A Review of Newly Approved Antineoplastic Medications - 2015

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Acknowledgements

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Objectives

- Explain mechanisms of action
- Discuss appropriate administration of these medications
- Identify potential adverse effects and how to monitor for these

*Indication(s): does not include off-label use

Medications

- Darzalex® (daratumumab)
- Empliciti® (elotuzumab)
- Imlygic® (talimogene laherparepvec)
- Keytruda® (pembrolizumab)
- Onivyde® (irinotecan liposomal)
- Opdivo® (nivolumab)
- Portrazza® (necitumumab)
- Unituxin® (dinutuximab)
- Varubi® (rolapitant)
- Yondelis® (trabectedin)
- Zarxio® (filgrastim-sndz)

Darzalex® (daratumumab)

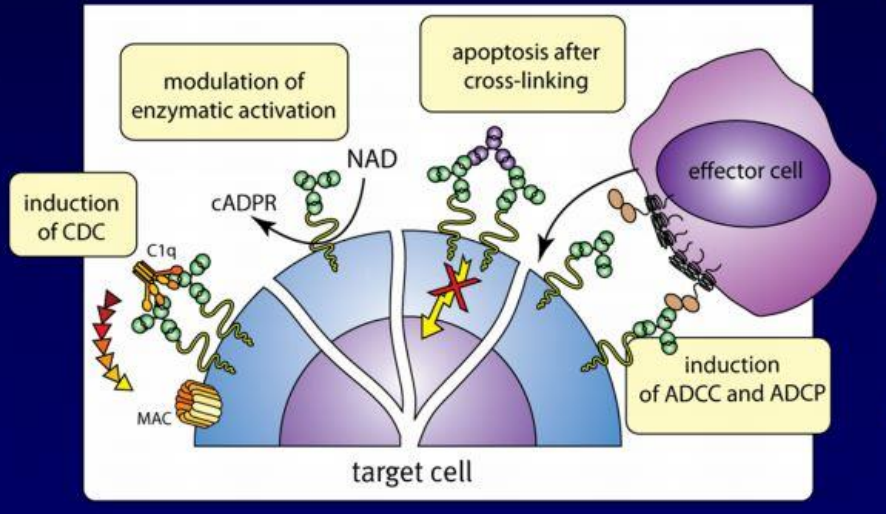
Approval Date	November 16, 2015
Indication	Relapsed/refractory multiple myeloma in patients who have received at least 3 prior lines of treatment • Including a proteasome inhibitor and an immunomodulatory agent or who are refractory to these
Mechanism of Action (MOA)	IgG1-kappa human monoclonal antibody that binds to CD38 on the surface of tumor cells and induces apoptosis (cell death)

Darzalex® (daratumumab) - MOA

DARA: Background

DARATUMUMAB

- A human CD38 mAb with broad-spectrum killing activity of CD38-expressing tumor cells
- DARA+LEN enhanced killing of MM cells *in vitro* and is hypothesized to lead to synergistically higher efficacy in clinical setting, as well as other agents (eg, bortezomib)



- Antibody-dependent cell-mediated cytotoxicity (ADCC)
- Antibody-dependent cellular phagocytosis (ADCP)
- Complement-dependent cytotoxicity (CDC)
- Apoptosis

Lokhorst H, et al. *J Clin Oncol.* 2014;21(5S): Abstract 8513. Plesner T, et al. *J Clin Oncol.* 2014;32(5S): Abstract 8533.

Darzalex® (daratumumab) - Administration

Pre-meds	IV corticosteroid, acetaminophen, and IV or oral antihistamine (approximately 60 min prior to infusion)
Infusion Set	Flow regulator with an inline, sterile, non-pyrogenic, low protein-binding polyethersulfone filter (0.22 or 0.2 micrometer) • Use polyurethane (PU), polybutadiene (PBD), PVC, PP or PE administrations sets
Administration	For IV infusion only. Do not give IV push or as a bolus.
	Infusion should be completed within 15 hours.
	Discard any unused portion of the solution.
Post-infusion	Post-infusion: oral corticosteroid on the 1st and 2nd day after all infusions • Reduce the risk of delayed infusion reactions

Darzalex® (daratumumab) - Stability

Handling	Gently invert the bag/container to mix. Do not shake.
Compatibility	Do not mix with or infuse with other medications. Compatible in NS.
Storage	The diluted solution may be refrigerated (36-46 °F), protected from light, for up to 24 hours. Do not freeze. Allow to come to room temperature, then use immediately.

Darzalex® (daratumumab) - Infusion Rates

	Dilution volume	Initial rate (first hour)	Rate increment	Maximum rate
First infusion	1,000 mL	50 mL/hour	50 mL/hour every hour	200 mL/hour
Second infusion[a]	500 mL	50 mL/hour	50 mL/hour every hour	200 mL/hour
Subsequent infusions[b]	500 mL	100 mL/hour	50 mL/hour every hour	200 mL/hour

[a]Escalate only if there were no grade 1 (mild) or greater infusion reactions during the first 3 hours of the first infusion.
[b]Escalate only if there were no grade 1 (mild) or greater infusion reactions during a final infusion rate of ≥ 100 mL/hour or more in the first 2 infusions.

Darzalex® (daratumumab) - Adverse Effects and Monitoring

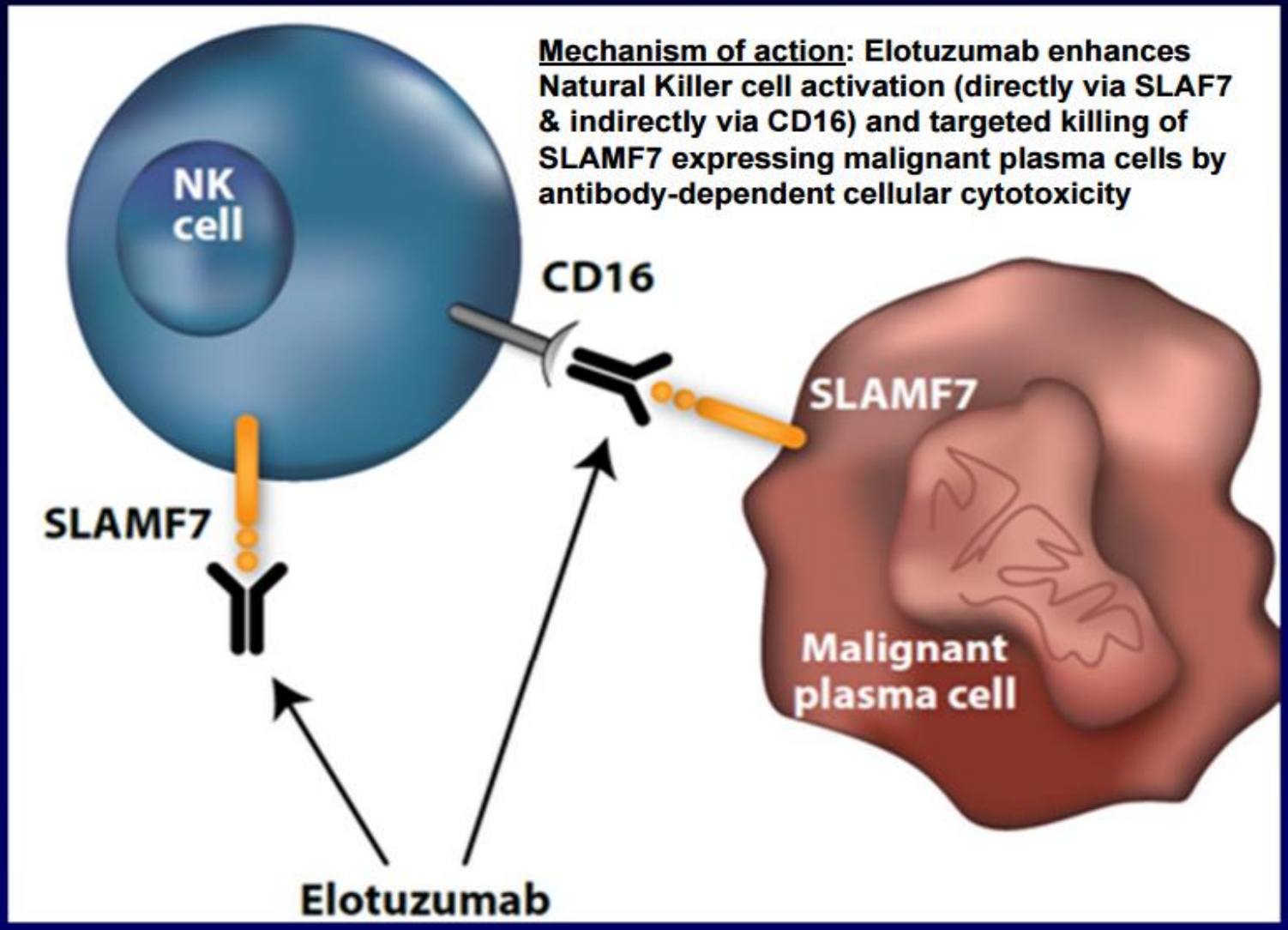
- Signs and symptoms of infusion reactions: flushing, itching, nausea, vomiting, diarrhea, throat tightness, dyspnea or chest discomfort.

- Side effects may include hypertension, cough, upper respiratory tract infection, pyrexia, fatigue, nausea, diarrhea, constipation, decreased appetite, vomiting, lymphocytopenia, neutropenia, thrombocytopenia, arthralgia, fever, and back pain.
- Complete blood cell counts as clinically necessary

Empliciti® (elotuzumab)

Approval Date	November 30, 2015
Indication	Relapsed/refractory multiple myeloma
Mechanism of Action	Humanized IgG1 monoclonal antibody targets a specific protein (SLAMF7), which is expressed on most myeloma and natural killer cells (but not on normal tissues) and stops the cancer cells from growing • Increases activation of natural killer cells and increases antitumor activity

Elotuzumab in MM
Mechanism of Action



http://blogs.shu.edu/cancer/2015/12/09/second-multiple-myeloma-antibody-approved-empliciti/

Empliciti® (elotuzumab) - Administration

Pre-meds	Dexamethasone, acetaminophen, and an H1- and H2-blocker (approximately 45 to 90 min prior to infusion)
Infusion Set	Use infusion set and a sterile, nonpyrogenic, low protein-binding filter (0.2 to 1.2 micrometer) • Use an automated infusion pump
Administration	For IV infusion only. Do not give IV push or as a bolus. • Complete infusion within 24 hours of reconstitution

Empliciti® (elotuzumab) – Stability

Handling	Gently swirl solution and invert vial to dissolve powder • Do not shake and avoid vigorous agitation
Compatibility	Do not mix with or infuse with other medications. Compatible in NS and D5W.
Storage	Solutions diluted for infusion may be stored refrigerated and protected from light for up to 24 hours and for a maximum of 8 hours at room temperature

Empliciti® (elotuzumab) - Infusion Rate

Cycle 1, Dose 1		**Cycle 1, Dose 2**		**Cycle 1, Dose 3 and 4 and all subsequent cycles[a]**
Time interval	Rate	Time interval	Rate	Rate
0 to 30 min	0.5 mL/min	0 to 30 min	1 mL/min	2 mL/min
30 to 60 min	1 mL/min	30 min or more	2 mL/min	
60 min or more	2 mL/min			

[a]In patients who have received 4 cycles of elotuzumab, the infusion rate may be increased to a maximum of 5 mL/min.

Empliciti® (elotuzumab) - Adverse Effects and Monitoring

- Monitor vital signs every 30 minutes during and for 2 hours after the end of the infusion in patients who experience an infusion reaction (flushing, itching, nausea, vomiting, and/or diarrhea, throat tightness, dyspnea or chest discomfort).

- Side effects may include fatigue, diarrhea, constipation, decreased appetite, cough, nasopharyngitis, upper respiratory tract infection, pneumonia, peripheral neuropathy, hyperglycemia, hypocalcemia, hyperkalemia, lymphocytopenia, leukopenia, thrombocytopenia, decreased heart rate, increased heart rate, and altered blood pressure.

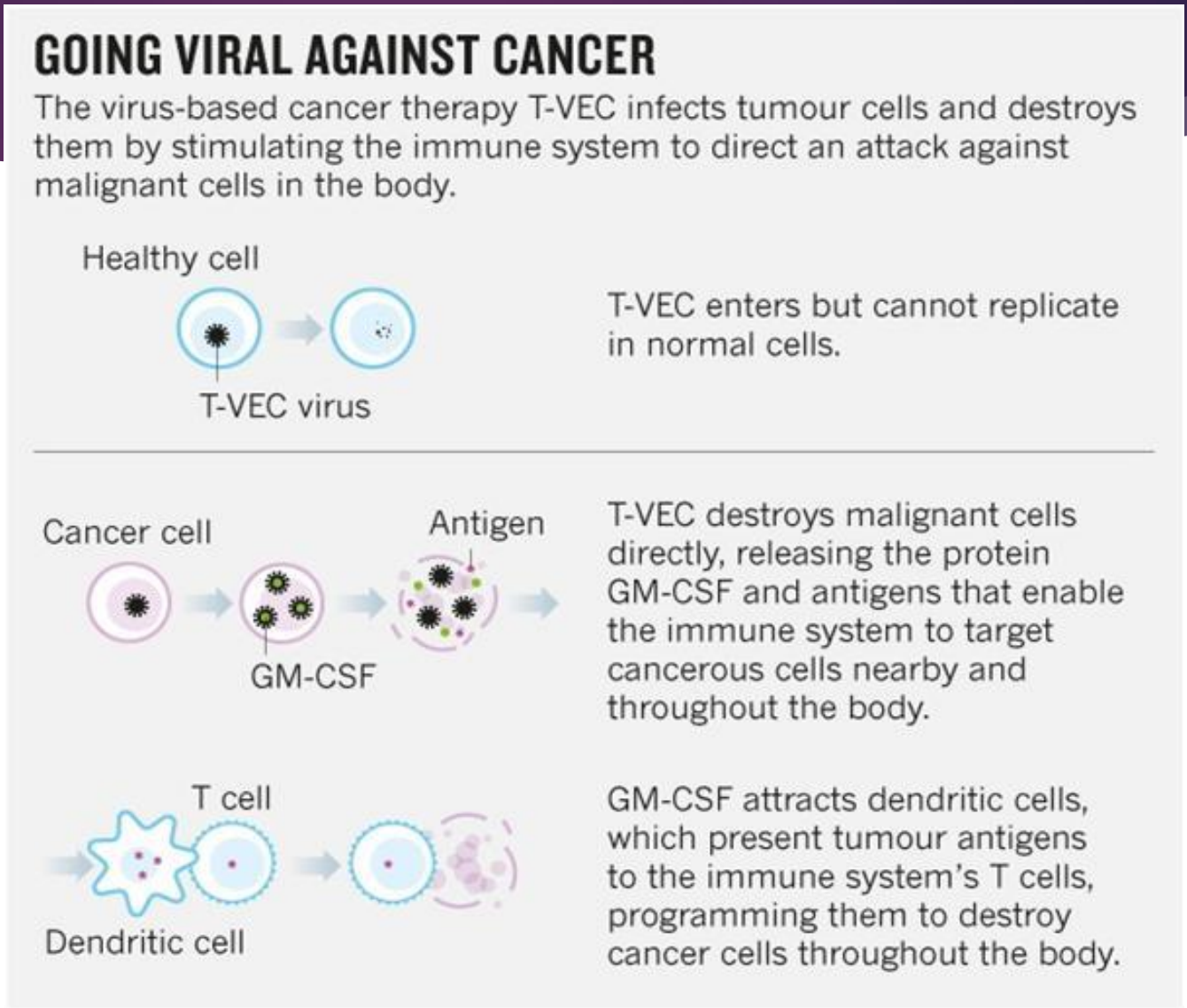
Empliciti® (elotuzumab) - Monitoring

- Monitoring: liver function tests periodically, signs and symptoms of infusion reactions, and second primary malignancies

Imlygic® (Talimogene laherparepvec)

Approval Date	October 27, 2015
Indication	Treatment (local) of unresectable cutaneous, subcutaneous, and nodal lesions in patients with melanoma recurrent after initial surgery
Mechanism of Action (MOA)	Genetically modified attenuated herpes simplex virus 1 (HSV), an oncolytic virus that selectively replicates in and lyses tumor cells

Imlygic® (Talimogene laherparepvec) - MOA



http://www.nature.com/news/cancer-fighting-viruses-win-approval-1.18651

Imlygic® (Talimogene laherparepvec) - Administration

Administration	Intralesional injection into cutaneous, subcutaneous, and/or nodal lesions that are visible, palpable, or detectable by ultrasound • Inject using a 22 to 26 gauge needle along multiple tracks as far as the needle allows within the lesion to achieve dispersion • Multiple lesion points may be used if a lesion is larger than the radial reach of the needle • Inject evenly and completely within the lesion by pulling the needle back without removing it from the lesion • Remove the needle from the lesion slowly to avoid leakage.

Imlygic® (Talimogene laherparepvec) – Post Administration

Post - Administration	• Apply pressure with sterile gauze for at least 30 seconds after the injection is completed • Swab the injection site(s) and surrounding areas with alcohol • Change gloves, then cover lesion(s) with absorbent pad and dry occlusive dressing, and wipe the exterior of the dressing with alcohol • The injection site should be covered for at least the first week after each treatment or longer if the injection site is weeping or oozing (replace dressing if it falls off)

Imlygic® (Talimogene laherparepvec) – Stability

Handling	• After thawed, do not shake. • Health care providers who are immunocompromised or pregnant should not prepare or administer talimogene laherparepvec and should not come into direct contact with injection sites, dressings, or body fluids of treated patients
Storage	• Store intact vials at -90°C to -70°C and protect from light • Thaw vials immediately prior to administration • If not used immediately, may store refrigerated (36°F to 46°F) for up to 12 hours for the 10^6 PFU per ml strength or up to 48 hours for 10^8 PFU per ml strength • Do not refreeze after thawing

Imlygic® (Talimogene laherparepvec) - Adverse Effects and Monitoring

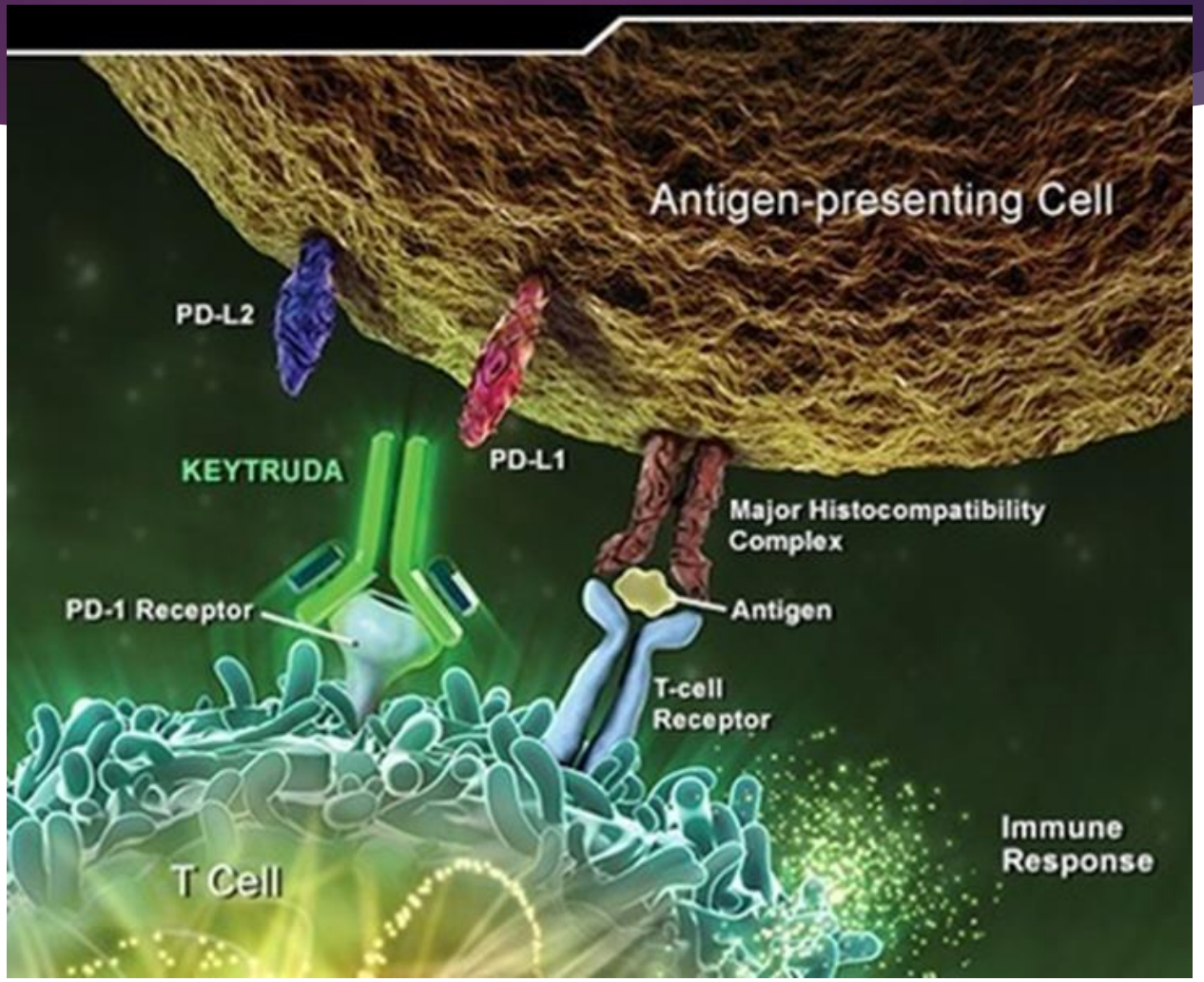
- Adverse effects include: Fatigue, chills, headache, dizziness, nausea, vomiting, diarrhea, pain at injection site, flu-like symptoms, and fever

- Monitor for signs/symptoms of herpetic infections (eg, cold sores and herpetic keratitis), injection site complications, and immune-mediated events.

Keytruda® (Pembrolizumab)

Approval Date	October 2, 2015
Indication	• Melanoma, unresectable or metastatic • Treatment of metastatic non-small cell lung cancer (NSCLC) in patients with PD-L1-expressing tumors (as determined by an approved test) who have disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression (on approved EGFR- or ALK-directed therapy) prior to receiving pembrolizumab

Keytruda® (Pembrolizumab) - MOA



https://www.genomeweb.com/molecular-diagnostics/aacr-study-shows-pd-l1-expression-can-id-best-responders-mercks-anti-pd-1

Keytruda® (Pembrolizumab) - Administration

Infusion Set	Use a 0.2 to 5 micron sterile, nonpyrogenic, low-protein-binding inline or add-on filter.
Administration	• For IV infusion only. Do not give IV push or as a bolus. • Infuse over 30 minutes • Do not infuse other medications through the same infusion line

Keytruda® (Pembrolizumab) - Stability

Handling	Do not shake or freeze
Compatibility	Compatible in NS and D5W.
Storage	Solutions diluted for infusion may be stored at room temperature for up to 6 hours (infusion must be completed within 6 hours of reconstitution) or refrigerated for no more than 24 hours

Keytruda® (Pembrolizumab) - Adverse Effects

- Adverse Effects: Peripheral edema, fatigue, headache, chills, pruritus, skin rash, hyperglycermia, nausea, cough, fever, arthralgia, and back pain.

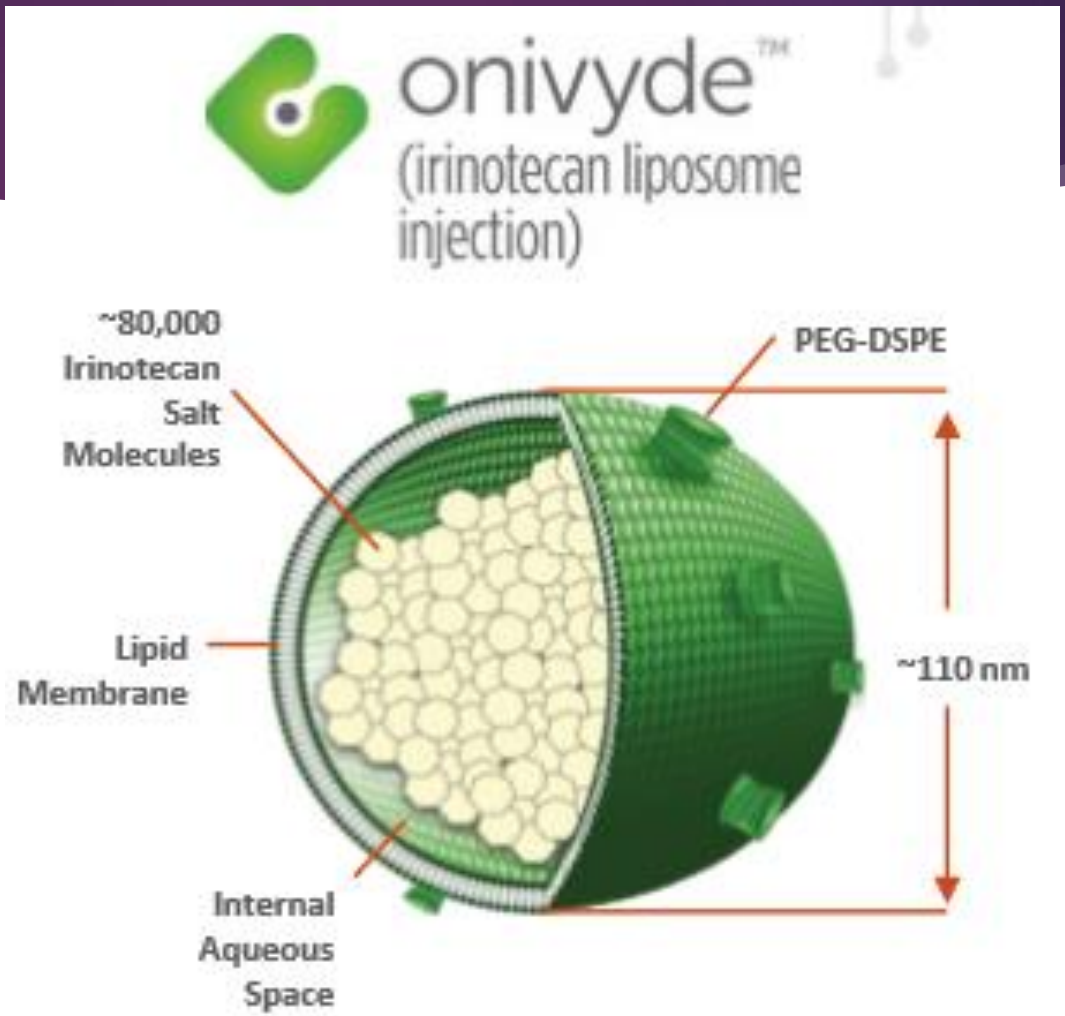
Keytruda® (Pembrolizumab) - Monitoring

- PD-L1 expression status in patients with NSCLC
- Liver function tests (AST, ALT, and total bilirubin; monitor for changes in liver function)
- Monitor for renal function changes; monitor for changes in thyroid function (at baseline, periodically during treatment, and as clinically indicated)
- Monitor for signs/symptoms of colitis, hypophysitis, thyroid disorders, pneumonitis, infusion reactions

Onivyde® (Irinotecan Liposomal)

Approval Date	October 22, 2015
Indication	Metastatic adenocarcinoma of the pancreas (in combination with fluorouracil and leucovorin) after disease progression following gemcitabine-based therapy
Mechanism of Action	Irinotecan and its active metabolite (SN-38) reversibly bind to topoisomerase 1-DNA complex and prevent repair of single strand breaks, leading to double-strand DNA damage and cell death • Encapsulated in a lipid bilayer (liposome) vesicle (allow drug to stay in the body longer)

Onivyde® (Irinotecan Liposomal) - MOA



http://seekingalpha.com/article/3816696-merrimack-pharmaceuticals-drive-higher-2016-onivyde-pipeline

Onivyde® (Irinotecan Liposomal) - Administration

Pre-Medications	A corticosteroid and an antiemetic (approximately 30 minutes prior to infusion)
Infusion Set	Do not use in-line filters for administration.
Administration	• Infuse over 90 minutes • Administer irinotecan (liposomal) prior to fluorouracil and leucovorin. Administer IV or subcutaneous atropine 0.25 to 1 mg (unless clinically contraindicated) for early onset diarrhea of any severity • Initiate loperamide for late-onset diarrhea of any severity

Onivyde® (Irinotecan Liposomal) - Stability

Compatibility	Compatible in NS and D5W.
Storage	Solution diluted for administration is stable for up to 4 hours when stored at room temperature, or up to 24 hours when refrigerated (administration should be completed within these time frames) • Allow diluted solution to come to room temperature prior to administration

FYI: Irinotecan (liposomal) and irinotecan hydrochloride are not interchangeable.

- Reduce the initial starting dose in patients known to be homozygous for the UGT1A1*28 allele.

Onivyde® (Irinotecan Liposomal) - Adverse Effects and Monitoring

- Side effects may include diarrhea, nausea, decreased appetite, stomatitis, fatigue, alopecia, anemia, neutropenia, thrombocytopenia, weakness, and fever.

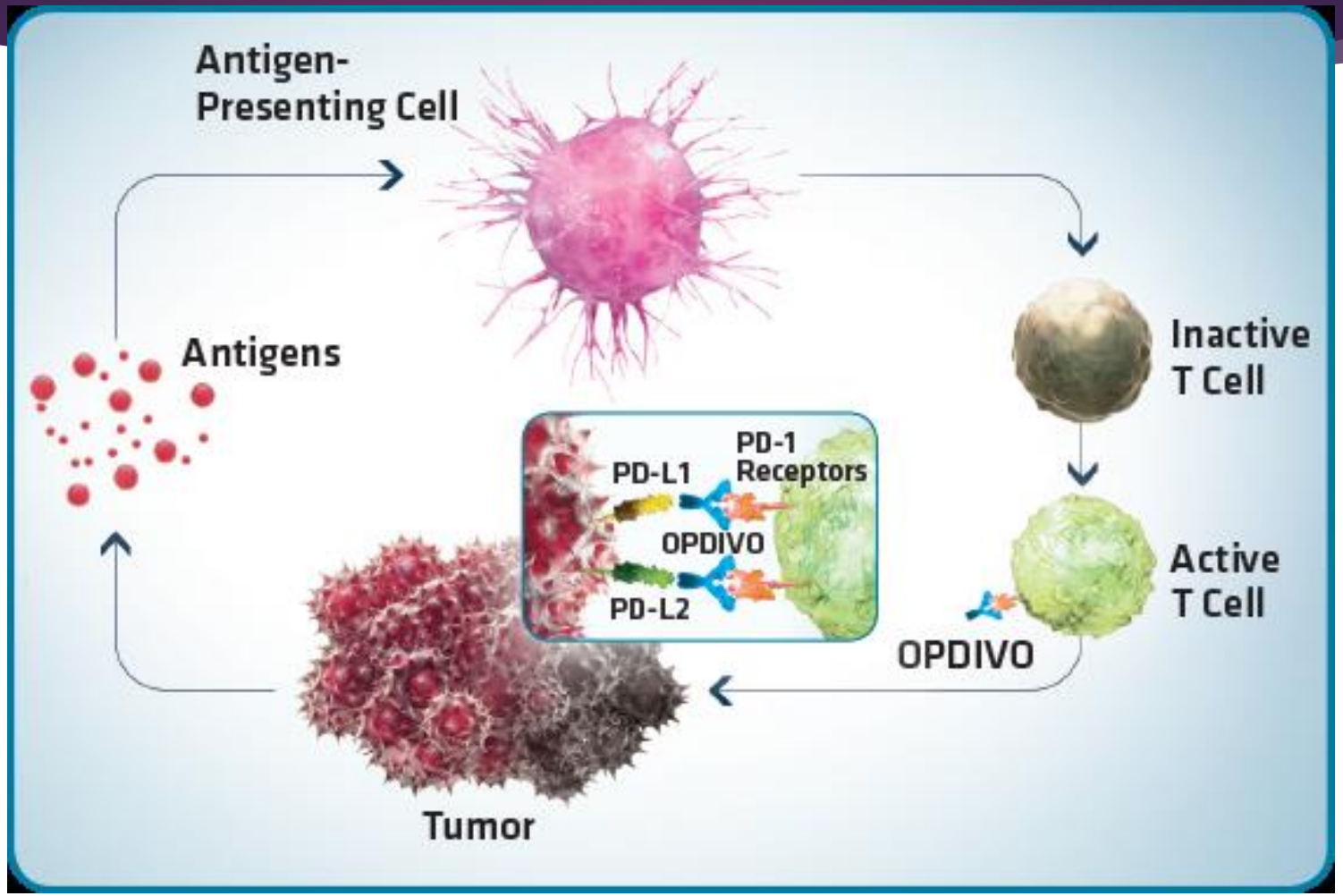
- Monitor:
  - Complete blood counts on days 1 and 8 of each cycle and as clinically indicated
  - Bilirubin, electrolytes (with severe diarrhea)
  - Bowel movements and hydration status
  - Signs/symptoms of pulmonary toxicity or hypersensitivity reactions

- Boxed warnings: bone marrow suppression and GI toxicity

Opdivo® (Nivolumab)

Approval Date	March 4, 2015
Indications	• BRAF V600 wild-type unresectable or metastatic melanoma; unresectable or metastatic BRAF V600 mutation-positive melanoma with disease progression following ipilimumab and a BRAF inhibitor; treatment of BRAF V600 wild-type, unresectable or metastatic melanoma (in combination with ipilimumab) • Metastatic non-small cell lung cancer (NSCLC) that has progressed on or after platinum-based chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression (on FDA-approved EGFR- or ALK-directed therapy) prior to receiving nivolumab • Advanced renal cell cancer in patients who have received prior anti-angiogenic therapy

Opdivo® (Nivolumab) - MOA



http://www.opdivohcp.bmscustomerconnect.com/metastatic-nsclc/opdivo-mechanism-of-action

Opdivo® (Nivolumab) - Administration

Infusion Set	Administer through a line with a sterile, nonpyrogenic, low protein binding 0.2 to 1.2 micrometer in-line filter.
Administration	• Infuse over 60 minutes • Do not administer other medications through the same IV line • Flush IV line at the end of the infusion
In Combination With Ipilimumab	When administered in combination with ipilimumab, infuse nivolumab first followed by ipilimumab on the same day Use separate infusion bags and filters for each infusion • If nivolumab therapy is withheld, ipilimumab should also be withheld

Opdivo® (Nivolumab) - Stability

Handling	Do not shake.
Compatibility	Compatible in NS and D5W.
Storage	After preparation, store the infusion solution at room temperature for no more than 4 hours (including infusion time) or refrigerated for up to 24 hours • Infusion must be completed within 24 hours of preparation

Opdivo® (Nivolumab) - Adverse Effects and Monitoring

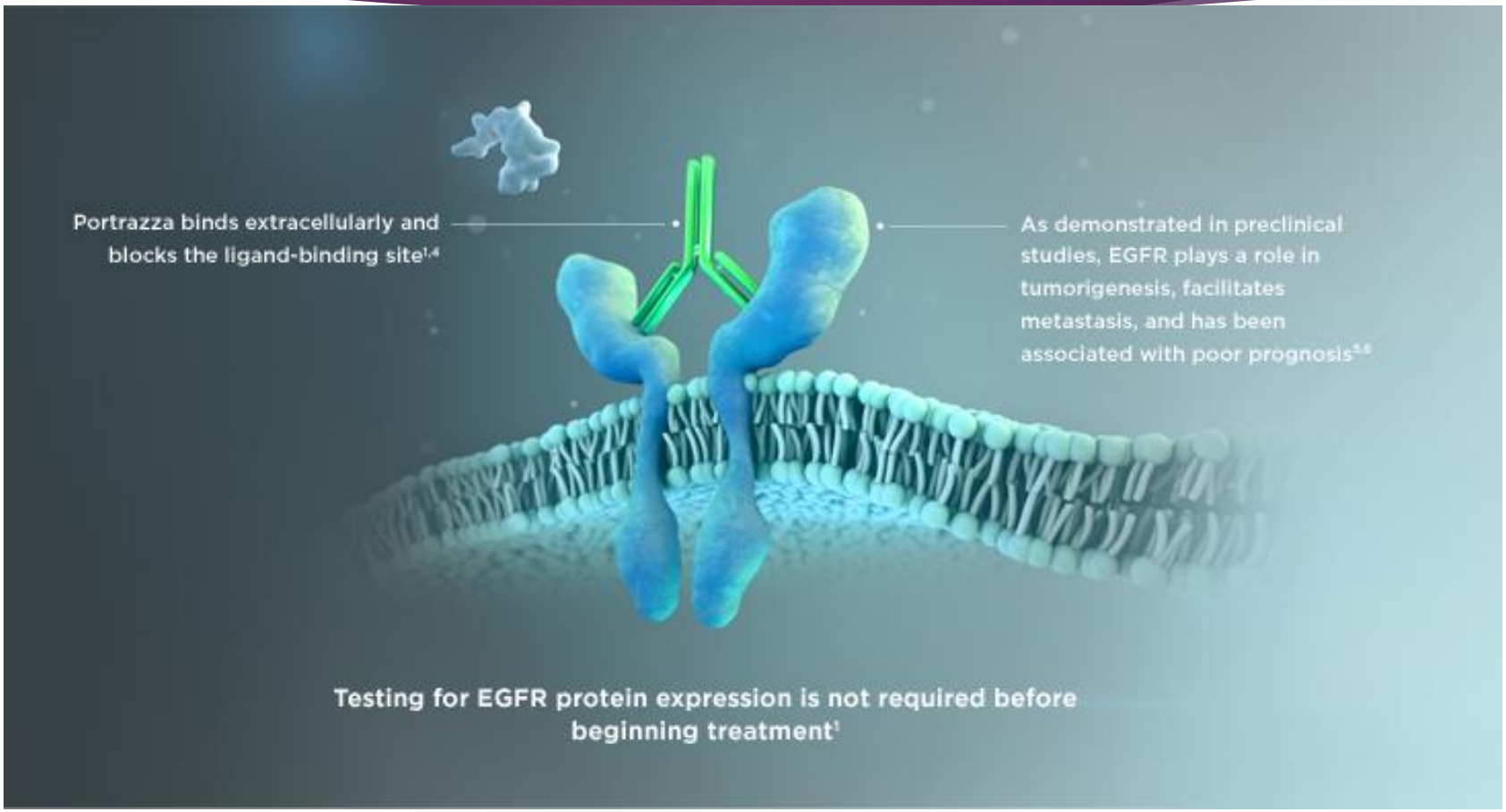
- Side effects may include: Edema, chest pain, fatigue, skin rash, decreased appetite, nausea, musculoskeletal pain, dyspnea, cough, and fever.

- Monitor:
  - Hepatic and renal function tests (baseline and periodic), thyroid function (baseline and periodically [eg, at treatment day 1 and every 6 weeks]), blood glucose.
  - Monitor for signs/symptoms of adrenal insufficiency, hypophysitis, thyroid disorders, immune-mediated colitis, pneumonitis, rash, encephalitis (changes in neurologic function); monitor for infusion reactions.

Portrazza® (Necitumumab)

Approval Date	November 24, 2015
Indication	First-line treatment of metastatic squamous non-small cell lung cancer (NSCLC) in combination with gemcitabine and cisplatin
Mechanism of Action	A recombinant human IgG1 EGFR monoclonal antibody that binds (with a high affinity) to the ligand binding site of the EGFR receptor to prevent receptor activation and downstream signaling

Portrazza® (Necitumumab) - MOA



www.portrazza.com

Portrazza® (Necitumumab)- Administration

Administration	• Infuse over 60 minutes using an infusion pump • Infuse through a separate line • Do not infuse with other medications or with electrolytes • Flush with sodium chloride 0.9% at the end of infusion
Infusion Reactions	Monitor and reduce infusion rate by 50% for grade 1 infusion reaction; interrupt infusion for grade 2 infusion reaction
Order of Administration	Should be administered prior to gemcitabine and cisplatin

Portrazza® (Necitumumab) - Stability

Handling	Do not shake. Do not freeze
Compatibility	Compatible in NS
Storage	Solutions diluted for infusion are stable for up to 4 hours at room temperature or 24 hours under refrigeration

Portrazza® (Necitumumab) - Adverse Effects and Monitoring

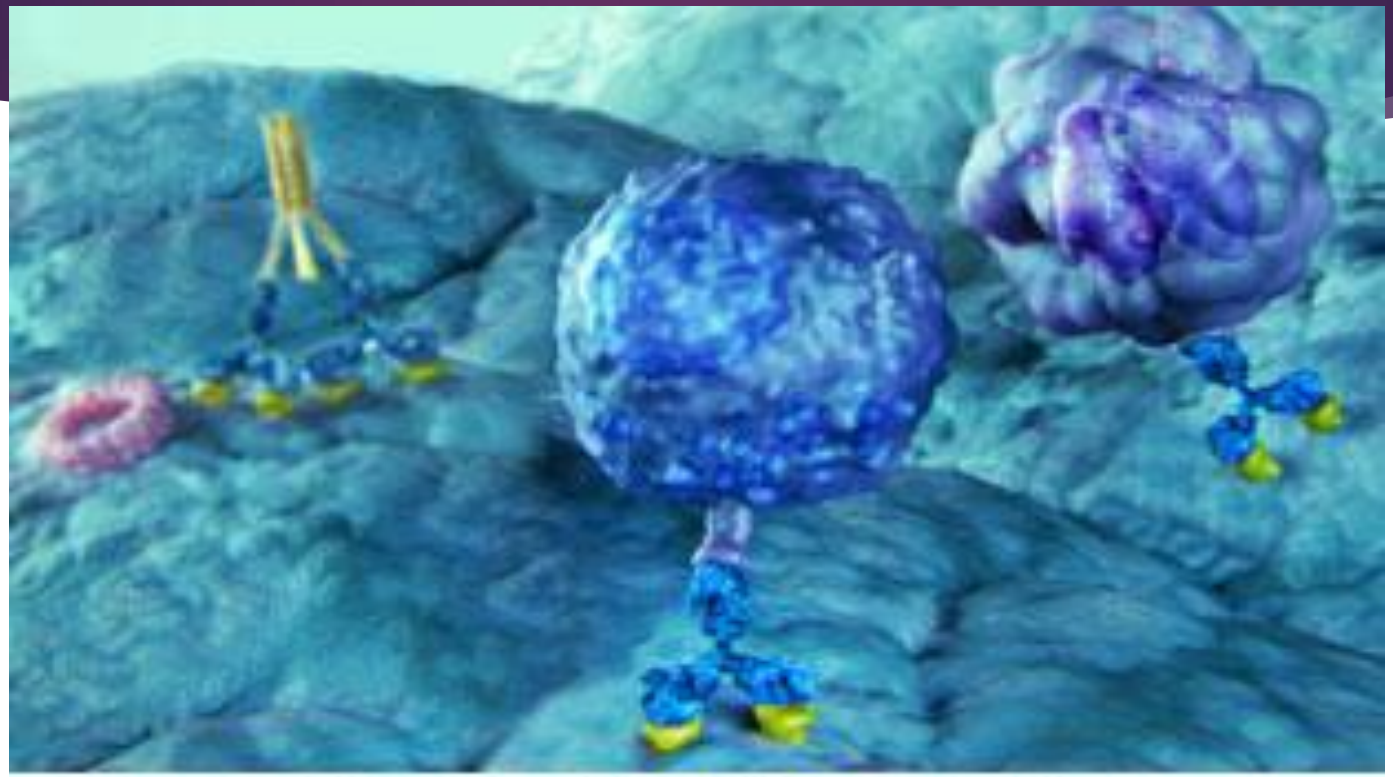
- Side effects may include headache, skin toxicity, skin rash, hypomagnesemia, hypocalcemia, hypophosphatemia, hypokalemia, vomiting, diarrhea, and stomatitis.

- Monitor:
  - Serum electrolytes, including magnesium, potassium, and calcium (prior to each dose during treatment and for at least 8 weeks following completion)
  - Signs/symptoms of infusion-related reactions, dermatologic toxicity, and thromboembolism

Unituxin® (Dinutuximab)

Approval Date	March 10, 2015
Indication	High-risk neuroblastoma (in combination with granulocyte-macrophage colony-stimulating factor [GM-CSF; sargramostim], interleukin-2 [IL-2; aldesleukin], and 13-cis-retinoic acid [isotretinoin]) in pediatric patients who achieve at least a partial response to prior first-line multiagent, multimodality therapy

Unituxin® (Dinutuximab) - MOA



NEUROBLASTOMA CELLS WITH mAbs BOUND TO GD2 ANTIGENS BEING ATTACKED THROUGH ADCC AND CDC.

Unituxin® (Dinutuximab) – Pre-Medications

Pre-Medications	
Analgesics	Morphine 50 mcg/kg IV immediately prior to dinutuximab infusion initiation; continue as a morphine drip at an infusion rate of 20 to 50 mcg/kg/hour during and for 2 hours following completion of infusion. May administer additional doses of 25 to 50 mcg/kg IV as needed up to once every 2 hours followed by an increase in the drip rate in clinically stable patients. Consider converting to fentanyl or hydromorphone if morphine is not tolerated; if pain is inadequately controlled with opioids, consider adjunct therapy with gabapentin or lidocaine

Unituxin® (Dinutuximab) – Pre-Medications

Pre-Medications	
Antihistamine	Administer an antihistamine (eg, diphenhydramine 0.5 to 1 mg/kg/dose; maximum dose 50 mg) IV over 10 to 15 minutes starting 20 minutes prior to dinutuximab infusion and every 4 to 6 hours as tolerated during the infusion
Antipyretics	Administer acetaminophen (10 to 15 mg/kg/dose; maximum dose 650 mg) 20 minutes prior to each infusion and every 4 to 6 hours as needed for fever and pain. May administer ibuprofen (5 to 10 mg/kg/dose) every 6 hours as needed for control of persistent fever or pain

Unituxin® (Dinutuximab)- Administration

Pre-Administration	IV hydration: Administer normal saline 10 mL/kg IV over 1 hour just prior to each dinutuximab infusion.
Administration	Administer as IV infusion only (do not administer as IV push or bolus) • Initiate infusion at 0.875 mg/m^2/hour for 30 minutes • Gradually increase rate as tolerated to a maximum rate of 1.75 m/m^2/hour to infuse over 10 to 20 hours each day

Unituxin® (Dinutuximab) - Stability

Handling	Do not shake
Compatibility	Compatible in NS
Storage	Solutions diluted for infusion should be stored at 36°F to 46°F • Initiate infusion within 4 hours of preparation • Discard diluted solution 24 hours after preparation

Unituxin® (Dinutuximab) - Adverse Effects and Monitoring

- Side effects may include hypotension, capillary leak syndrome, tachycardia, hypertension, pain, peripheral neuropathy, urticarial, hyponatremia, vomiting, diarrhea, hypoxia, fever, infusion related reaction.

- Monitor:
  - CBC with differential, serum electrolytes, renal function, blood pressure
  - Monitor for signs/symptoms of infusion reactions (during and for at least 4 hours after infusion), pain, peripheral neuropathy, capillary leak syndrome, infection/sepsis, hemolytic uremic syndrome, and ocular toxicity

Varubi® (rolapitant)

Approval Date	September 2, 2015
Indication	Prevention of delayed chemotherapy-induced nausea and vomiting
Mechanism of Action	Selective and competitive substance P/neurokinin-1 (NK1) receptor antagonist with antiemetic activity

Varubi® (rolapitant) - MOA

Brainstem Vomiting Center

- Area postrema
  - Chemoreceptor trigger zone (CTZ)
- Nucleus tractus solitarius
- Dorsal motor nucleus of the vagus nerve

- **Substance P/neurokinin$_1$ (NK$_1$) receptors**
- Serotonin/5-HT$_3$ receptors

GI Vagal Afferent Nerve Fibers

- **Serotonin/5-HT$_3$ receptors**
- Substance P/NK$_1$ receptors

http://apm.amegroups.com/article/view/1033/1265

Varubi® (rolapitant)- Administration

Administration	Administer orally approximately 1-2 hours prior to each chemotherapy cycle (day 1 only) • Give with or without meals • Administer at no less than 2-week intervals
Highly emetogenic chemotherapy	Use in combination with dexamethasone (day 1, 2, 3, and 4) and a 5-HT3 receptor antagonist (day 1)
Moderately emetogenic chemotherapy	Use in combination with dexamethasone (day 1) and a 5-HT3 receptor antagonist (based on selected agent)

Varubi® (rolapitant) -Adverse Effects and Monitoring

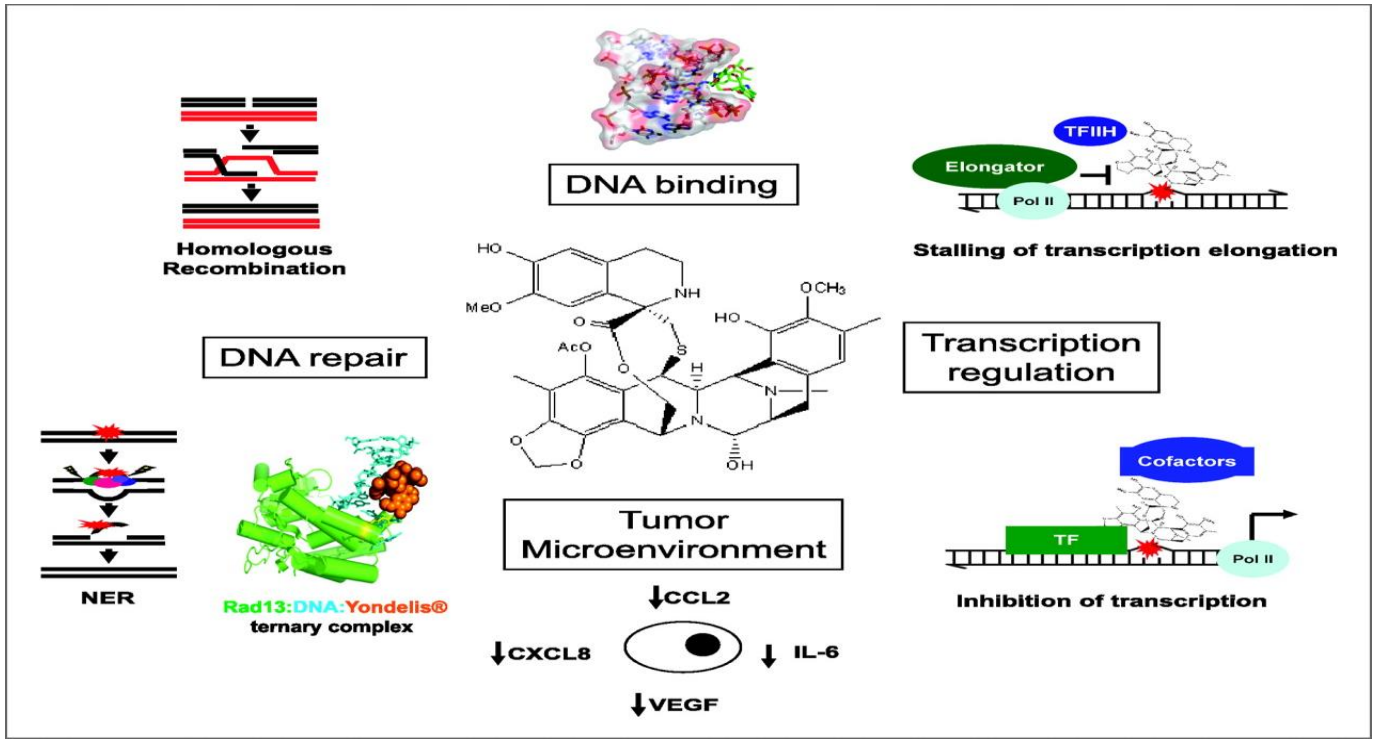
- Side effects may include dizziness, decreased appetite, and hiccups

- Educate patient about signs of a significant reaction:
  - Itching/hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing

Yondelis® (Trabectedin)

Approval Date	October 23, 2015
Indication	Unresectable or metastatic soft tissue sarcoma (liposarcoma or leiomyosarcoma) in patients who have received a prior anthracycline-containing regimen
Mechanism of Action	A marine-derived compound which blocks the cell cycle at the G2/M phase by covalently binding to the minor DNA groove, bending the helix toward the major groove and altering DNA transcription. Also alters DNA repair mechanism

Yondelis® (Trabectedin) - MOA



http://mct.aacrjournals.org/content/9/8/2157/F4.expansion

Yondelis® (Trabectedin)- Administration

Pre-Meds	Premedicate with a corticosteroid (eg, dexamethasone IV) 30 minutes prior to treatment • Additional antiemetics may be needed
Infusion Set	Through a central line with a 0.2 micron polyethersulfone filter
Vesicant	Ensure proper needle or catheter placement prior to and during infusion to avoid extravasation
Administration	• Single-agent therapy: continuous infusion over 24 hours • Infusion must be completed within 30 hours of reconstitution

Yondelis® (Trabectedin) - Stability

Compatibility	Compatible in NS, D5W
Storage	Solutions diluted for infusion should be used within 30 hours of reconstitution (infusion should be completed within that 30 hours)

Yondelis® (Trabectedin) - Adverse Effects and Monitoring

- Side effects may include phlebitis, fatigue, headache, skin rash, palmar-plantar erythrodysesthesia, nausea, vomiting, constipation, anemia, increased ALT, AST, catheter site reaction, dyspnea, fever.

- Monitor:
  - Complete blood cell count with differential (baseline and periodically during treatment cycles); total bilirubin (prior to each cycle), ALT, AST, and alkaline phosphatase (prior to each cycle); renal function (baseline and during treatment); CPK (prior to each treatment cycle), evaluate LVEF via MUGA or echocardiogram (baseline and every 2 to 3 months); monitor infusion site for signs/symptoms of extravasation.

Zarxio® (filgrastim-sndz)

Approval Date	March 6, 2015
Indication	Acute myeloid leukemia following induction or consolidation chemotherapy, bone marrow transplant, myelosuppressive chemotherapy recipients with nonmyeloid malignancies, peripheral blood progenitor cell collection and therapy, severe chronic neutropenia
Mechanism of Action	Human granulocyte colony-stimulating factor (G-CSF) stimulates the production, maturation, and activation of neutrophils; filgrastim activates neutrophils to increase both their migration and cytotoxicity • Reduce time to neutrophil recovery and duration of fever

Zarxio® (filgrastim-sndz)- Administration

Administration	Do not administer earlier than 24 hours after or in the 24 hours prior to cytotoxic chemotherapy
Subcutaneous	Peripheral blood progenitor cell collection, severe chronic neutropenia, CIN, hematopoietic radiation injury syndrome • Administer into the outer upper arm, abdomen (except within 2 inches of navel), front middle thigh, or the upper outer buttocks area • Rotate injection site • Do not inject into areas that are tender, red, bruised, hardened, or scarred, or sites with stretch marks
Intravenous	Short infusion over 15-30 minutes (chemotherapy-induced neutropenia - CIN) or by continuous infusion (CIN) or as an infusion no longer than 24 hours (bone marrow transplantation)

Zarxio® (filgrastim-sndz) - Stability

Handling	Do not shake. Discard unused portion of syringe
Compatibility	Compatible in D5W ** incompatible with NS**
Storage	• Prior to injection, allow to reach room temperature for up to 30 min and a maximum of 24 hours • Solutions diluted for infusion may be stored at room temperature for up to 24 hours (infusion must be completed within 24 hours of preparation) • Discard any prefilled syringe left at room temperature for more than 24 hours

Zarxio® (filgrastim-sndz) -Adverse Effects and Monitoring

- Side effects may include fatigue, dizziness, nausea, back pain, arthralgia, nausea, fever or ostealgia.

- Monitor:
  - Complete blood cell count with differential and platelets
  - Educate patient about signs of a significant reaction (eg, wheezing; chest tightness; fever; itching; bad cough; blue skin color; seizures; or swelling of face, lips, tongue, or throat)

References

- Micromedex
- Facts & Comparisons
- Lexi-Comp, Inc. (Lexi-Drugs®). Lexi-Comp, Inc.; April 10, 2016.

Questions?

Thank you!

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