Pharmacology Update 2021

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Disclosures

Speaker Honoraria: ION division AmerisourceBergen, Physicians' Education Resource

Advisory Board Honoraria: Frenesius Kabi

Objectives

- Identify new drugs/agents that have been FDA approved for cancer treatment in 2021.
- Recognize how new drugs/agents are given generic names.
- Identify how to gain information about new drugs based on the generic naming system

Progress in Cancer Therapy 2021

- **New FDA Approved Cancer Treatment Agents (1/1/2021 to 6/16/2021)**
  - **11: 6 solid tumor & 5 hematologic malignancies**
    - **8 Molecularly Targeted/Immunotherapy**
    - **2 Cellular Therapies**
    - **1 Alkylating Agent**

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Progress in Cancer Therapy 2021

- **New FDA Approved Cancer Treatment Agent Indications (1/1/2021 to 6/16/2021)**
  - ***11 drugs with 18 new disease indications***

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Trends

Trends 2021

- Immunotherapy and Molecular Therapies
  - Subcutaneous formulations of monoclonal antibodies
  - Expanded indications
    - Neoadjuvant/adjuvant
    - Metastatic and locally advanced treatment
    - Maintenance after primary treatment
    - New generations of drugs to treat drug resistance

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Trends 2021

- **Biosimilars**
  - **A biological product that is approved based on a showing that it is highly similar to an already-approved biological product, known as a reference product.**
  - **The biosimilar also must show it has no clinically meaningful differences in terms of safety and effectiveness from the reference product.**
  - **Only minor differences in clinically inactive components are allowable in biosimilar products.**

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Trends 2021

- **Cellular Gene Therapies**
  - **2017: “The U.S. Food and Drug Administration issued a historic action today making the first gene therapy available in the United States, ushering in a new approach to the treatment of cancer and other serious and life-threatening diseases.”**
  - **5 new therapies FDA approved for cancer treatment since 2017; more in development with expanding indications**

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Trends 2021

- **Tumor Agnostic Drugs**
  - **Drugs designed to treat genomic alterations; not tumor histology specific**

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Progress in Cancer Therapy 2021

- **Non-Small Cell Lung Cancer (NSCLC)**
  - ***lorlatinib Lorbrena® Pfizer Inc.: for patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive***
  - ***cemiplimab-rwlc Libtayo® Regeneron Pharmaceuticals, Inc.: first-line treatment of patients with advanced non-small cell lung cancer (NSCLC) (locally advanced who are not candidates for surgical resection or definitive chemoradiation or metastatic) whose tumors have high PD-L1 expression (Tumor Proportion Score [TPS] > 50%) as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations***

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Progress in Cancer Therapy 2021

- **Breast**
  - ***sacituzumab govitecan-hziy TRODELVY™ Immunomedics, Inc.: adult patients with unresectable locally advanced metastatic triple-negative breast cancer who received at least two prior therapies for metastatic disease***
- **Endometrial**
  - **dostarlimab-gxly Jemperli GlaxoSmithKline LLC: adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following a prior platinum-containing regimen**
- **Basal Cell Carcinoma**
  - ***cemiplimab-rwlc Libtayo® Regeneron Pharm.: locally advanced and metastatic basal cell carcinoma***

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Progress in Cancer Therapy 2021

- **Renal Cell**
  - **tivozanib Fotivda® AVEO Pharmaceuticals, Inc.: adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies**
  - ***nivolumab Opdivo® Bristol-Myers Squibb Co. and cabozantinib Cabometyx® Exelixis) as first-line treatment for patients with advanced renal cell carcinoma (RCC)***

- **Urothelial**
  - ***sacituzumab govitecan-hziy TRODELVY™ Immunomedics Inc: advanced urothelial cancer***

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Progress in Cancer Therapy 2021

- **Gastric or gastroesophageal (GEJ) adenocarcinoma**
  - ***fam-trastuzumab deruxtecan-nxki Enhertu® Daiichi Sankyo: adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen***
  - ***pembrolizumab KEYTRUDA® Merck Sharp & Dohme Corp.: in combination with platinum and fluoropyrimidine-based chemotherapy for patients with metastatic or locally advanced esophageal or gastroesophageal (GEJ) (tumors with epicenter 1 to 5 centimeters above the gastroesophageal junction) carcinoma who are not candidates for surgical resection or definitive chemoradiation***
  - ***nivolumab Opdivo® Bristol-Myers Squibb Company: in combination with fluoropyrimidine- and platinum-containing chemotherapy for advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma***
  - ***pembrolizumab Keytruda® Merck & Co.: in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma***

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Progress in Cancer Therapy 2021

Amyloidosis

- ***daratumumab plus hyaluronidase Darzalex Faspro™ Janssen Biotech Inc.: in combination with bortezomib, cyclophosphamide and dexamethasone for newly diagnosed light chain (AL) amyloidosis***

- **Anaplastic Large Cell Lymphoma**

  - ***crizotinib Xalkori® Pfizer Inc.: pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. The safety and efficacy of crizotinib have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL***

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Progress in Cancer Therapy 2021

- **Diffuse Large B-Cell lymphoma (DLBCL)**
  - **lisocabtagene maraleucel Breyanzi ® Juno Therapeutics, Inc.: the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B**
  - **loncastuximab tesirine-lpyl Zynlonta™ ADC Therapeutics SA: a CD19-directed antibody and alkylating agent conjugate, for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma**

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Progress in Cancer Therapy 2021

- **Follicular Lymphoma**
  - ***axicabtagene ciloleucel Yescarta® Kite Pharma, Inc.: adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy***

- **Follicular Lymphoma/Marginal Zone Lymphoma**
  - **umbralisib Ukoniq™ TG Therapeutics:**
    - **Adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen**
    - **Adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy**

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

Progress in Cancer Therapy 2021

- **Multiple Myeloma**
  - **melphalan flufenamide Pepaxto® Oncopeptides AB: in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD-38 directed monoclonal antibody**
  - **idecabtagene vicleucel Abecma® Bristol Myers Squibb: treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. This is the first FDA-approved cell-based gene therapy for multiple myeloma**
  - ***isatuximab-irfc SARCLISA® Sanofi-Aventis U.S. LLC: in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy***

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

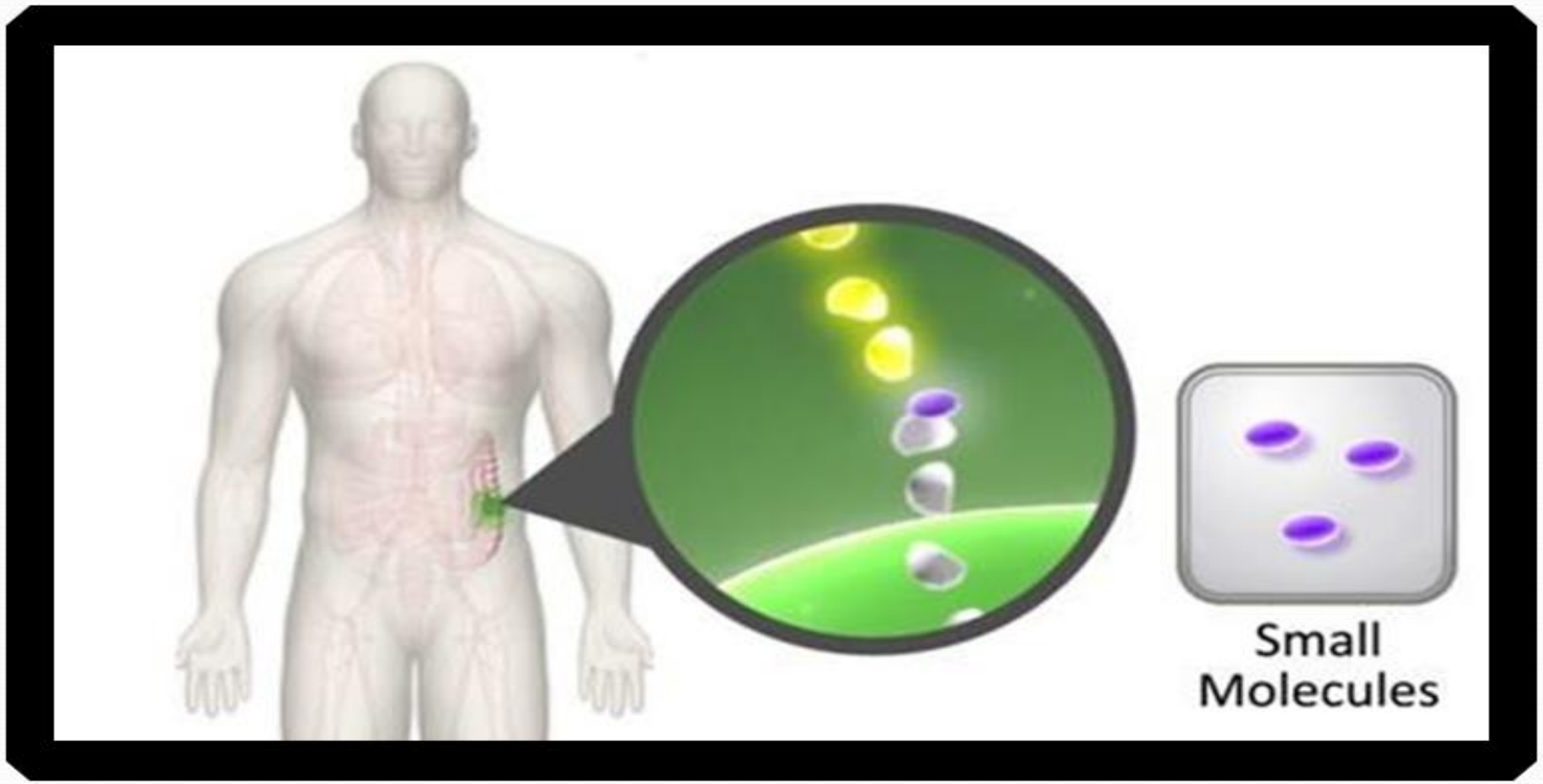
Tips for Learning about New Cancer Therapies

- **Know the type of drug/agent**
  - **Small molecule, monoclonal antibody, cellular gene therapy, vaccine, cytotoxic**
- **Know the generic name**
- **Know the target and what is does normally in the body/what other FDA approved drugs are similar**
- **Know if the drug is genomically specific and if testing is needed before administration**

I know the generic name; but how do I pronounce it and how do I learn more??

- http://www.cancer.gov/dictionary
- http://www.mycancergenome.org/content/molecular-_medicine/overview-of-targeted-therapies-for-cancer/

Once potential targets are identified, then drugs are designed to best attack the target



http://www.cancer.gov/cancertopics/understandingcancer/targetedtherapies

Small Molecules

- **Majority are oral, although a few are IV or subcutaneous.**
- **Implications for orals:**
  - **Adherence**
  - **Possible drug/food , drug/drug interactions**
  - **Patient education regarding taking medication correctly**
- **Targets vary and side effects are related to targets**

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

Small Molecules Naming Conventions

- **tinibs:**
  - **tyrosine kinase inhibitors**
    - **erlotinib, sunitinib, ponatinib, imatinib, dasatinib,, ruxolitinib, dacomitinib, lorlatinib, larotrectinib, gilteritinib, neratinib, erdafitinib, pexidartinib, fedratinib, entrectinib, avapritinib, tucatinib, pemigatinib, ripretinib, selpercatinib, pralsetinib, tepotinib, infigratinib**

- **brutinib**
  - **Bruton's kinase inhibitor**
    - **ibrutinib, acalabrutinib, zanubrutinib**

- **zanibs:**
  - **kinase inhibitor**
    - **tivozanib**

- **rafenibs/metinibs**
  - **RAF/RAS/MEK kinase inhibitors**
    - **sorafenib, dabrafenib, trametinib, vemurafenib, encorafenib, binimetinib, capmatinib, selumetinib**

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

tepotinib Tepmetko®

tepotinib Tepmetko® EMD Serono Inc.: adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.

- ***Small molecule, oral kinase inhibitor***
- ***Drug/drug interactions with strong CYP3A inducers. Combined P-gp and strong CYP3A inhibitors. Certain P-gp substrates.***
- ***Targets MET exon 14 skipping alterations***
- ***Genomic alteration testing needed prior to administration***
- ***Side effects: Interstitial lung disease, hepatotoxicity, edema, fatigue, nausea, diarrhea, musculoskeletal pain, and dyspnea. The most common Grade 3 to 4laboratory abnormalities (≥ 2%) were decreased lymphocytes, decreased albumin, decreased sodium, increased gamma-glutamyltransferase, increased amylase, increased ALT, increased AST, and decreased hemoglobin***

www. TEPMETKO.com

tivozanib Fotivda®

tivozanib Fotivda® AVEO Pharmaceuticals, Inc.: adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies (2021)

- ***Small molecule, oral kinase inhibitor***
- ***Drug/drug interactions with strong CYP3A inducers.***
- ***Targets VEGFR-1, VEGFR-2, VEGFR-3, c-kit, PDGFR***
- ***No genomic alteration testing needed prior to administration***
- ***Side effects: fatigue, hypertension, diarrhea, decreased appetite, nausea, dysphonia, hypothyroidism, cough, and stomatitis, and the most common Grade 3 or 4 laboratory abnormalities (≥5%) were sodium and phosphate decreases, lipase increased. Hypertensive crisis, cardiac failure, arterial and venous thromboembolic events hemorrhagic events, proteinuria, impaired wound healing, RPLS, allergic rxns***

www. FOTIVDA.com

infigratinib Truseltiq™

infigratinib Truseltiq™ QED Therapeutics, Inc.: a kinase inhibitor for adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test

- ***Small molecule, oral kinase inhibitor***
- ***Drug/drug interactions with strong or moderate CYP3A inducers and inhibitors as well as gastric acid reducing agents..***
- ***Targets FGFR2***
- ***Genomic alteration testing needed prior to administration***
- ***Side effects: Ocular toxicity, nail toxicity, stomatitis, dry eye, fatigue, alopecia, palmar-plantar erythrodysesthesia syndrome, arthralgia, dysgeusia, constipation, abdominal pain, dry mouth, eyelash changes, diarrhea, dry skin, decreased appetite, vision blurred and vomiting. increased creatinine, increased phosphate, decreased phosphate, increased alkaline phosphatase, decreased hemoglobin, increased alanine aminotransferase, increased lipase, increased calcium, decreased lymphocytes, decreased sodium, increased triglycerides, increased aspartate aminotransferase, increased urate, decreased platelets, decreased leukocytes, decreased albumin, increased bilirubin and decreased potassium. Hyperphosphatemia and soft tissue mineralization.***

www. Truseltiq.com

Small Molecules
Naming Conventions

- **paribs**
  - **PARP inhibitors: inhibitors of mammalian polyadenosine 5’-diphosphoribose polymerase (PARP) enzyme.**
    - **olaparib, rucaparib, niraparib, talazoparib**

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

Small Molecules
Naming Conventions

- **lisibs:**
  - **PI3 kinase inhibitors**
    - **idelalisib, copanlisib, duvelisib, alpelisib, umbralisib**

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

umbralisib Ukoniq™ TG Therapeutics:

Adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen

Adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy

www. UKONIQ.com

umbralisib Ukoniq™

umbralisib Ukoniq™ TG Therapeutics:

Adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen

Adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.

- ***Small molecule, oral kinase inhibitor***
- ***No drug/drug interactions known***
- ***Targets multiple kinases, including PI3K***
- ***No genomic alteration testing needed prior to administration***
- ***Side effects: infections, hepatotoxicity, neutropenia, severe cutaneous rxns, increased creatinine, diarrhea-colitis, allergic rxns to FD&C Yellow No. 5, fatigue, nausea, neutropenia, transaminase elevation, musculoskeletal pain, anemia, thrombocytopenia, upper respiratory tract infection, vomiting, abdominal pain, decreased appetite, and rash***

www. UKONIQ.com

Small Molecules
Naming Conventions

- **degibs:**
  - **Sonic hedgehog pathway inhibitors**
    - **sonidegib, vismodegib, glasdegib**

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

Small Molecules
Naming Conventions

- **denibs:**
  - **Isocitrate dehydrogenase IDH enzyme inhibitors**
    - **enasidenib (IDH2), ivosidenib (IDH1)**

- **ciclibs:**
  - **Cyclin dependent kinase (CDK) 4 & 6 inhibitors**
    - **palbociclib, ribociclib, abemaciclib**

- **zomibs:**
  - **Proteasome inhibitors**
    - **bortezomib, carfilzomib, ixazomib**

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

Small Molecules
Naming Conventions

- **rasibs**
  - **First in class for KRAS mutations: sotorasib**

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

sotorasib Lumakras™ Amgen, Inc : a RAS GTPase family inhibitor, for adult patients with KRAS G12C mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy

www. Lumakras.com

sotorasib Lumakras™

sotorasib Lumakras™ Amgen, Inc : a RAS GTPase family inhibitor, for adult patients with KRAS G12C mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy

- ***Small molecule, oral inhibitor of KRAS. First in class.***
- ***Drug/drug interactions with strong CYP3A inducers and CYP3A substrates as well as gastric acid reducing agents and P-gp substrates***
- ***Targets RAS GTPase family, including KRAS***
- ***Genomic alteration testing needed prior to administration***
- ***Side effects: diarrhea, musculoskeletal, pain, nausea, fatigue, hepatotoxicity, and cough. Decreased lymphocytes, decreased hemoglobin, increased aspartate aminotransferase, increased alanine aminotransferase, decreased calcium, increased alkaline phosphatase, increased urine protein, and decreased sodium. Hepatotoxicity, interstitial lung disease.***

www. Lumakras.com

Small Molecules
Naming Conventions

- **toclax:**
  - **BCL-2 inhibitors**
    - **venetoclax**

- **inostats:**
  - **Histone deacetylase inhibitors (HDAC inhibitors)**
    - **vorinostat, belinostat, panobinostat**

- **metostats:**
  - **Methyltransferase inhibitor (new classification)**
    - **tazemetostat (first in class)**

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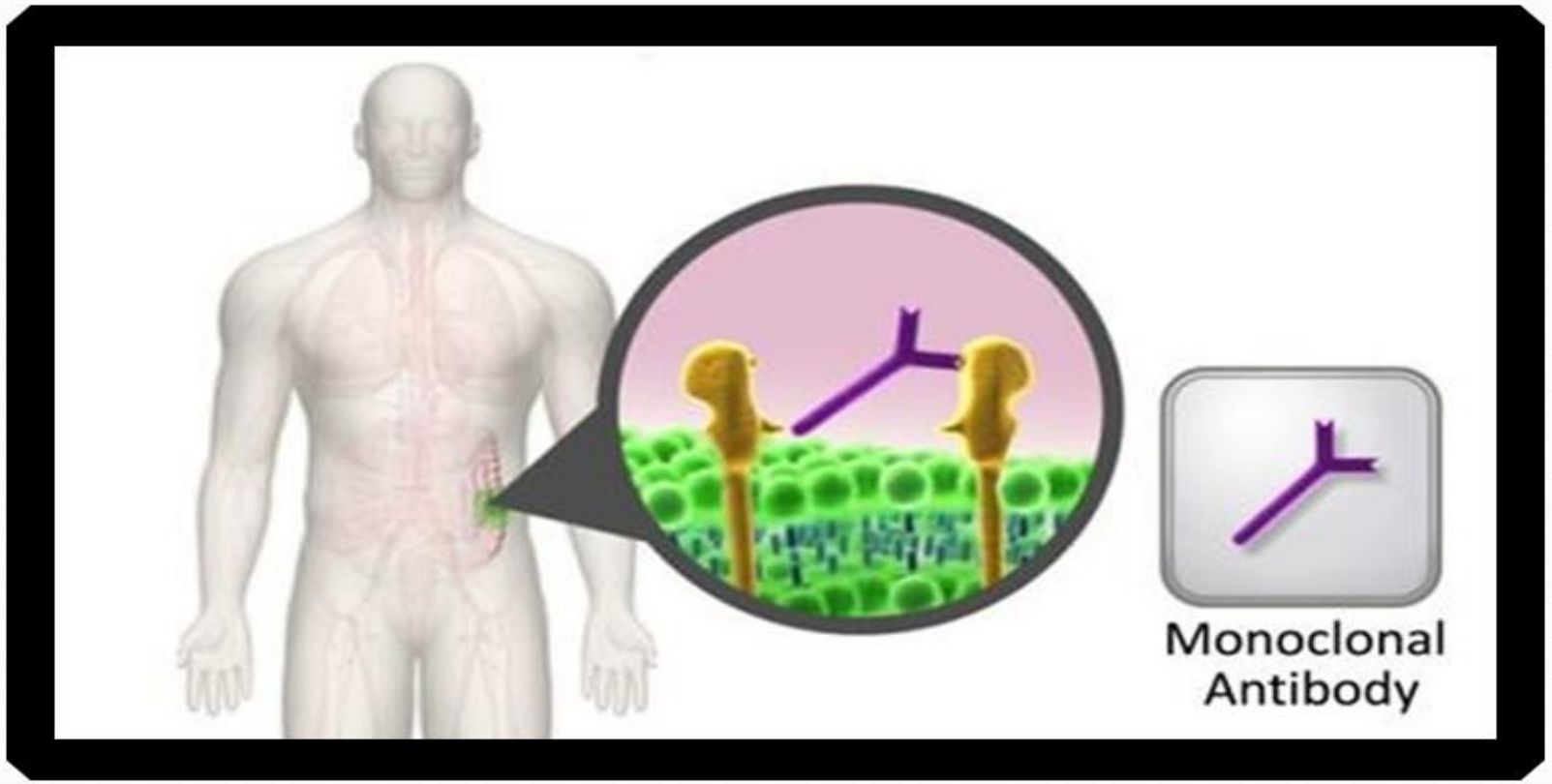
Small Molecules
Naming Conventions

- **Nexor (new classification)**
  - **small molecule inhibitor of CRM1 (chromosome region maintenance 1 protein, exportin 1 or XPO1), with potential antineoplastic activity. Via the approach of selective inhibition of nuclear export (SINE), restores endogenous tumor suppressing processes to selectively eliminate tumor cells while sparing normal cells.**
    - **selinexor (first in class)**

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

Once potential targets are identified, then drugs are designed to best attack the target



http://www.cancer.gov/cancertopics/understandingcancer/targetedtherapies

Monoclonal Antibody Naming Conventions

Monoclonal antibody = mab

- tositu**mo**mab and iodine 131
  - mo = mouse
- ritu**xi**mab
  - xi = chimeric or cross between mouse and human
- trastu**zu**mab, bevaci**zu**mab
  - zu = humanized
- panitum**u**mab
  - u = fully human (may also leave out the u)
- Decision recently made to eliminate the source inflix

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

What does the name mean?

t , ta, or tu = tumor

trastuzumab

ci = circulatory

bevacizumab

li or l = immunomodulator

ipilimumab

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What does the name mean?

- **One or two words added to name indicates it is a conjugated monoclonal antibody. May be combined with:**
  - **Radioactive particle: ibritumomab tiuxetan**
  - **Drug (antibody-drug conjugate): ado-trastuzumab emtansine**
- **Two words joined by "plus" or "and" indicates the combination of monoclonal antibody and a second agents**
  - **daratumumab plus hyaluronidase**

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What does the name mean?

- **Biosimilars originally had the reference product generic name as the "core" with "4 lower case letters devoid of meaning" attached by a hyphen as a suffix:**
  - **bevacizumab-awwb Mvasi™**
  - **trastuzumab-dskt Ogivri™**
  - **trastuzumab-pkrb Herzuma®**
  - **rituximab-abbs Truxima®**

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What does the name mean?

- **In 2017, the FDA made the decision to name all new biologics (not just biosimilars) with"4 lower case letters devoid of meaning" attached by a hyphen as a suffix:**
  - **There was concern that the suffix on biosimilars would serve as a barrier to their use; creating a misimpression that they were inferior to the reference (originator) products**
  - **Resulted in the FDA deciding to attached the suffix to all new biologics; not just biosimilars**
  - **Change in naming advances patient safety and creates a high quality, competitive market**
  - **FDA does not intend to modify the proper names of biological products that have already been licensed or approved under the Public Health Service Act without an FDA-designated suffix in their proper names.**

http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

dostarlimab-gxly Jemperli

dostarlimab-gxly Jemperli GlaxoSmithKline LLC: adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following a prior platinum-containing regimen

- ***Humanized monoclonal antibody***
- ***Potential infusion reactions***
- ***Targets programmed death receptor-1 (PD-1)***
- ***Drug/drug interactions with UGT1A1 inhibitors or inducers***
- ***Genomic alteration testing needed prior to administration***
- ***Side effects: fatigue/asthenia, nausea, diarrhea, anemia, and constipation. Immune mediated adverse events such as pneumonitis, colitis, hepatitis, endocrinopathies, nephritis, dermatologic rxns.***

www. jemperlicom

loncastuximab tesirine-lpyl Zynlonta™ ADC Therapeutics SA: a CD19-directed antibody and alkylating agent conjugate, for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma

www. Zynlonta.com

loncastuximab tesirine-lpyl Zynlonta™

loncastuximab tesirine-lpyl Zynlonta™ ADC Therapeutics SA: a CD19-directed antibody and alkylating agent conjugate, for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma

- ***Humanized monoclonal antibody-drug (alkylating agent) conjugate targeting tumor***
- ***Targets CD19***
- ***No genomic alteration testing needed prior to administration***
- ***Side effects: thrombocytopenia, increased gamma-glutamyltransferase, neutropenia, anemia, hyperglycemia, transaminase elevation, fatigue, hypoalbuminemia, rash, edema, nausea, and musculoskeletal pain. Effusion and edema, myelosuppression, infections, cutaneous rxns***

www. Zynlonta.com

amivantamab-vmjw Rybrevant™ Janssen Biotech, Inc.: adult patients with locally advanced or metastatic non-small cell lung cancer with EGFR exon 20 insertion mutations that progressed on or after platinum-based chemotherapy

www. Rybrevant.com

amivantamab-vmjw Rybrevant™

amivantamab-vmjw Rybrevant™ Janssen Biotech, Inc.: adult patients with locally advanced or metastatic non-small cell lung cancer with EGFR exon 20 insertion mutations that progressed on or after platinum-based chemotherapy

- ***Bispecific monoclonal antibody targeting 2 tumor targets***
- ***Potential infusion rxns; premedicate***
- ***Targets both EGF and MET receptors***
- ***Genomic alteration testing needed prior to administration***
- ***Side effects: Rash, IRR, paronychia, musculoskeletal pain, dyspnea, nausea, fatigue, edema, stomatitis, cough, constipation, and vomiting. Decreased lymphocytes, decreased albumin, decreased phosphate, decreased potassium, increased alkaline phosphatase, increased glucose, increased gamma-glutamyl transferase, and decreased sodium. Infusion rxns, interstitial lung disease/pneumonitis, dermatologic rxns, ocular toxicity.***

www. Rybrevant.com

Living Drugs/ Genetically Engineered Cells

leucel

- **Cellular therapies; “living drugs”; immune effector cells**
- **Intravenous; currently must be given at approved centers**
- **Precision: Cells from patient, genetically engineered and given back to pt**
- **Examples**
  - **sipuleucel-T, tisagenlecleucel, axicabtagene ciloleucel, brexucabtagene autoleucel, lisocabtagene maraleucel, idecabtagene vicleucel**

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lisocabtagene maraleucel Breyanzi® Juno Therapeutics, Inc.: the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

www. BREYANZI.com

lisocabtagene maraleucel Breyanzi®

lisocabtagene maraleucel Breyanzi® Juno Therapeutics, Inc.: the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.

- ***Cellular therapies; immune effector cell therapy (CAR-T)***
- ***Genetically modified autologous T cell immunotherapy***
- ***Directed toward CD-19***
- ***Potential for hypersensitivity reactions, cytokine release syndrome and neurologic toxicities; needs pre-meds , supportive care and /or corticosteroids. Available through REMS program. Must have tocilizumab available.***
- ***Side effects: fatigue, cytokine release syndrome, neurologic toxicities, prolonged cytopenias, hypogammaglobulinemia, secondary malignancies, effects on ability to drive and use machines, musculoskeletal pain, nausea, headache, encephalopathy, infections (pathogen unspecified), decreased appetite, diarrhea, hypotension, tachycardia, dizziness, cough, constipation, abdominal pain, vomiting, and edema***

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idecabtagene vicleucel Abecma® Bristol Myers Squibb: treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. This is the first FDA-approved cell-based gene therapy for multiple myeloma.

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- ***Cellular therapies; immune effector cell therapy (CAR-T)***
- ***Genetically modified autologous T cell immunotherapy***
- ***B-cell maturation antigen (BCMA)- directed***
- ***Potential for hypersensitivity reactions, cytokine release syndrome and neurologic toxicities; needs pre-meds , supportive care and /or corticosteroids. Available through REMS program. Must have tocilizumab available.***
- ***Side effects: CRS, infections – pathogen unspecified, , fatigue, musculoskeletal pain, hypogammaglobulinemia, diarrhea, upper respiratory tract infection, nausea, viral infections, encephalopathy, edema, pyrexia, cough, headache, decreased appetite, neutropenia, leukopenia, lymphopenia, thrombocytopenia, anemia, secondary malignancies, hemophagocytic lymphohistiocytosis/macrophage activation syndrome, prolonged cytopenias with fatal outcome***

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Radiolabeled Pharmaceutical Agents

Radiolabeled Pharmaceutical Agents

- **lutetium Lu 177 dotatate, LUTATHERA® Advanced Accelerator Applications USA, Inc. (a radiolabeled somatostatin analog, for the treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors in adults)**

- **iobenguane I 131 AZEDRA® Progenics (adult and pediatric pts 12 and older with iobenguane scan-positive, unresectable, locally advanced or metastatic paragangliomas or pheochromocytomas that require systemic anticancer therapy)**

http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm

The Others

melphalan flufenamide Pepaxto® Oncopeptides AB: in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD-38 directed monoclonal antibody

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melphalan flufenamide Pepaxto®

melphalan flufenamide Pepaxto® Oncopeptides AB: in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD-38 directed monoclonal antibody.

- ***Alkylating agent (IV); not molecularly targeted***
- ***No known drug/drug interactions***
- ***No genomic alteration testing needed prior to administration***
- ***Side effects: fatigue, nausea, diarrhea, pyrexia and respiratory tract infection, laboratory abnormalities (≥50%) are leukocytes decrease, platelets decrease, lymphocytes decrease, neutrophils decrease, hemoglobin decrease and creatinine increase, secondary malignancies***

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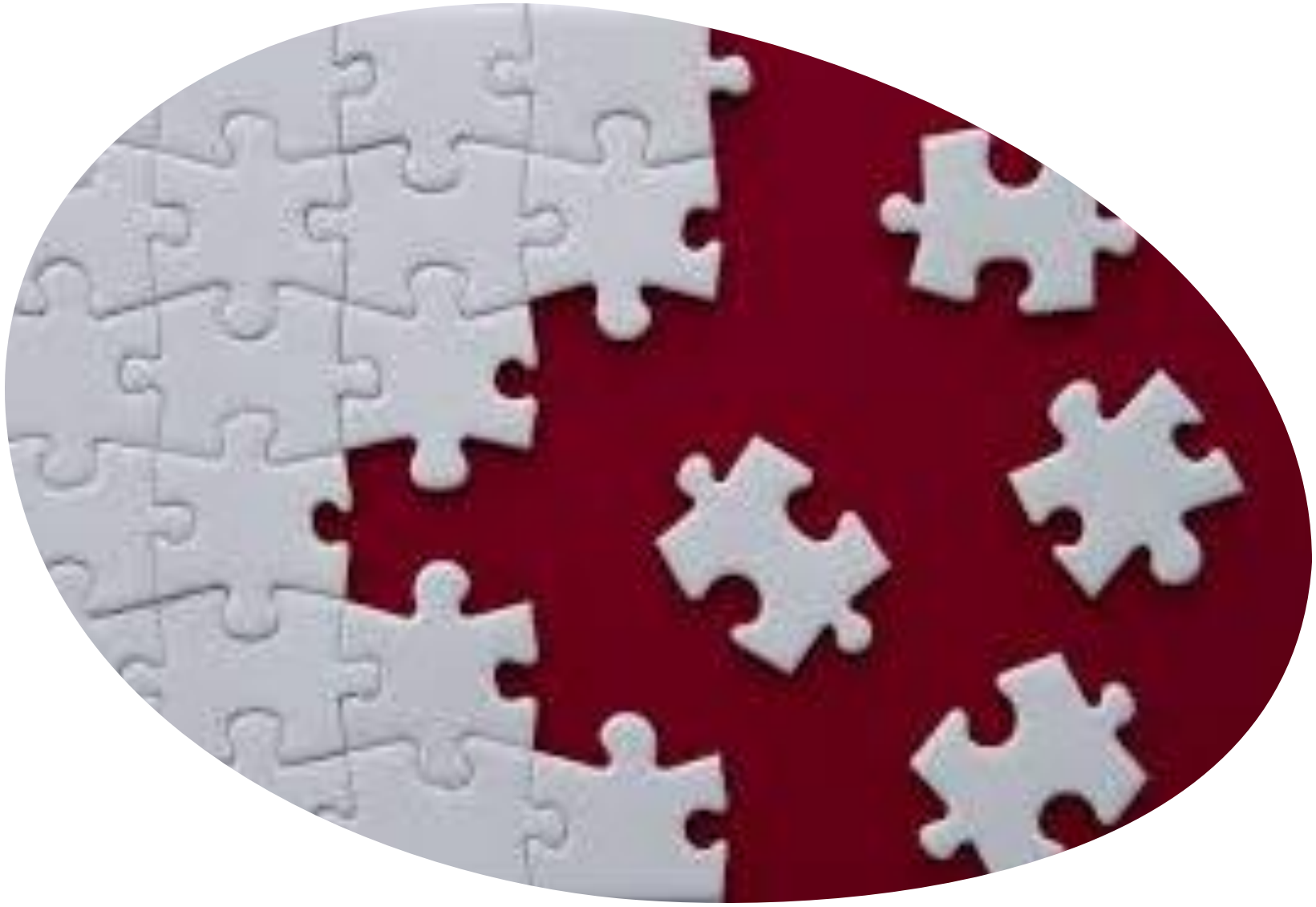

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- http://www.mycancergenome.org