Pharmacology Update 2023

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Disclosures

Speaker Honoraria: ION division AmerisourceBergen, Physicians' Education Resource, McKesson

Advisory Board Honoraria: Frenesius Kabi

Objectives

- Identify new drugs/agents that have been FDA approved for cancer treatment in 2023, as well as notable approvals in 2022.
- Recognize how new drugs/agents are given generic (non-proprietary) names.
- Identify how to gain information about new drugs based on the generic (non-proprietary) naming system

Progress in Cancer Therapy 2023

- **New FDA Approved Cancer Treatment Agents (1/1/2023 to 5/25/23)**

  4 drugs : 2 solid tumor indications
  2 hematologic malignancy

  - **3 Molecularly Targeted/Immunotherapy**
  - **1 Endocrine Receptor Antagonist**

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

Progress in Cancer Therapy 2023

- **Additional FDA Approved Cancer Treatment Agent Indications (1/1/2023 to 5/25/2023)**
  - ***13 drugs with 8 additional disease indications***

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

Trends

Trends

- **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

- **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.**
  - **As of 5/25/23 the number of cancer biosimilars approved by the FDA include:**
    - **10 for cancer supportive care**
    - **12 for cancer treatment**

https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

Trends

- **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.”**
  - **6 new therapies FDA approved for cancer treatment since 2017, with expanding indications; more in clinical trials development**

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

Trends

- **Adenoviral vector-based gene therapy**
  - **First in class drug approved for high risk Bacillus Calmette-Guerin (BCG) unresponsive non-muscle invasive bladder cancer**

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

Trends

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

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

Trends

- **Bispecific Immunomodulatory Drugs**
  - **Fusion Proteins**
  - **Monoclonal Antibodies**

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

Trends

- Genomic Taxonomy: Use of appropriate terminology to ensure patient safety and quality
  - A shift from use of “mutation” to “variant”
    - Use of the term “mutation” can cause confusion and medical errors
    - DNA sequencing technology has evolved rapidly and can detect multiple types of genomic variations which can be:
      - Benign
      - Likely benign
      - Of uncertain significance
      - Likely pathogenic
      - Pathogenic (disease causing)
  - A shift to “Biomarkers and Biomarker Testing” rather than terms such as molecular, tumor or genomic profiling

https://www.ons.org/genomics-taxonomy

Progress in Cancer Therapy 2023

- **Non-Small Cell Lung Cancer (NSCLC)**
  - ***pembrolizumab Keytruda® Merck: adjuvant treatment following resection and platinum-based chemotherapy for stage IB (T2a ≥4 cm), II, or IIIA non-small cell lung cancer (NSCLC) (2023)***

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

Of Note 2022: Non-Small Cell Lung Cancer

- **Increasing biomarker specific drug approvals for advanced/metastatic NSCLC:**
  - ***(MET) exon 14 skipping***
  - ***HER2 Mutant***
  - ***rearranged during transfection (RET) gene fusion***
  - **KRAS G12C¬-mutated**

- **First drug approved for HER2-mutant NSCLC**
  - ***fam-trastuzumab deruxtecan-nxki Enhertu® Daiichi Sankyo, Inc.: adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating human epidermal growth factor receptor 2 HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy. This is the first drug approved for HER2-mutant NSCLC (2022)***

- **2 bevacizumab biosimilars approved for advanced disease**

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

Progress in Cancer Therapy 2023

- **Breast**
  - **elacestrant Orserdu™ Stemline Therapeutics, Inc.: postmenopausal women or adult men with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy (2023)**
  - ***abemaciclib Verzenio® Eli Lilly and Company with endocrine therapy (tamoxifen or an aromatase inhibitor): adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence (2023)***

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

Of Note 2022: Breast Cancer

- **fam-trastuzumab deruxtecan-nxki Enhertu® received 2 approvals with 1 being:**
  - **adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy**
  - **Offers a new option for HER2-low metastatic/recurrent breast cancer**

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

Progress in Cancer Therapy 2023

- **Urothelial Carcinoma**
  - ***enfortumab vedotin-ejfv Padcev® Astellas Pharma with pembrolizumab Keytruda® Merck: patients with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy (2023)***
- **Endometrial**
  - ***dostarlimab-gxly (Jemperli, GlaxoSmithKline LLC) for 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 in any setting and are not candidates for curative surgery or radiation (2023)***
- **Colorectal**
  - ***tucatinib Tukysa® Seagen Inc. in combination with trastuzumab: RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy (2023)***

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

Progress in Cancer Therapy 2023

- **Glioblastoma**
  - ***dabrafenib Tafinlar® Novartis with trametinib Mekinist® Novartis: pediatric patients 1 year of age and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. The FDA also approved new oral formulations of both drugs suitable for patients who cannot swallow pills (2023)***

- **Merkel Cell carcinoma**
  - **retifanlimab-dlwr Zynyz® Incyte Corporation: adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) (2023)**

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

Of Note 2022: Bladder Cancer

- **Non-Muscle Invasive Bladder Cancer**
  - **nadofaragene firadenovec-vncg Adstiladrin® Ferring Pharmaceuticals: adult patients with high-risk Bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors (2022)**

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

Of Note 2022: Prostate Cancer

- **Prostate**
  - **lutetium Lu 177 vipivotide tetraxetan Pluvicto® Advanced Accelerator Applications USA, Inc., a Novartis company: adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy (2022)**

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

Of Note: Melanoma 2022

- **Melanoma**
  - **tebentafusp-tebn Kimmtrak® Immunocore Limited: a bispecific gp100 peptide-HLA-directed CD3 T cell engager, for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (2022)**
  - **nivolumab and relatlimab-rmbw Opdualag™ Bristol-Myers Squibb Company: adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. Opdualag is a fixed-dose combination of the LAG-3-blocking antibody relatlimab and the programmed death receptor-1 blocking antibody nivolumab (2022)**

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

Of Note: Tumor Agnostic Drugs 2022

Offer treatment options based on Biomarkers in any type of advanced cancer in which the biomarker is discovered. Potential treatment options when others may have been exhausted.

- ***alpelisib Vijoice® Novartis Pharmaceuticals: adult and pediatric patients two years of age and older with severe manifestations of PIK3CA-related overgrowth spectrum (PROS) who require systemic therapy (2022)***
- ***dabrafenib Tafinlar® Novartis in combination with trametinib Mekinist® Novartis: for the treatment of adult and pediatric patients ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options (2022)***
- ***selpercatinib Retevmo™ Eli Lilly and Company: adult patients with locally advanced or metastatic solid tumors with a rearranged during transfection (RET) gene fusion that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options (2022)***

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

Progress in Cancer Therapy 2023

- **Mantle Cell Lymphoma**
  - **pirtobrutinib Jaypirca™ Eli Lilly and Company: relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor (2023)**
- **Chronic Lymphocytic Leukemia or Small Lymphocytic Leukemia**
  - ***zanubrutinib Brukinsa® BeiGene USA, Inc.: for chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) (2023)***

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

Of Note 2022: Follicular Lymphoma

- **Follicular Lymphoma**
  - ***tisagenlecleucel Kymriah® Novartis Pharmaceuticals Corporation: adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (2022)***
  - **mosunetuzumab-axgb Lunsumio™ Genentech, Inc.: a bispecific CD20-directed CD3 T-cell engager for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (2022)**

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

Progress in Cancer Therapy 2023

- **Large B-Cell lymphoma (DLBCL)**
  - ***polatuzumab vedotin-piiq Polivy® Genentech, Inc. with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP): adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS), or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index (IPI) score of 2 or greater (2023)***
  - **epcoritamab-bysp Epkinly™ Genmab US, Inc.: relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy (2023)**

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

Of Note 2022: Large B-Cell Lymphoma

- **Large B-Cell lymphoma (DLBCL)**
  - ***axicabtagene ciloleucel Yescarta® Kite Pharma, Inc.: adult patients with large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy. It is not indicated for the treatment of patients with primary central nervous system lymphoma (2022)***
  - ***lisocabtagene maraleucel Breyanzi® Juno Therapeutics, Inc.: adult patients with large B-cell lymphoma (LBCL) who have refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age. It is not indicated for the treatment of patients with primary central nervous system lymphoma (2022)***

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

Of Note 2022: Multiple Myeloma

- **Multiple Myeloma**
  - **ciltacabtagene autoleucel CARVYKTI™ Janssen Biotech, Inc.: adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody (2022)**
  - **teclistamab-cqyv Tecvayl™ Janssen Biotech, Inc.: the first bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody (2022)**

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

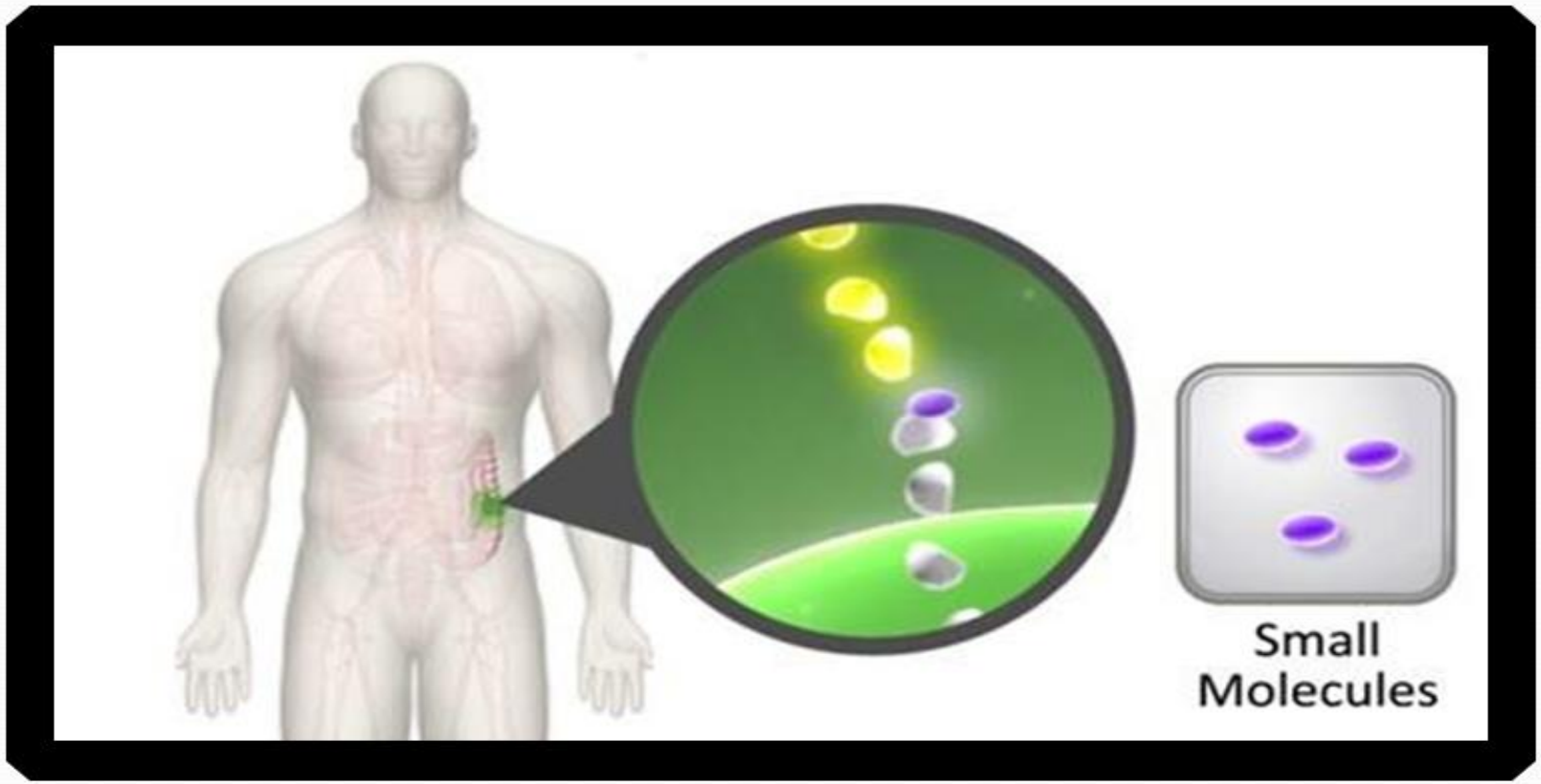
Tips for Learning about New Cancer Therapies

- **Know the type of drug/agent**
  - **Small molecule, monoclonal antibody, cellular gene therapy, vaccine, cytotoxic, fusion protein**
- **Know the generic (non-proprietary) 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 to an actionable variant and if biomarker 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**

https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-naming-guidelines

Of Note: Small Molecules

Only 1 new small molecule for cancer treatment approved by the FDA thus far in 2023 (4 in 2022)

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

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, cabozantinib, tepotinib, infigratinib, mobocertinib , pacritinib, futibatinib**

- **IDH inhibitors**
  - **olutasidenib**

- **Bruton's Kinase Inhibitor**
  - **pirtobrutinib**

- **RAS inhibitors**
  - **adagrasib**

https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-naming-guidelines

pirtobrutinib Jaypirca™ Eli Lilly and Company: relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor (2023)

www.jaypirca.com

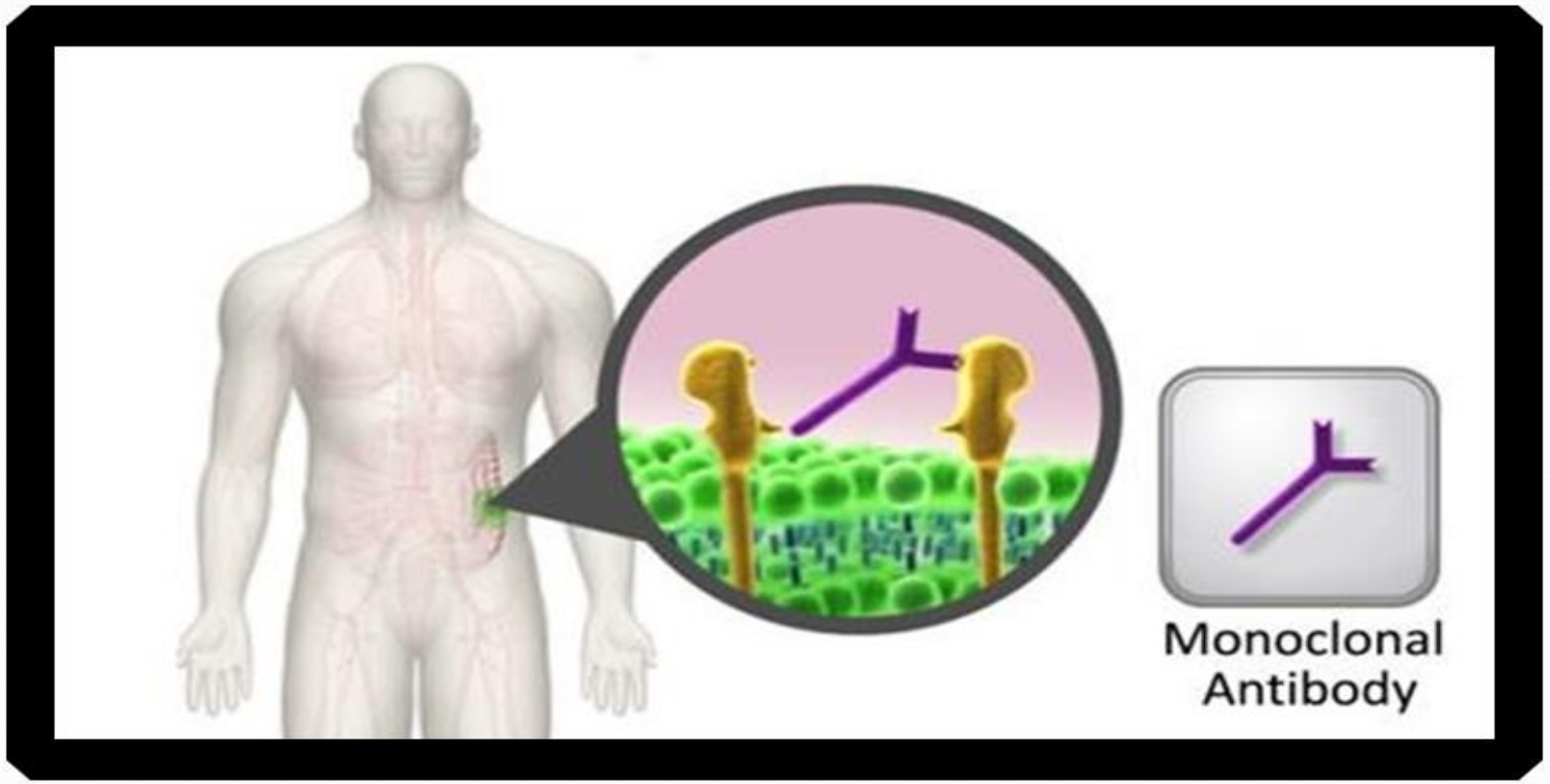
pirtobrutinib Jaypirca™

pirtobrutinib Jaypirca™ Eli Lilly and Company: relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor (2023)

- ***Oral kinase inhibitor; small molecule***
- ***Drug interactions with strong CYP3A inhibitors; strong or moderate CYP3A inducers; sensitive CYP2C8, CYP2C19, CYP3A, P-gp, or BCRP substrates***
- ***Targets Bruton's tyrosine kinase (BTK)***
- ***No Biomarker testing needed prior to administration***
- ***Side effects: fatigue, musculoskeletal pain, diarrhea, edema, dyspnea, pneumonia, and bruising, infections, hemorrhage, cytopenias, atrial fibrillation, atrial flutter, second primary malignancies.***

www.jaypirca.com

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

- tositumomab and iodine 131
  - mo = mouse
- rituximab
  - xi = chimeric or cross between mouse and human
- trastuzumab, bevacizumab
  - zu = humanized
- panitumumab
  - u = fully human (may also leave out the u)
- Decision recently made to eliminate the source inflix

https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-naming-guidelines

What does the name mean?

t , ta, or tu = tumor

trastuzumab

ci = circulatory

bevacizumab

li or l = immunomodulator

ipilimumab

https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-naming-guidelines

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**

https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-naming-guidelines

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.**

https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-naming-guidelines

nivolumab and relatlimab-rmbw Opdualag™ Bristol-Myers Squibb Company: adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. Opdualag is a fixed-dose combination of the LAG-3-blocking antibody relatlimab and the programmed death receptor-1 blocking antibody nivolumab (2022)

www.Opdualag.com

nivolumab and relatlimab-rmbw Opdualag™

nivolumab and relatlimab-rmbw Opdualag™ Bristol-Myers Squibb Company: adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. Opdualag is a fixed-dose combination of the LAG-3-blocking antibody relatlimab and the programmed death receptor-1 blocking antibody nivolumab (2022)

- ***Human monoclonal antibodies combined in single dose vial. Dual immunotherapy.***
- ***Infusion related reactions***
- ***Targets LAG-3 receptor (relatlimab) and PD-1 (nivolumab)***
- ***No Biomarker testing needed prior to administration***
- ***Side effects: Immune related adverse events, infusion reactions, complications of allogeneic HSCT, musculoskeletal pain, fatigue, rash, pruritus, and diarrhea. Laboratory abnormalities (≥20%) are decreased hemoglobin, decreased lymphocytes, increased AST, increased ALT, and decreased sodium***

www.Opdualag.com

retifanlimab-dlwr Zynyz® Incyte Corporation: adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) (2023)

www.Zynyz.com

retifanlimab-dlwr Zynyz®

retifanlimab-dlwr Zynyz® Incyte Corporation: adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma (MCC) (2023)

- ***Monoclonal antibody targeting the immune system***
- ***Infusion related reactions and serious immune related adverse events***
- ***Targets Programmed death receptor-1 (PD-1)***
- ***Side effects: Immune related adverse events, fatigue, musculoskeletal pain, pruritus, diarrhea, rash, pyrexia, nausea, complications of allogeneic HSCT***

www.zynyz.com

Bispecific Immunomodulatory Drugs

Fusion Proteins

Monoclonal Antibodies

epcoritamab-bysp Epkinly™ Genmab US, Inc.: relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy (2023)

www.epkinly.com

epcoritamab-bysp Epkinly™

epcoritamab-bysp Epkinly™ Genmab US, Inc.: relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy (2023)

- ***Bispecific monoclonal antibody ; subcutaneous***
- ***Premedicate for potential cytokine release syndrome (CRS) and monitor for immune effector associated neurotoxicity syndrome (ICANS)***
- ***Target: CD20 directed CD3 T-cell engager***
- ***Side effects: CRS, ICANS, infections, cytopenias, fatigue, musculoskeletal pain, injection site reactions, pyrexia, abdominal pain, nausea, and diarrhea.***

www.epkinly.com

teclistamab-cqyv Tecvayli™ Janssen Biotech, Inc.: the first bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody (2022)

www.tecvayli.com

teclistamab-cqyv Tecvayli™

teclistamab-cqyv Tecvayli™ Janssen Biotech, Inc.: the first bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager, for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody (2022)

- ***Bispecific monoclonal antibody; targets in immune system and tumor***
- ***Infusion related reactions; subcutaneous***
- ***Targets B-cell maturation antigen (BCMA) and CD3 T-cell receptor***
- ***Side effects: hepatotoxicity, infections, immune effector cell neurotoxicity syndrome pyrexia, cytokine release syndrome, musculoskeletal pain, injection site reaction, fatigue, upper respiratory tract infection, nausea, headache, pneumonia, and diarrhea, decreased lymphocytes, decreased neutrophils, decreased white blood cells, decreased hemoglobin, and decreased platelets. Available through REMS program.***

www.tecvayli.com

mosunetuzumab-axgb Lunsumio™ Genentech, Inc.: a bispecific CD20-directed CD3 T-cell engager for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (2022)

www.lunsumio.com

mosunetuzumab-axgb Lunsumio™

mosunetuzumab-axgb Lunsumio™ Genentech, Inc.: a bispecific CD20-directed CD3 T-cell engager for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (2022)

- ***Bispecific humanized monoclonal antibody; targets in immune system and tumor***
- ***Infusion related reactions and cytokine release syndrome; premedicate***
- ***Targets CD20 and CD3 T-cell receptor***
- ***Side effects: cytokine release syndrome, neurologic toxicity, infections, tumor flare, fatigue, rash, pyrexia, headache. decreased lymphocyte count, decreased phosphate, increased glucose, decreased neutrophil count, increased uric acid, decreased white blood cell count, decreased hemoglobin, and decreased platelets.***

www.lunsumio.com

tebentafusp-tebn Kimmtrak® Immunocore Limited: a bispecific gp100 peptide-HLA-directed CD3 T cell engager, for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (2022)

www.kimmtrak.com

tebentafusp-tebn Kimmtrak®

tebentafusp-tebn Kimmtrak® Immunocore Limited: a bispecific gp100 peptide-HLA-directed CD3 T cell engager, for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma (2022)

- ***Bispecific T cell engager; fusion protein***
- ***Gp100 peptide HLA directed CD3 T cell engager***
- ***Potential for cytokine release syndrome; monitor for at least 16 hours following first 3 infusions and then as clinically indicated***
- ***Biomarker testing needed prior to administration***
- ***Side effects: cytokine release syndrome, rash, pyrexia, pruritus, fatigue, nausea, chills, abdominal pain, edema, hypotension, dry skin, headache, vomiting. decreased lymphocyte count, increased creatinine, increased glucose, increased aspartate aminotransferase, increased alanine aminotransferase, decreased hemoglobin, and decreased phosphate***

www.kimmtrak.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, ciltacabtagene autoleucel**

https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-naming-guidelines

ciltacabtagene autoleucel CARVYKTI™ Janssen Biotech, Inc.: treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody (2022)

www.CARVYKTI.com

ciltacabtagene autoleucel CARVYKTI™

ciltacabtagene autoleucel CARVYKTI™ Janssen Biotech, Inc.: treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody (2022)

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. Available through REMS program. Must have tocilizumab available.***
- ***Side effects: pyrexia, cytokine release syndrome, immune effector cell associated neurotoxicity syndrome, hypogammaglobulinemia, hypotension, musculoskeletal pain, fatigue, infections-pathogen unspecified, cough, chills, diarrhea, nausea, encephalopathy, decreased appetite, upper respiratory tract infection, headache, tachycardia, dizziness, dyspnea, edema, viral infections, coagulopathy, constipation, vomiting, secondary malignancies. Prolonged and recurrent cytopenias, aminotransferase elevation and hypoalbuminemia. Parkinsonism and Guillain-Barré syndrome. Hemophagocytic Lymphohistiocytosis/Macrophage Activation Syndrome (HLH/MAS)***

www.CARVYKTI.com

Adenoviral Vector-Based Gene Therapy

nadofaragene firadenovec-vncg Adstiladrin® Ferring Pharmaceuticals: adult patients with high-risk Bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors (2022)

https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/adstiladrin

nadofaragene firadenovec-vncg Adstiladrin®

nadofaragene firadenovec-vncg Adstiladrin® Ferring Pharmaceuticals: adult patients with high-risk Bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors (2022)

- ***Intravesical***
- ***Non-replicating adenoviral vector-based gene therapy***
- ***Pre-medication with an anticholinergic advised; contraindicated in pts with hypersensitivity to interferon alfa or any component***
- ***No Biomarker testing needed prior to administration***
- ***Side effects: glucose increased, instillation site discharge, triglycerides increased, fatigue, bladder spasm, micturition, creatinine increased, hematuria , phosphate decreased, chills, pyrexia, and dysuria. Risk of disseminated adenovirus infection in persons immunocompromised or immunodeficient.***

https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/adstiladrin

Radiolabeled Pharmaceutical Agents

lutetium Lu 177 vipivotide tetraxetan Pluvicto® Advanced Accelerator Applications USA, Inc., a Novartis company: adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy (2022)

www.pluvicto.com

lutetium Lu 177 vipivotide tetraxetan Pluvicto®

lutetium Lu 177 vipivotide tetraxetan Pluvicto® Advanced Accelerator Applications USA, Inc., a Novartis company: adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy (2022)

- ***Radioligand therapeutic agent***
- ***No known drug/drug interactions***
- ***Biomarker testing needed prior to administration (PSMA expression detected by an approved PSMA-11 imaging agent)***
- ***Side effects: fatigue, dry mouth, nausea, anemia, decreased appetite, and constipation. Most common laboratory abnormalities (≥ 30%) are decreased lymphocytes, myelosuppression, decreased leukocytes, decreased calcium, and decreased sodium. Renal toxicity, infertility, risk for radiation exposure***

www.pluvicto.com

Estrogen Receptor Antagonist

elacestrant Orserdu™ Stemline Therapeutics, Inc.: postmenopausal women or adult men with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy (2023)

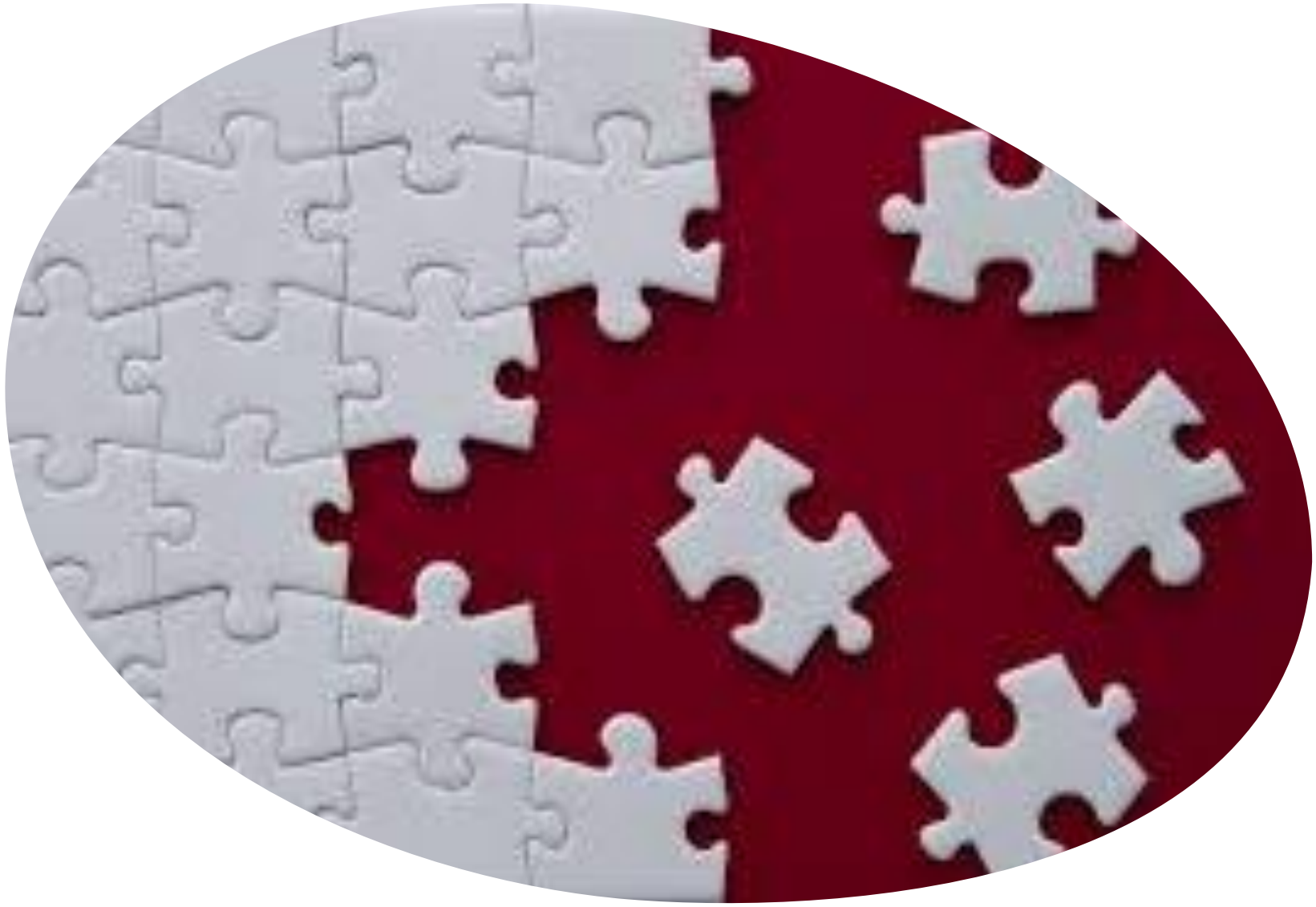
www.orserdu.com

elacestrant Orserdu™

elacestrant Orserdu™ Stemline Therapeutics, Inc.: postmenopausal women or adult men with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy (2023)

- ***Oral estrogen receptor antagonist***
- ***Drug interactions with strong and moderate CYP3A4 inducers and inhibitors***
- ***Biomarker testing needed prior to administration: ER, HER2 and ESR-1***
- ***Side effects: dyslipidemia, musculoskeletal pain, nausea, increased cholesterol, increased AST, increased triglycerides, fatigue, decreased hemoglobin, vomiting, increased ALT, decreased sodium, increased creatinine, decreased appetite, diarrhea, headache, constipation, abdominal pain, hot flush, and dyspepsia***

www.orserdu.com



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- https://www.fda.gov/drugs/biosimilars/biosimilar-product-information

- **Search proprietary or non proprietary name of any drug to reach the web site dedicated to that drug. Prescribing information will be available on each web site.**