cervical Cancer



Oesophageal Squamous Cell Carcinoma

Small Cell Lung Cancer
Non-Small Cell Lung Cancer

Triple-Negative Breast Cancer

Gastric & GEJ Carcinoma

Classical Hodkin Lymphoma

PMBCL

Locally Adv. or Met. Urothelial Carcinoma
BCG-unresponsive High-Risk NMIBC

Updated on 05-Jun-2020 - citations on last page - ©medi-paper.com

U.S. FDA Approved Immune-Checkpoint Inhibitors

Name	Company	Target	Indications	Details
Pembrolizumab (Keytruda®)[1]	**Merck (MSD)**	**PD-1**	• Adj. treatment of melanoma	• Patients with lymph node involvement, and • Underwent complete resection
			• 1L inoperable or metastatic melanoma	• Single agent
			• 1L metastatic Merkel cell carcinoma	• Adult and paediatric patients
			• 1L metastatic *non-squamous* NSCLC	• In combination with pemetrexed and a platinum chemotherapy • No known EGFR/ALK tumour-driver mutations
			• 1L metastatic *squamous* NSCLC	• In combination with carboplatin and paclitaxel *or* nab-paclitaxel
			• 1L stage III or metastatic NSCLC	• No known EGFR/ALK tumour-driver mutations • TPS≧1% • (Stage III only) Patients not candidates for surgical resection or definitive chemoradiation
			• 2L metastatic NSCLC with PD-L1 expression	• PD on or after platinum-containing chemotherapy • TPS≧1%
			• 3L metastatic SCLC	• PD on or after platinum-based chemotherapy
			• 1L metastatic or unresectable, recurrent head and neck squamous cell carcinoma (HNSCC)	• In combination with platinum and FU
			• 1L metastatic or unresectable, recurrent HNSCC with PD-L1 expression	• As a single agent • CPS ≥1
			• 2L recurrent or metastatic HNSCC	• As a single agent • PD on or after platinum-containing chemotherapy
			• 4L refractory classical Hodgkin lymphoma	• Adult and paediatric patients with disease relapse after 3 prior treatments
			• 3L refractory PMBCL	• Adult and paediatric patients relapsed ≧2 or more prior lines of therapy. • **Limitation of use:** not recommended when PMBCL patient requires urgent cytoreductive therapy
			• 1L locally advanced or metastatic urothelial carcinoma	• Ineligible for cisplatin chemotherapy and a CPS≥10 • Ineligible for platinum chemotherapy irrespective of PD-L1 expression
			• 2L locally advanced or metastatic urothelial carcinoma	• PD during or following platinum-containing chemotherapy • PD within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy

U.S. FDA Approved Immune-Checkpoint Inhibitors

Name	Company	Target	Indications	Details
Pembrolizumab (Keytruda®)[1]	**Merck (MSD)**	**PD-1**	• BCG-unresponsive, high-risk, non-muscle invasive bladder cancer	• Carcinoma in situ with or without papillary tumours • Ineligible for or have elected not to undergo cystectomy
			• MSI-H or dMMR cancers	• Adult and paediatric patients • PD in solid tumours following prior treatment and no other, satisfactory alternative treatment options • Colorectal cancer progressed following fluoropyrimidine, oxaliplatin, and irinotecan • **Limitation of use**: safety and effectiveness not established in paediatric patients with MSI-H CNS cancers
			• Recurrent locally advanced or metastatic gastric or GEJ adenocarcinoma	• CPS≥1 • Disease progression ≥2 prior lines of therapy, including fluoropyrimidine- and platinum-containing chemotherapy • PD following HER2-targeted therapy, if indicated
			• 2L recurrent locally advanced or metastatic squamous cell carcinoma of the oesophagus	• CPS≥10
			• Recurrent or metastatic cervical cancer	• CPS≥1 and PD on or after chemotherapy
			• 2L hepatocellular carcinoma	• Previously treated with sorafenib
			• Recurrent locally advanced or metastatic Merkel cell carcinoma	• Adult and paediatric patients
			• 1L advanced renal cell carcinoma	• In combination with axitinib
			• 2L advanced endometrial carcinoma	• In combination with Lenvatinib • Not MSI-H or dMMR • PD following prior systemic therapy • Not candidates for curative surgery or radiation
			• Additional recommended dosage regimen for adults	• 400mg every 6 weeks for all adult indications

U.S. FDA Approved Immune-Checkpoint Inhibitors

Name	Company	Target	Indications	Details
Nivolumab (Opdivo®)[2]	**Bristol-Myers Squibb**	**PD-1**	• Adj./1L Inoperable or metastatic melanoma	• Single agent *or* in combination with ipilimumab
			• Adj. treatment of melanoma	• Patients with lymph node involvement or metastatic disease, and • Underwent complete resection
			• 1L metastatic NSCLC	• In combination with ipilimumab • PD-L1 ≥1% • No EGFR or ALK genomic tumour aberrations
			• 1L metastatic or recurrent NSCLC	• In combination with ipilimumab and 2 cycles of platinum-doublet chemotherapy • No EGFR or ALK genomic tumour aberrations
			• 2L metastatic NSCLC	• PD on or after platinum-based chemotherapy • Patients with EGFR or ALK genomic tumour aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving nivolumab
			• 3L metastatic SCLC	• Progression on at least two lines of prior treatment • Including: one line of platinum-based therapy
			• 1L intermediate or poor risk renal cell carcinoma	• In combination with ipilimumab
			• 2L advanced renal cell carcinoma	• After prior treatment with anti-angiogenic drug
			• 3L/4L classical Hodgkin lymphoma	• Adult patients • After prior auto-HSCT and (3L-only) brentuximab vedotin (BV)
			• 1L recurrent or metastatic head and neck squamous cell carcinoma	• PD on *or* after (adjuvant) platinum chemotherapy
			• 1L/2L locally advanced or metastatic urothelial carcinoma	• Failure on prior platinum chemotherapy • PD<12 months after (neo)adjuvant platinum chemotherapy
			• MSI-H or dMMR metastatic colorectal cancer	• Single agent or in combination with ipilimumab • Adult and paediatric patients (≧12 years) • PD following fluoropyrimidine, oxaliplatin, and irinotecan
			• 2L heptocellular carcinoma	• PD on prior sorafenib • Single agent or in combination with ipilimumab

U.S. FDA Approved Immune-Checkpoint Inhibitors

Name	Company	Target	Indications	Details
Ipilimumab (Yervoy®)[3]	**Bristol-Myers Squibb**	**CTLA4**	• 1L inoperable or metastatic melanoma	• Adult and paediatric patients (≧12 years) • Single agent *or* in combination with nivolumab (see Opdivo® USPI)
			• Adj. treatment of cutaneous melanoma	• Patients with pathological involvement of the regional lymph nodes >1 mm who underwent complete resection, including total lymphadenectomy
			• 1L advanced, intermediate or poor risk renal cell carcinoma	• In combination with nivolumab
			• MSI-H or dMMR metastatic colorectal cancer	• Single agent or in combination with nivolumab • Adult and paediatric patients (≧12 years) • PD following fluoropyrimidine, oxaliplatin, and irinotecan
			• 2L hepatocellular carcinoma	• In combination with nivolumab • PD with sorafenib
			• 1L metastatic NSCLC	• PD-L1 ≥1% • No EGFR or ALK genomic tumour aberrations
			• 1L metastatic or recurrent NSCLC	• In combination with nivolumab and cycles of platinum-doublet chemotherapy • No EGFR or ALK genomic tumour aberrations

U.S. FDA Approved Immune-Checkpoint Inhibitors

Name	Company	Target	Indications	Details
Atezolizumab (Tecentriq®)[4]	**Roche & Genentech**	**PD-L1**	• 1L/2L locally advanced or metastatic urothelial carcinoma	• Ineligible for cisplatin chemotherapy and PD-L1 expression (PD-L1 stained tumour-infiltrating immune cells [IC] covering ≥ 5% of the tumor area) • Ineligible for platinum chemotherapy regardless of PD-L1 expression • Failure on prior platinum chemotherapy • PD<12 months after (neo)adjuvant platinum chemotherapy
			• 1L metastatic *non-squamous* NSCLC	• In combination with bevacizumab, paclitaxel, and carboplatin • No EGFR or ALK genomic tumour aberrations
			• 2L metastatic NSCLC	• Irrespective of PD-L1 expression • Failure on platinum chemotherapy • Failure on targeted agent (if applicable)
			• 1/L unresectable locally advanced or metastatic triple-negative breast cancer	• In combination with paclitaxel protein-bound • PD-L1 stained tumour-infiltrating immune cells (IC) of any intensity covering ≥1% of the tumour area
			• 1L extensive-stage small cell lung cancer	• In combination with carboplatin and etoposide
			• 1L unresectable or metastatic HCC	• In combination with bevacizumab
Avelumab (Bavencio®)[5]	**Merck Serono & Pfizer**	**PD-L1**	• 1L metastatic Merkel cell carcinoma	• Adult and paediatric patients (≧12 years)
			• 1L/2L locally advanced or metastatic urothelial carcinoma	• Failure on prior platinum chemotherapy • PD<12 months after (neo)adjuvant platinum chemotherapy
			• 1L advanced renal cell carcinoma	• In combination with axitinib
Durvalumab (Imfinzi®)[6]	**AstraZeneca**	**PD-L1**	• 1L/2L locally advanced or metastatic urothelial carcinoma	• Failure on prior platinum chemotherapy • PD<12 months after (neo)adjuvant platinum chemotherapy
			• Maintenance for unresectable, stage III NSCLC	• No PD following concurrent platinum-based chemotherapy and radiation therapy
			• 1L extensive-stage small cell lung cancer	• In combination with etoposide and either carboplatin or cisplatin
Cemiplimab (Libtayo®)[7]	**Sanofi**	**PD-L1**	• 1L metastatic cutaneous squamous cell carcinoma (CSCC)	• Not amenable for curative surgery or curative radiation

Abbreviations and Citations

Abbreviations

1L: first-line

2L: second-line

3L: third-line

4L: fourth-line

Adv: advanced

ALK: anaplastic lymphoma kinase

auto-HSCT: autologous haematopoietic stem cell transplantation

BV: brentuximab vedotin

CNS: central nervous system

CPS: combined proportion score

dMMR: mismatch-repair deficient

EGFR: epidermal growth factor receptor

GEJ: gastroesophageal junction

HER2: human epidermal growth factor receptor 2

Met: metastatic

MSI-H: microsatellite instability-high

Mu: mutation

NMIBC: non-muscle invasive bladder cancer

NSCLC: non-small cell lung cancer

PMBCL: primary mediastinal B-cell lymphoma

PD: progression disease

PD-1: programmed death 1

PD-L1: programmed death ligand 1

TPS: tumour proportion score

WT: wild-type

Citations

1 Prescribing information pembrolizumab (Keytruda®), revised: 04/2020. Available at: https://www.merck.com/product/usa/pi_circulars/k/keytruda/keytruda_pi.pdf (Accessed 5th June 2020).

2 Prescribing information nivolumab (Opdivo®), revised: 05/2020. Available at: https://packageinserts.bms.com/pi/pi_opdivo.pdf (Accessed 5th June 2020).

3 Prescribing information ipilimumab (Yervoy®), revised: 05/2020. Available at: https://packageinserts.bms.com/pi/pi_yervoy.pdf (Accessed 5th June 2020).

4 Prescribing information atezolizumab (Tecentriq®), revised: 05/2020. Available at: https://www.gene.com/download/pdf/tecentriq_prescribing.pdf (Accessed 5th June 2020).

5 Prescribing information avelumab (Bavencio®), revised: 05/2019. Available at: https://www.emdserono.com/us-en/pi/bavencio-pi.pdf (Accessed 5th June 2020).

6 Prescribing information durvalumab (Imfinzi®), revised: 03/2020. Available at: https://www.azpicentral.com/imfinzi/imfinzi.pdf (Accessed 5th June 2020).

7 Prescribing information cemiplimab (Libtayo®), revised: 09/2018. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761097s000lbl.pdf (Accessed 5th June 2020).