Pharmacology Update

Sunday, May 20 • 8–9:30 am

Note one action you'll take after attending this session: _____

_____

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Key Session Takeaways

1. Identify new drugs/agents that have been FDA approved for cancer treatment in 2017 and thus far in 2018.
2. Recognize how new drugs/agents are given generic names.
3. Identify how to gain information about new drugs based on the generic naming system.

Pharmacology Update 2018

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Disclosures

No conflicts to disclose

Objectives

- Identify new drugs/agents that have been FDA approved for cancer treatment in 2017 and thus far in 2018.
- 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 2017/18

- New FDA Approved Cancer Treatment Agents
  - 21 total: 11 solid tumor & 10 hematologic
    - 1 new formulation as liposomal cytotoxic chemotherapy
    - 1 radiolabeled somatostatin analog
    - 1 androgen receptor inhibitor
    - 18 Molecularly Targeted/Immunotherapy
      - 1 new formulation as subcutaneous
      - 1 re-approval
      - 2 biosimilars (first 2 for cancer treatment)
      - 2 living cell therapies

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

Progress in Cancer Therapy 2017/18

- 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

Progress in Cancer Therapy 2017/18

- Cellular Gene Therapies
  - "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."

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

Progress in Cancer Therapy 2017/18

- New FDA Approved Cancer Treatment Agent Indications
  - 32 drugs with 47 new indications
    - 33 solid tumor indications
    - 14 hematologic indications

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

Progress in Cancer Therapy 2017/18

- **Non-Small Cell Lung Cancer (NSCLC)**
  - **brigatinib ALUNBRIG™ Takeda (metastatic ALK positive NSCLC progressed on or are intolerant to crizotinib)**
  - **bevacizumab-awwb MVASI™ Amgen Inc. (non-squamous NSCLC with chemotherapy first line tx)**
  - ***afatinib GILOTRIF® Boehringer Ingelheim (first-line tx of metastatic NSCLC whose tumors have non-resistant epidermal growth factor receptor (EGFR) mutations)***
  - ***ceritinib ZYKADIA® Novartis (metastatic ALK positive NSCLC)***
  - ***alectinib ALECENSA® Hoffmann-La Roche (metastatic ALK positive NSCLC)***

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

Progress in Cancer Therapy 2017/18

- Non-Small Cell Lung Cancer (NSCLC)
  - *pembrolizumab KEYTRUDA® Merck (in combination with pemetrexed and carboplatin for the tx of previously untreated metastatic non-squamous NSCLC)*
  - *osimertinib TAGRISSO® AstraZeneca (metastatic EGFR T790M mutation positive NSCLC with disease progression on or after EGFR tyrosine kinase therapy and for 1st line tx of metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations)*
  - *dabrafenib and trametinib TAFINLAR ® and MEKINIST ® Novartis (metastatic NSCLC with BRAF V600E mutation)*
  - *durvalumab IMFINZI ® AstraZeneca (maintenance for unresectable Stage III NSCLC when disease has not progressed following concurrent RT and platinum based chemo)*

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

Progress in Cancer Therapy 2017/18

- Breast
  - **neratinib NERLYNX™** Puma Biotechnology (extended adjuvant treatment of adult patients with early stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy)
  - **ribociclib KISQALI®** Novartis (in combination with an aromatase inhibitor as initial endocrine based tx for postmenopausal women with hormone receptor positive, HER2 negative advanced or metastatic breast cancer)
  - **abemaciclib VERZENIO™** Eli Lilly (in combination with fulvestrant for hormone receptor (HR)-positive, (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy **or** monotherapy following endocrine therapy and prior chemotherapy in the metastatic setting. **Also** with an aromatase inhibitor as initial tx for postmenopausal women with hormone receptor positive HER2 negative advanced or metastatic breast cancer)

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

Progress in Cancer Therapy 2017/18

- Breast
  - **trastuzumab-dskt Ogivri™** Mylan (HER2 overexpressing breast cancer in adjuvant or metastatic setting)
  - *palbociclib IBRANCE® Pfizer (hormone receptor positive, HER2 negative advanced or metastatic breast cancer in combindtion with an aromatase inhibitor as initial endocrine based tx in postmenopausal women)*
  - *olaparib LYNPARZA® Astra Zeneca (deleterious or suspected deleterious germline BRCA-mutated Her2 negative metastatic breast cancer after tx with chemo in neoadjuvant, adjuvant or metastatic setting)*
  - *pertuzumab PERJETA® Genentech (in combination with trastuzumab and chemo as adjuvant tx of HER2 positive early breast cancer at high risk of recurrence)*

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

Progress in Cancer Therapy 2017/18

- Cervical
  - **bevacizumab-awwb MVASI™** Amgen Inc. (with chemo in persistent, recurrent or metastatic disease)
- Ovarian
  - **niraparib ZEJULA™** Tesaro (maintenance tx of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete response to platinum-based chemotherapy)
  - *olaparib tablets Lynparza™ AstraZeneca (for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy)*
  - *rucaparib RUBRACA® Clovis (maintenance tx of recurrent ovarian, fallopian tube, or primary peritoneal cancer)*

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

Progress in Cancer Therapy 2017/18

- Melanoma
  - *nivolumab OPDIVO® Bristol Myers Squibb (adjuvant tx of melanoma with involvement of lymph nodes or in metastatic disease after complete resection)*
  - *dabrafenib TAFINLAR® and trametinib MEKINIST® Novartis (in combination for adjuvant tx of melanoma with BRAF V600E or V600K mutations, involvement of lymph nodes after complete resection)*
- Hepatocellular (HCC)
  - *regorafenib STIVARGA® Bayer (HCC previously treated with sorafenib)*
  - *nivolumab OPDIVO® Bristol Myers Squibb (HCC previously treated with sorafenib)*

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

Progress in Cancer Therapy 2017/18

- Renal Cell
  - **bevacizumab-awwb MVASI™** Amgen Inc. (with Interferon alfa for metastatic RCC)
  - *cabozantinib Cabometyx® Exelixis (advanced renal cell)*
  - *sunitinib Sutent® Pfizer (adjuvant tx of adults at high risk of recurrent renal cell following nephrectomy)*
  - *nivolumab OPDIVO® and ipilimumab YERVOY® Bristol Myers Squibb (in combination of intermediate or poor risk , previously untreated advanced renal cell carcinoma)*

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

Progress in Cancer Therapy 2017/18

- **Gastric or GE Junction**
  - **trastuzumab-dskt Ogivri™ Mylan (HER2 overexpressing metastatic gastric or GE junction adenocarcinoma)**
  - ***pembrolizumab KEYTRUDA® Merck (recurrent locally advanced or metastatic tumors that express PD-L1)***
- **Merkel Cell**
  - **avelumab BAVENCIO® EMD Serono (Adult and pediatric pts 12 and older with metastatic disease)**

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

ONS Congress

Progress in Cancer Therapy 2017/18

- **Urothelial**
  - **durvalumab IMFINZI™ AstraZeneca (locally advanced or metastatic with disease progression during or following platinum-containing chemotherapy or progression within 12 mos of neoadjuvant or adjuvant treatment with platinum-containing regimen)**
  - ***avelumab BAVENCIO® EMD Serono (locally advanced or metastatic with disease progression during or following platinum-containing chemotherapy or progression within 12 mos of neoadjuvant or adjuvant treatment with platinum-containing regimen)***
  - ***atezolizumab TECENTRIQ® Genentech (pts not eligible for cisplatin-containing chemotherapy)***

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

ONS Congress

Progress in Cancer Therapy 2017/18

- **Urothelial**
  - ***nivolumab OPDIVO™ Bristol Myers Squibb (locally advanced or metastatic with disease progression during or following platinum-containing chemotherapy or progression within 12 mos of neoadjuvant or adjuvant treatment with platinum-containing regimen)***
  - ***pembrolizumab KEYTRUDA® Merck (locally advanced or metastatic with disease progression during or following platinum-containing chemotherapy or progression within 12 mos of neoadjuvant or adjuvant treatment with platinum-containing regimen)***

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

ONS Congress

Progress in Cancer Therapy 2017/18

- Prostate Cancer
  - **apalutamide ERLEADA™ Janssen (treatment of patients with non-metastatic castration-resistant prostate cancer)**
  - ***cabazitaxel JEVTANA® Sanofi-Aventis (lower dose approved in combination with prednisone for metastatic castration-resistant prostate cancer previously treated with docetaxel containing regimen)***
  - ***abiraterone acetate Zytiga® Janssen Biotech (in combination with prednisone for metastatic high-risk castration-sensitive disease)***

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

Progress in Cancer Therapy 2017/18

- Glioblastoma
  - **bevacizumab-awwb MVASI™ Amgen Inc. (single agent for progressive disease following prior tx)**
- Tumor Agnostic: Adult and pediatric patients with unresectable or metastatic, microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) solid tumors that have progressed following prior tx and have no satisfactory alternative treatment options
  - ***pembrolizumab KEYTRUDA® Merck***

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

Progress in Cancer Therapy 2017/18

- Colorectal Cancer Metastatic:
  - **bevacizumab-awwb MVASI™ Amgen Inc. (with chemotherapy for first or second line tx)**
  - ***pembrolizumab KEYTRUDA® Merck (MSI-H or dMMR, progressed following tx with a fluoropyrimidine, oxaliplatin, and irinotecan)***
  - ***nivolumab OPDIVO™ Bristol Myers Squibb (pts 12 or older MSI-H or dMMR, progressed following tx with a fluoropyrimidine, oxaliplatin, and irinotecan)***

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

Progress in Cancer Therapy 2017/18

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

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

Progress in Cancer Therapy 2017/18

- Acute Myeloid Leukemia (AML)
  - **liposome encapsulated combination of daunorubicin and cytarabine VYXEOS™** Jazz Pharmaceuticals (adults with newly diagnosed therapy related AML or AML with myelodysplasia related changes)
  - **enasidenib IDHIFA®** Celgene Corp. (adults with relapsed or refractory AML with an IDH2 mutation)
  - **midostaurin RYDAPT®** Novartis (adults with newly diagnosed AML FLT3 mutation positive, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation)

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

Progress in Cancer Therapy 2017/18

- Acute Myeloid Leukemia (AML)
  - ****gemtuzumab ozogamicin Mylotarg™** Pfizer Inc. (treatment of newly-diagnosed CD33-positive acute myeloid leukemia (AML) in adults and for treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older. Gemtuzumab ozogamicin may be used in combination with daunorubicin and cytarabine for adults with newly-diagnosed AML, or as a stand-alone treatment for certain adult and pediatric patients)

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

Progress in Cancer Therapy 2017/18

- Acute Lymphoblastic Leukemia (ALL) B-cell precursor
  - **inotuzumab ozogamicin BESPONSA™** Wyeth Pharmaceuticals (adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia [ALL])
  - **tisagenlecleucel (KYMRIAH®)** Novartis (treatment of pediatric patients up to age 25 years with B-cell precursor acute lymphoblastic leukemia [ALL] that is refractory or in second or later relapse)
  - ***blinatumomab BLINCYTO®*** *Amgen (relapsed or refractory B-cell precursor ALL in adults and children and ALL in 1st or 2nd complete remission with minimal residual disease greater or equal to 0.1% in adults and children)*

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

Progress in Cancer Therapy 2017/18

- Chronic Graft versus Host Disease (cGVHD)
  - ***ibrutinib IMBRUVICA®*** *Pharmacyclics (adult cGVHD after failure of 1 or more lines of systemic therapy)*
- Chronic Myelogenous Leukemia (CML)
  - ***bosutinib BOSULIF®*** *Pfizer (newly diagnosed chronic phase Philadelphia chromosome positive CML)*
  - ***dasatinib SPRYCEL®*** *Bristol Myers Squibb (pediatric pts with Philadelphia chromosome positive CML in chronic phase)*
  - ***nilotinib TASIGNA®*** *Novartis (pediatric pts 1 year or older with newly diagnosed Philadelphia chromosome positive CML in chronic phase)*

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

Progress in Cancer Therapy 2017/18

- Multiple Myeloma (MM)
  - ***lenalidomide REVLIMID®*** *Celgene Corp (maintenance therapy for patients with MM following autologous SCT)*
- Hodgkin lymphoma (HD)
  - ***pembrolizumab KEYTRUDA®*** *Merck (adult and pediatric pts with refractory classical HD or those relapsed after 3 or more prior lines of tx)*
  - ***brentuximab vedotin ADCETRIS®*** *Seattle Genetics (adult pts with previously untreated stage III or IV classical Hodgkin lymphoma)*

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

Progress in Cancer Therapy 2017/18

- Non Hodgkin Follicular Lymphoma (FL)
  - **copanlisib ALIQOPA™** Bayer HealthCare Pharmaceuticals Inc (for the treatment of adult patients with relapsed FL who have received at least two prior systemic therapies)
  - ***obinutuzumab GAZYVA®*** *Genentech (in combination with chemo, followed by obinutuzumab monotherapy, in pts achieving at least a partial remission in adults with previously untreated stage II bulky, stage III, or stage IV FL)*
- Non Hodgkin Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL)
  - **rituximab and hyaluronidase human RITUXAN HYCELA™** Genentech (adult pts with follicular, diffuse large B-cell NHL and CLL; subcutaneous formulation)

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

Progress in Cancer Therapy 2017/18

- Non Hodgkin Large B-Cell Lymphoma (including diffuse large B-cell [DLBCL] not otherwise specified, primary mediastinal large B-cell, high grade B-cell, and DLBCL arising from follicular lymphoma
  - **axicabtagene ciloleucel YESCARTA™** Kite (adult pts with relapsed or refractory disease after 2 or more lines of therapy)
- Non Hodgkin Large B-Cell Lymphoma (including diffuse large B-cell [DLBCL] not otherwise specified, high grade B-cell, and DLBCL arising from follicular lymphoma
  - ***tisagenlecleucel KYMRIAH®*** *Novartis (adult pts with relapsed or refractory disease)*

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

Progress in Cancer Therapy 2017/18

- Mantle Cell Lymphoma
  - **acalabrutinib Calquence®** AstraZeneca (MCL after at least one prior therapy)
- Primary Cutaneous Anaplastic Large Cell Lymphoma (pcALCL) or CD30-expressing Mycosis Fungoides (MF)
  - ***brentuximab vedotin ADCETRIS®*** *Hoffmann-La Roche (pts who have received prior systemic therapy)*
- Erdheim Chester Disease (ECD)
  - ***vemurafenib ZELBORAF®*** *Hoffmann La-Roche (ECD with BRAF V600 mutation)*

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

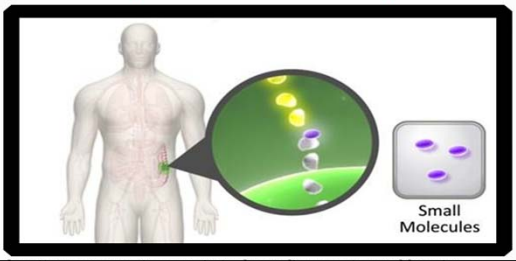
Tips for Learning about New Cancer Therapies

- Know the type of drug/agent
  - Small molecule, monoclonal antibody, 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 "personalized" to tumor's genomic profile

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/
- Reference list at end of slide set

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



nibs (tinibs)

- Small molecules; tyrosine kinase inhibitors
- Oral
  - Adherence
  - Possible drug/food , drug/drug interactions
  - Patient education regarding taking medication correctly
- Targets vary: EGFR, VEGFR, and others
- Examples
  - erlotinib, sunitinib, ponatinib, imatinib, dasatinib, ibrutinib

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

nibs (rafenibs, metanib)

- Small molecules; kinase inhibitors targeting the RAF/RAS/MEK pathways
- Oral
  - Adherence
  - Possible drug/food , drug/drug interactions
  - Patient education regarding taking medication correctly
- Examples
  - sorafenib, dabrafenib, trametinib, vemurafenib

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ibs (paribs)

- Small molecules; PARP inhibitors of mammalian polyadenosine 5'-diphosphoribose polymerase (PARP) enzyme.
- Oral
  - Adherence
  - Possible drug/food , drug/drug interactions
  - Patient education regarding taking medication correctly
- Examples: olaparib, rucaparib, niraparib

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

ibs (lisib)

- Small molecules; PI3 kinase inhibitors (PI3K)
- Oral
  - Adherence
  - Possible drug/food , drug/drug interactions
  - Patient education regarding taking medication correctly
- Examples: idelalisib, copanlisib

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ibs (degibs)

- Small molecules; sonic hedgehog pathway inhibitors
- Oral
  - Adherence
  - Possible drug/food , drug/drug interactions
  - Patient education regarding taking medication correctly
- Examples:
  - sonidegib, vismodegib

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

nibs (denibs)

- Small molecules; inhibitor of isocitrate dehydrogenase 2 (IDH2) enzyme
- Oral
  - Adherence
  - Possible drug/food , drug/drug interactions
  - Patient education regarding taking medication correctly
- Examples:
  - enasidenib

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

ibs (ciclibs)

- Small molecules; inhibitor of cyclin dependent kinase (CDK) 4 & 6
- Oral
  - Adherence
  - Possible drug/food , drug/drug interactions
  - Patient education regarding taking medication correctly
- Examples: palbociclib, ribociclib, abemaciclib

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

ibs (zomibs)

- Small molecules; proteasome inhibitors
- May be IV/subq or oral
  - If IV
    - Only slight chance of infusion reactions; not monoclonal antibodies
  - If oral
    - Adherence
    - Possible drug/food , drug/drug interactions
    - Patient education regarding taking medication correctly
- Examples
  - 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

inostat

- Small molecules; histone deacetylase inhibitors (HDAC inhibitors)
- May be IV or oral
  - If IV
    - Only slight chance of infusion reactions; not monoclonal antibodies
  - If oral
    - Adherence
      - Possible drug/food , drug/drug interactions
  - Patient education regarding taking medication correctly
- Examples
  - vorinostat, belinostat, panobinostat

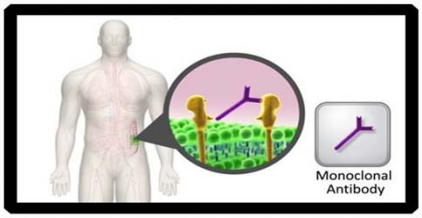
http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/naming-biologics/monoclonal-antibodies.page

toclax

- Small molecules; BCL-2 inhibitors
- Oral
  - Adherence
  - Possible drug/food , drug/drug interactions
  - Patient education regarding taking medication correctly
- Examples
  - venetoclax

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

What does the name mean?
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

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 or tu = tumor
trastuzumab

ci = circulatory
bevacizumab

li or l = immunomodulator
ipilimumab

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?

- 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

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?

- Biosimilars have 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™

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

Living Drugs/ Genetically Engineered Cells

leucel

- Cellular therapies; "living drugs"
- Intravenous; currently must be given at approved centers
- Personalized: Cells from patient, genetically engineered and given back to pt
- Examples
  - sipuleucel-T, tisagenlecleucel, axicabtagene ciloleucel

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

The New Kids on the Block

Let's Build the Slides

liposome encapsulated combination of daunorubicin and cytarabine VYXEOS™

liposome encapsulated combination of daunorubicin and cytarabine VYXEOS™ Jazz Pharmaceuticals (adults with newly diagnosed therapy related AML or AML with myelodysplasia related changes)

- *Monoclonal antibody or small molecule?*
- *Infusion rxns or drug/drug drug/food interactions?*
- *Target?*
- *Personalized?*
- *Side effects?*

www.vyxeos.com

liposome encapsulated combination of daunorubicin and cytarabine VYXEOS™

liposome encapsulated combination of daunorubicin and cytarabine VYXEOS™ Jazz Pharmaceuticals (adults with newly diagnosed therapy related AML or AML with myelodysplasia related changes)

- ***Not a monoclonal antibody or small molecule; liposome encapsulated cytotoxic chemotherapy***
- ***Infusion rxns possible; no premedication needed***
- ***Not targeted therapy or personalized***
- ***Do not interchange with other daunorubicin and/or cytarabine products***
- ***Side effects: Hemorrhage, cardiotoxicity, febrile neutropenia, rash, edema, N/V, mucositis, diarrhea, constipation, copper overload, musculoskeletal pain, fatigue, abdominal pain, dyspnea, headache, cough, decreased appetite, arrhythmia, tissue necrosis***

www.vyxeos.com

lutetium Lu 177 dotatate LUTATHERA®

- **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):
  - *Monoclonal antibody or small molecule or what?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.LUTATHERA.com

lutetium Lu 177 dotatate LUTATHERA®

- **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):
  - *Radiolabeled somatostatin analog*
  - *Give amino acids before, during and after infusion to decrease reabsorption and decrease damage to kidneys. Discontinue long acting somatostatins 4 weeks prior and octreotide 24 hours prior to infusion*
  - *Targets somatostatin receptors*
  - Side effects: *risk of radiation exposure, myelosuppression, increased risk of MDS & leukemia, lymphopenia, renal toxicity, hepatotoxicity, increased GGT, vomiting, nausea, symptomatic management, increased AST, increased ALT, hyperglycemia and hypokalemia, neuroendocrine hormonal crisis*

www.LUTATHERA.com

brigatinib ALUNBRIG™

- **brigatinib ALUNBRIG™** Takeda (metastatic ALK positive NSCLC progressed on or are intolerant to crizotinib)
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.alunbrig.com

brigatinib ALUNBRIG™

- **brigatinib ALUNBRIG™** Takeda (metastatic ALK positive NSCLC progressed on or are intolerant to crizotinib)
  - *Small molecule, oral, multi tyrosine kinase inhibitor*
  - *Drug/drug interactions with strong CYP3A inducers, inhibitors, substrates. Avoid grapefruit products*
  - *Targets ALK, ROS1, insulin-like growth factor-1 receptor (IGF-1R), and FLT-3 as well as EGFR deletion and point mutations*
  - *Personalized to ALK positive NSCLC*
  - *Side effects: Hypertension, interstitial lung disease, bradycardia, visual disturbances, hyperglycemia*

www.alunbrig.com

neratinib NERLYNX™

- **neratinib NERLYNX™** Puma Biotechnology (extended adjuvant treatment of adult patients with early stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy)
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.nerlynx.com

neratinib NERLYNX™

- **neratinib NERLYNX™** Puma Biotechnology (extended adjuvant treatment of adult patients with early stage HER2 overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy)
  - *Small molecule; oral multi kinase inhibitor*
  - *Drug/drug interactions with PPIs, H_2-receptor antagonists, strong or moderate CYP3A4 inducers and inhibitors, P-gp substrates. No grapefruit products.*
  - *Targets EGFR, HER2, HER4*
  - *Personalized to HER2 overexpressed/amplified*
  - *Side effects: Diarrhea (needs prophylactic & aggressive management), nausea, abdominal pain, fatigue, vomiting, rash, hepatotoxicity, stomatitis, decreased appetite, muscle spasms, nail/skin issues*

www.nerlynx.com

acalabrutinib Calquence ®

- **acalabrutinib Calquence®** AstraZeneca (Mantle Cell Lymphoma after at least one prior therapy)
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.calquence.com

acalabrutinib Calquence ®

- **acalabrutinib Calquence®** AstraZeneca (Mantle Cell Lymphoma after at least one prior therapy)
  - *Small molecule; oral kinase inhibitor*
  - *Drug/drug interactions with, strong CYP3A inducers and inhibitors, PPIs, H2-receptor antagonists and antacids (stagger dosing).*
  - *Targets Bruton tyrosine kinase (BTK)*
  - *Not personalized*
  - *Side effects: hemorrhage, infection, cytopenias, second primary malignancies, atrial fibrillation/flutter, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising.*

www.calquence.com

niraparib ZEJULA™

- **niraparib ZEJULA™** Tesaro (maintenance tx of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete response to platinum-based chemotherapy)
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.zejula.com

niraparib ZEJULA™

- **niraparib ZEJULA™** Tesaro (maintenance tx of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete response to platinum-based chemotherapy)
  - *Small molecule; oral poly (ADP-ribose) polymerase (PARP) enzyme inhibitor*
  - *Drug/drug drug/food interactions: None known*
  - *Targets PARP*
  - *Not personalized*
  - *Side effects: Bone marrow suppression, HTN, cardiovascular effects, N/V, diarrhea, stomatitis, GI disturbances, AST/ALT elevations, arthralgias, headache, infections, fatigue, secondary MDS/AML*

www.zejula.com

ribociclib KISQALI®

- **ribociclib KISQALI®** Novartis (in combination with an aromatase inhibitor as initial endocrine based tx for postmenopausal women with hormone receptor positive, HER2 negative advanced or metastatic breast cancer)
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.kisqali.com

ribociclib KISQALI®

- **ribociclib KISQALI®** Novartis (in combination with an aromatase inhibitor as initial endocrine based tx for postmenopausal women with hormone receptor positive, HER2 negative advanced or metastatic breast cancer)
  - *Small molecule, oral kinase inhibitor of cyclin-dependent kinase (CDK) 4 & 6*
  - *Drug/drug interactions with CYP3A4 inducers, inhibitors and substrates plus drugs that prolong QT interval. Avoid grapefruit and pomegranate products*
  - *Targets CDK 4 & 6*
  - *Not personalized*
  - *Side effects: QT interval prolongation, hepatobiliary toxicity, neutropenia*

www.kisqali.com

abemaciclib VERZENIO™

- **abemaciclib VERZENIO™** Eli Lilly (in combination with fulvestrant for hormone receptor [HR]-positive, [HER2]-negative advanced or metastatic breast cancer with disease progression following endocrine therapy OR monotherapy following endocrine therapy and prior chemotherapy in the metastatic setting)
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.verzenio.com

abemaciclib VERZENIO™

- **abemaciclib VERZENIO™** Eli Lilly (in combination with fulvestrant for hormone receptor [HR]-positive, [HER2]-negative advanced or metastatic breast cancer with disease progression following endocrine therapy OR monotherapy following endocrine therapy and prior chemotherapy in the metastatic setting)
  - *Small molecule, oral kinase inhibitor of cyclin-dependent kinase (CDK) 4 & 6*
  - *Drug/drug interactions with CYP3A4 inducers and inhibitors. Avoid grapefruit products*
  - *Targets CDK 4 & 6*
  - *Not personalized*
  - *Side effects: diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia ,leukopenia, decreased appetite, vomiting, headache, thrombocytopenia, and hepatobiliary toxicity*

www.verzenio.com

enasidenib IDHIFA®

- **enasidenib IDHIFA®** Celgene Corp. (adults with relapsed or refractory AML with an IDH2 mutation)
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.idhifa.com

enasidenib IDHIFA®

- **enasidenib IDHIFA®** Celgene Corp. (adults with relapsed or refractory AML with an IDH2 mutation)
  - *Small molecule, oral inhibitor of isocitrate dehydrogenase 2 (IDH2) enzyme*
  - *Drug/drug drug/food interactions: None known*
  - *Targets IDH2*
  - *Personalized to AML with an IDH2 mutation in blood or bone marrow*
  - *Side effects: N/V, diarrhea, elevated bilirubin, decreased appetite, differentiation syndrome, tumor lysis syndrome, GI effects*

www.idhifa.com

copanlisib ALIQOPA™

copanlisib ALIQOPA™ Bayer HealthCare Pharmaceuticals Inc (for the treatment of adult patients with relapsed follicular lymphoma who have received at least two prior systemic therapies)

- *Monoclonal antibody or small molecule?*
- *Infusion rxns or drug/drug drug/food interactions?*
- *Target?*
- *Personalized?*
- *Side effects?*

www.aliqopa.com

copanlisib ALIQOPA™

copanlisib ALIQOPA™ Bayer HealthCare Pharmaceuticals Inc (for the treatment of adult patients with relapsed follicular lymphoma who have received at least two prior systemic therapies)

- *Small molecule, IV kinase inhibitor*
- *Drug/drug interactions with CYP3A4 inducers and inhibitors*
- *Targets PI3K*
- *Not personalized*
- *Side effects: hyperglycemia, pneumonitis, infections, severe cutaneous rxns, diarrhea, decreased general strength and energy, hypertension, leukopenia, neutropenia, nausea, lower respiratory tract infections, thrombocytopenia*

www.aliqopa.com

midostaurin RYDAPT®

- **midostaurin RYDAPT®** Novartis (adults with newly diagnosed AML FLT3 mutation positive, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation and
- adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.rydapt.com

midostaurin RYDAPT®

- **midostaurin RYDAPT®** Novartis (adults with newly diagnosed AML FLT3 mutation positive, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation and
- adult patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL).
  - *Small molecule, oral multi tyrosine kinase inhibitor*
  - *Drug/drug interactions with strong CYP3A4 inducers and inhibitors*
  - *Targets FLT3, KIT, PDGFR, VEGFR2, PKC*
  - *Personalized to AML with FLT3 mutation; not personalized for other indications*
  - *Side effects: Pulmonary toxicity, febrile neutropenia, N/V, mucositis, diarrhea, edema, fatigue, epistaxis, hyperglycemia, headache*

www.rydapt.com

durvalumab IMFINZI™

- **durvalumab IMFINZI™** AstraZeneca (locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy or progression within 12 mos of neoadjuvant or adjuvant treatment with platinum-containing regimen)
- maintenance for unresectable Stage III NSCLC when disease has not progressed following concurrent RT and platinum based chemo
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.imfinzi.com

durvalumab IMFINZI™

- **durvalumab IMFINZI™** AstraZeneca (locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy or progression within 12 mos of neoadjuvant or adjuvant treatment with platinum-containing regimen)
- maintenance for unresectable Stage III NSCLC when disease has not progressed following concurrent RT and platinum based chemo
  - *Human monoclonal antibody targeting the immune system via the programmed death ligand 1 (PD-L1)*
  - *Infusion rxns: Yes uncommon, but can be severe*
  - *Targets PD-L1*
  - *Not personalized*
  - *Side effects: Immune mediated pneumonitis, hepatitis, ,colitis, nephritis, and other immune related adverse events, fatigue, musculoskeletal pain, constipation, nausea*

www.imfinzi.com

avelumab BAVENCIO®

- **avelumab BAVENCIO®** EMD Serono (adults and pediatrics pts 12 and older with metastatic Merkel cell carcinoma) and
- locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy or progression within 12 mos of neoadjuvant or adjuvant treatment with platinum-containing regimen
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.bavencio.com

ONS Congress

avelumab BAVENCIO®

- **avelumab BAVENCIO®** EMD Serono (adults and pediatrics pts 12 and older with metastatic Merkel cell carcinoma) and
- locally advanced or metastatic urothelial carcinoma with disease progression during or following platinum-containing chemotherapy or progression within 12 mos of neoadjuvant or adjuvant treatment with platinum-containing regimen
  - *Human monoclonal antibody targeting the immune system via the programmed death ligand 1 (PD-L1)*
  - *Infusion rxns as high as 25% in trials; can be severe; premedicate for 1st 4 infusions and as needed*
  - *Targets PD-L1*
  - *Not personalized*
  - *Side effects: Immune mediated pneumonitis, hepatitis, ,colitis, nephritis, and other immune related adverse events, fatigue, musculoskeletal pain, diarrhea, nausea, rash, peripheral edema, decreased appetite, UTI*

www.bavencio.com

ONS Congress

inotuzumab ozogamicin BESPONSA™

- **inotuzumab ozogamicin BESPONSA™** Wyeth Pharmaceuticals (adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia [ALL])
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.besponsa.com

ONS Congress

inotuzumab ozogamicin BESPONSA™

- **inotuzumab ozogamicin BESPONSA™** Wyeth Pharmaceuticals (adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia [ALL])
  - *Humanized monoclonal antibody-drug conjugate with target on tumor; cytotoxic agent attached*
  - *Infusion rxns; premedicate prior to all infusions; monitor during and at least 1 hour after infusions*
  - *Targets CD22 antigen*
  - *Not personalized ; CD22 expressed in almost all B-ALL cells*
  - *Side effects: Hepatotoxicity including veno-occlusive disease, myelosuppression, QT prolongation, infections, fatigue, headache, hyperbilirubinemia,, hemorrhage, pyrexia, increased risk of post-HSCT non-relapse mortality*

www.besponsa.com

gemtuzumab ozogamicin Mylotarg™

- **gemtuzumab ozogamicin Mylotarg™** Pfizer Inc. (treatment of newly-diagnosed CD33-positive acute myeloid leukemia [AML] in adults and for treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older)
- may also be used in combination with daunorubicin and cytarabine for adults with newly-diagnosed AML, or as a stand-alone treatment for certain adult and pediatric patients.
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.mylotarg.com

gemtuzumab ozogamicin Mylotarg™

- **gemtuzumab ozogamicin Mylotarg™** Pfizer Inc. (treatment of newly-diagnosed CD33-positive acute myeloid leukemia [AML] in adults and for treatment of relapsed or refractory CD33-positive AML in adults and in pediatric patients 2 years and older)
- may also be used in combination with daunorubicin and cytarabine for adults with newly-diagnosed AML, or as a stand-alone treatment for certain adult and pediatric patients.
  - *Humanized monoclonal antibody-drug conjugate. Attached to a cytotoxic agent.*
  - *Infusion rxns: yes. Can cause anaphylaxis. Pre-med and monitor during and at least 1 hours post infusion*
  - *Targets CD33*
  - *Personalized to CD33 positive AML*
  - *Side effects: Hepatotoxicty that can lead to veno-occlusive disease, hemorrhage, infection, fever, nausea, vomiting, constipation, headache, increased AST and ALT, rash, and mucositis*

www.mylotarg.com

rituximab and hyaluronidase human RITUXAN HYCELA™

- **rituximab and hyaluronidase human RITUXAN HYCELA™** Genentech (adult pts with follicular lymphoma, diffuse large B-cell NHL and chronic lymphocytic lymphoma [CLL] ; only given after one full dose of IV rituximab successfully administered)
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.rituxanhycela.com

tisagenlecleucel KYMRIAH®

- **tisagenlecleucel (KYMRIAH®)** Novartis (treatment of patients up to age 25 years with B-cell precursor acute lymphoblastic leukemia [ALL] that is refractory or in second or later relapse)
- Also approved for patients with relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic therapy including diffuse large B-cell lymphoma not otherwise specified, high grade B-cell lymphoma and DCBCL arising from follicular lymphoma
  - *Monoclonal antibody or small molecule OR WHAT?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.kymriah.com

tisagenlecleucel KYMRIAH®

- **tisagenlecleucel (KYMRIAH®)** Novartis (treatment of patients up to age 25 years with B-cell precursor acute lymphoblastic leukemia [ALL] that is refractory or in second or later relapse)
- Also approved for patients with relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic therapy including diffuse large B-cell lymphoma not otherwise specified, high grade B-cell lymphoma and DCBCL arising from follicular lymphoma
  - *CD19-directed genetically modified autologous T cell immunotherapy: Chimeric Antigen Receptor T cell therapy (CAR-T)*
  - *Infusion rxns and cytokine release syndrome (CRS) possible. Treat severe or life-threatening CRS with tocilizumab (newly FDA approved indication for this purpose). Restricted use under REMS.*
  - *Targets CD19*
  - *Personalized to CD19 using patients own genetically engineered T cells*
  - *Side effects: CRS, neurotoxicity, hypogammaglobulinemia, infections-pathogen unspecified, prolonged cytopenias, pyrexia, decreased appetite, headache, encephalopathy, hypotension, bleeding episodes, tachycardia, nausea, diarrhea, vomiting, viral infections*

www.kymriah.com

axicabtagene ciloleucel YESCARTA™

- **axicabtagene ciloleucel YESCARTA™** Kite (adult pts with relapsed or refractory Non Hodgkin large B-Cell lymphoma after 2 or more lines of systemic tx including diffuse large B-cell [DLBCL], primary mediastinal large B-cell, high grade B-cell, and DLBCL arising from follicular lymphoma)
  - *Monoclonal antibody or small molecule OR WHAT?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.yescarta.com

ONS Congress

axicabtagene ciloleucel YESCARTA™

- **axicabtagene ciloleucel YESCARTA™** Kite (adult pts with relapsed or refractory Non Hodgkin large B-Cell lymphoma after 2 or more lines of systemic tx including diffuse large B-cell [DLBCL], primary mediastinal large B-cell, high grade B-cell, and DLBCL arising from follicular lymphoma)
  - *CD19-directed genetically modified autologous T cell immunotherapy: Chimeric Antigen Receptor T cell therapy (CAR-T)*
  - *Infusion rxns and cytokine release syndrome (CRS) possible. Treat severe or life-threatening CRS with tocilizumab (newly FDA approved indication for this purpose) or tocilizumab and corticosteroids. Restricted use under REMS.*
  - *Targets CD19/Personalized to CD19 using patients own genetically engineered T cells*
  - *Side effects: CRS, neurotoxicity, hypogammaglobulinemia, infections-pathogen unspecified, prolonged cytopenias, pyrexia, decreased appetite, headache, encephalopathy, hypotension, bleeding episodes, tachycardia, nausea, diarrhea, vomiting, viral infectious disorders, hypoxia, fatigue, acute kidney injury, and delirium, secondary malignancies. Refrain from driving or operating heavy or potentially dangerous machinery after YESCARTA infusion until at least 8 weeks after infusion*

www.yescarta.com

ONS Congress

bevacizumab-awwb Mvasi™

- **bevacizumab-awwb Mvasi ™** Amgen Inc. a biosimilar to Avastin (bevacizumab, Genentech Inc.). Approved for: non-squamous non-small cell lung cancer (NSCLC), in combination with chemotherapy for metastatic colorectal cancer (mCRC), glioblastoma, metastatic renal cell carcinoma in combination with interferon alfa and in combination with chemotherapy for persistent, recurrent, or metastatic carcinoma of the cervix.
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.mvasi.com

ONS Congress

bevacizumab-awwb Mvasi™

- **bevacizumab-awwb Mvasi ™** Amgen Inc. a biosimilar to Avastin (bevacizumab, Genentech Inc.). Approved for: non-squamous non-small cell lung cancer (NSCLC), in combination with chemotherapy for metastatic colorectal cancer (mCRC), glioblastoma, metastatic renal cell carcinoma in combination with interferon alfa and in combination with chemotherapy for persistent, recurrent, or metastatic carcinoma of the cervix.
  - *Humanized monoclonal antibody targeting the circulatory system*
  - *Infusion rxns uncommon*
  - *Targets VEGF on endothelial cells*
  - *Not personalized*
  - *Side effects: Perforations/fistulas, arterial thrombotic events, venous thromboembolic events, hypertension, posterior reversible*

www.mvasi.com

trastuzumab-dskt Ogivri™

- **trastuzumab-dskt Ogivri™** Mylan **a biosimilar to Herceptin (trastuzumab, Genentech, Inc.)** approved for HER2 overexpressing breast in adjuvant or metastatic setting and metastatic gastric or GE junction adenocarcinoma
  - *Monoclonal antibody or small molecule?*
  - *Infusion rxns or drug/drug drug/food interactions?*
  - *Target?*
  - *Personalized?*
  - *Side effects?*

www.Ogivri.com

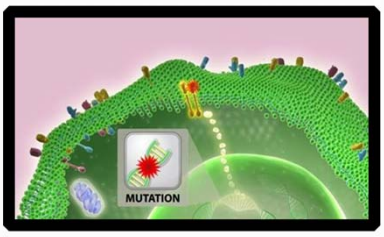
trastuzumab-dskt Ogivri™

- **trastuzumab-dskt Ogivri™** Mylan **a biosimilar to Herceptin (trastuzumab, Genentech, Inc.)** approved for HER2 overexpressing breast in adjuvant or metastatic setting and metastatic gastric or GE junction adenocarcinoma
  - *Biosimilar humanized monoclonal antibody with target on tumor*
  - *Infusion rxns can be severe*
  - *Targets HER2 neu*
  - *Personalized to HER2 protein overexpression or gene amplification*
  - *Side effects: Cardiomyopathy, infusion reactions, pulmonary toxicity, headache, diarrhea, nausea, fever, chills. headache, infection, insomnia, cough, and rash. Exacerbation of chemo induced neutropenia, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections*

www.Ogivri.com

Future Directions

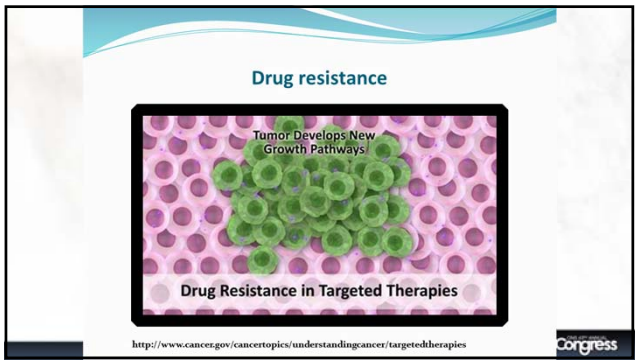
Targeting genetic alterations in the tumor

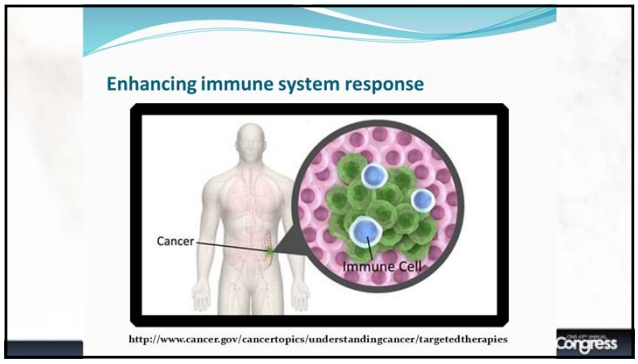


http://www.cancer.gov/cancertopics/understandingcancer/targetedtherapies

Drug resistance

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





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