New Drug Update

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Disclosures

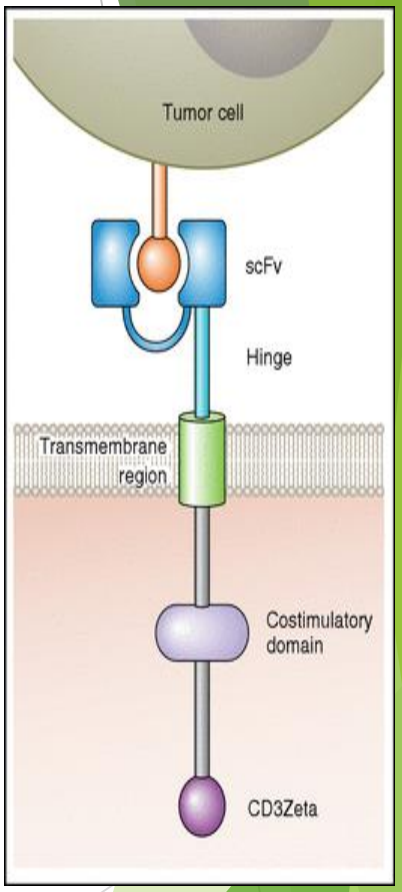
- I have nothing to disclose related to the content of this presentation

Objectives

- Review pharmacology of newly approved agents
- Review clinical data supporting approval of new agents
- Describe common toxicities of newly approved agents and discuss associated monitoring parameters
- Identify clinical pearls and place in therapy for newly approved agents

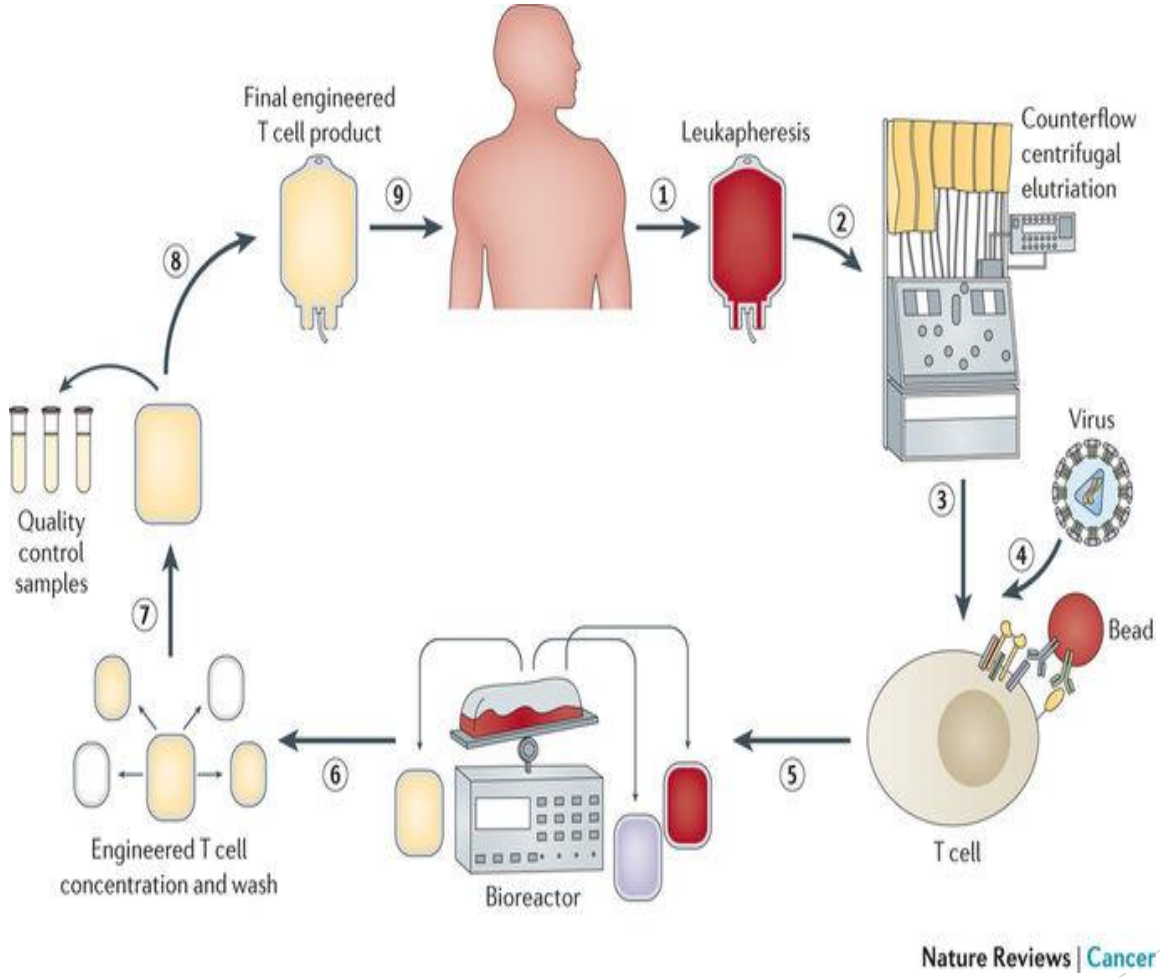
Chimeric Antigen Receptor T-cells (CAR-T)

- Genetically engineered autologous T-cells modified to express a chimeric antigen receptor (CAR)
- CAR is a recombinant receptor construct
- Bind to specific “antigens” on tumor cell surfaces
  - Major histocompatibility complex independent
- Binding of CAR to target initiates immune response



Mikkilineni L, et al. Blood 2017;130:2594-2602
Holzinger A, et al. Cancer Immunol Immunother 2016;65:1433–1450

CAR-T Cell Production



Fesnak A, et al. Nat Rev Can 2016;16;566–581

Conditioning/Lymphodepletion Regimen

- High dose chemotherapy directed at lymphodepletion
  - Decrease in regulatory T-cells
  - Tumor debulking
  - Reduces reaction to murine single-chain fragment on an antibody
- Agents used:
  - Cyclophosphamide
  - Fludarabine
  - Bendamustine

Shank BR, et al. Pharmacotherapy. 2017 Mar;37(3):334-345.

CAR-T Cell Dose

- No standard dose
- Varies based on:
  - Product
  - Population
  - Disease state
- Dose range
  - 0.2 to 5.0 x 10^6 cells/kg
  - Weight based versus standard dosing
  - Fractionated versus single dosing

KYMRIAH™ [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2017; YESCARTA™ [package insert]. Santa Monica, CA: Kite Pharma Inc; 2017; Shank BR, et al. Pharmacotherapy. 2017 Mar;37(3):334-345.

Tisagenlecleucel (Kymriah®)

- Approved in August 2017 for treatment of patients up to age 25 with B cell acute lymphoblastic leukemia (ALL) that is refractory or in a second or later relapse
- In May 2018, second indication added for treatment of relapsed or refractory large B cell lymphoma after 2 or more lines of systemic therapy
- MOA: CD-19 directed autologous T cell immunotherapy
  - 4-1BB costimulatory domain
  - lentivirus vector

KYMRIAH™ [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2017

Dosage and administration

- Dose is based on the number of chimeric antigen receptor (CAR)+ viable T cells
- B-cell ALL
  - Pts < 50 kg: 0.2 to 5 x 10^6 CAR-T cells per kg IV
  - Pts < 50 kg: 0.1 to 2.5 x 10^8 CAR-T cells per kg IV
- Relapsed/refractory diffuse large B cell lymphoma (DLBCL)
  - 0.6 to 6 x 10^8 CAR-T cells per kg IV

KYMRIAH™ [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2017

Clinical data

- ELIANA trial
  - Multicenter, phase 2, single cohort trial of tisagenlecleucel in pediatric and adult patients with R/R ALL
  - Primary endpoint of overall response rate (ORR) within 3 months
  - Lymphodepletion:
    - Fludarabine 30mg/m2 daily for 4 days
    - Cyclophosphamide 500mg/m2 daily for 2 days
- Median duration of follow up: 13.1 months
- Median weight-adjusted dose of 3.1 x 10^6 cells/kg

Maude SL, et al. N Engl J Med 2018; 378:439-448

ELIANA results

Response rates		Overall survival		Event free survival	
ORR	81%	OS 6 mo	90%	EFS 6 mo	73%
CR	60%	OS 12 mo	76%	EFS 12 mo	60%
CRi	21%	Median OS	19.1 months	Median EFS	NR

CR: complete response
CRi: complete response with incomplete hematologic recovery
EFS: event free survival

Maude SL, et al. N Engl J Med 2018; 378:439-448

ELIANA - Adverse events

Event (n=75)	Any grade
Cytokine release syndrome	58 (77)
Neurologic event	30 (40)
Tumor lysis syndrome	3 (4)
B-cell aplasia	62 (83)

Grade 3 or 4 CRS: 46%

Grade 3 or 4 neurologic event: 13%

Maude SL, et al. N Engl J Med 2018; 378:439-448

Clinical pearls

- REMS training required in order to order, dispense or administer tisagenlecleucel
- Supply of tocilizumab must be on site prior to product infusion
- Myeloid growth factors should be avoided during first 3 weeks after product infusion
- B-cell aplasia may persist up to a year post therapy
  - Increased risk for infections
- Can cause false positive HIV test

Axicabtagene ciloleucel (Yescarta®)

- Approved in October 2017 for treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of therapy

- MOA: CD-19 directed autologous T cell immunotherapy
  - CD-28 costimulatory domain
  - retroviral vector

YESCARTA™ [package insert]. Santa Monica, CA: Kite Pharma Inc; 2017

Dosage and administration

- Dose is based on the number of chimeric antigen receptor (CAR)+ viable T cells
- Target dose: 2 x 10^6 CAR-T cells per kg IV
- Max dose: 2 x 10^8 CAR-T cells per kg IV

YESCARTA™ [package insert]. Santa Monica, CA: Kite Pharma Inc; 2017

Clinical data

- ZUMA trial
  - Multicenter, phase 2, **single arm** trial in adult patients with R/R DLBCL or primary mediastinal B-cell lymphoma (PMBCL)/transformed follicular lymphoma (TFL)
  - Primary endpoint of overall response rate (ORR)
  - Lymphodepletion:
    - Fludarabine 30mg/m2 daily for 3 days
    - Cyclophosphamide 500mg/m2 daily for 3 days
- Median duration of follow up: 15.4 months

Neelapu SS, et al. N Engl J Med 2017; 377:2531-2544

ZUMA results

Response rates		Overall survival		Progression free survival	
ORR	82%	OS 6 mo	78%	PFS 6 mo	49%
CR	58%	OS 18 mo	52%	PFS 15 mo	41%
PR	29%	Median OS	NR	Median PFS	5.8 mo

PR: partial response
PFS: progression free survival

Neelapu SS, et al. N Engl J Med 2017; 377:2531-2544

ZUMA Trial– Adverse events

Adverse Events (n=101)	Any grade	Grade 3	Grade 4
Any	101 (100)	5 (5)	96 (95)
Cytokine release syndrome	94 (93)	81 (80)	13 (13)
Neurologic event	65 (64)	37 (37)	28 (28)

Most common: pyrexia (85%), neutropenia (84%), and anemia (66%)

Neelapu SS, et al. N Engl J Med 2017; 377:2531-2544

Clinical pearls

- REMS training required in order to order, dispense or administer axibtagene
- Supply of tocilizumab must be on site prior to product infusion
- Myeloid growth factors may be used during period of neutropenia along with empiric antibiotics
- B-cell aplasia may persist up to a year post therapy
  - Increased risk for infections
- Patients should receive seizure prophylaxis as well as tumor lysis syndrome (TLS) prophylaxis depending on disease burden

Audience response question #1

Axicabtagene is CD-19 directed CAR-T therapy that is indicated for treatment of following:

a. B cell ALL in adults
b. Relapsed or refractory DLBCL in adults
c. Relapsed or refractory DLBCL in pediatric patients
d. None of the above

Answer: B

Acalabrutinib (Calquence®)

- Approved in October 2017 for adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy
- MOA: selective and irreversible second generation Bruton's tyrosine kinase inhibitor that causes decreased malignant B-cell proliferation and survival
- Dosing: 100 mg by mouth twice daily until disease progression or unacceptable toxicity

Calquence (acalabrutinib) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2017.

Clinical data

- ACE-LY-004 – phase 2 open label trial
  - 124 patients with MCL who received at least one prior therapy
  - - acalabrutinib 100 mg by mouth twice daily
  - 100 mg by mouth once daily until disease progression or unacceptable toxicity
  - Median time to response 1.9 months (range 1.5 – 4.4 mos)

Response,* n (%)	Investigator Assessed	IRC Assessed
ORR (CR + PR)	100 (81)	99 (80)
Best response		
▪ CR	49 (40)	49 (40)
▪ PR	51 (41)	50 (40)
▪ SD	11 (9)	9 (7)
▪ PD	10 (8)	11 (9)
▪ Not evaluable	3 (2)	5 (4)

Wang M, et al. ASH Meeting Abstracts 2017: Abstract 155

Adverse events

- The most common ADRs in > 20% of patients
  - Anemia
  - Thrombocytopenia
  - Neutropenia
  - Headache
  - Diarrhea
  - Fatigue
  - Myalgia
  - Bruising

Wang M, et al. ASH Meeting Abstracts 2017: Abstract 155

Place in therapy and clinical pearls

- Second line treatment option for patients with MCL who received at least one prior therapy

- Monitor for drug-drug interactions as dose adjustments are needed when used with CYP3A inhibitors or inducers
- Increased risk of bleeding in patients on anticoagulation or antiplatelet therapy
- Temporary lymphocytosis in 31.5% of patients
  - May persist for 6 to 7 weeks

Copanlisib (Aliqopa®)

- Approved in September 2017 for treatment of relapsed follicular lymphoma who received at least two prior systemic therapies
- MOA: inhibits phosphatidylinositol-3-kinase (PI3K alpha and delta) expressed in malignant B cells resulting in decreased cell proliferation and apoptosis
- Dosing: 60 mg given IV over 60 minutes on days 1, 8, and 15 every 28 days

Aliqopa (copanlisib) [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc; 2017

Clinical data

- CHRONOS-1 single arm phase 2 trial
  - 104 patients with relapsed follicular lymphoma (FL)
  - Copanlisib 0.8 mg/kg or 60 mg given on days 1,8,and 15
  - Median PFS was 11.2 months

Response	Investigator assessed %
Objective RR	57.8%
CR	14.4%
PR	44.2%

Dreyling MH, et al. JCO. 2017;35:15. Abstr 7535

Adverse reactions

- The most common ADRs in > 20% of patients
  - Hyperglycemia
  - Diarrhea
  - Fatigue
  - Hypertension
  - Leukopenia, neutropenia and thrombocytopenia
  - Lower respiratory tract infections

Dreyling MH, et al. JCO. 2017;35:15. Abstr 7535

Place in therapy and clinical pearls

- Third line option for treatment of FL for patients that are refractory to at least 2 prior therapies
- Monitor for drug-drug interactions as dose adjustment is needed when used with strong CYP3A4 inhibitors

Inotuzumab ozogomicin (Besponsa®)

- Approved in August 2017 for treatment of relapsed or refractory B-Cell ALL

- MOA: Fully humanized anti-CD22 antibody conjugated to calicheamicin, which causes DNA strand breaks and leads to cell cycles arrest and apoptosis

- Dosing:

  1st cycle: 0.8 mg/kg on day 1

  0.5 mg/kg on days 8 and 15 on 21 day cycle

  *subsequent cycles based on response

Besponsa [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; 2017

Clinical data

- INO-VATE ALL, phase 3 open label trial
  - 326 patients with Ph+ or Ph- relapsed/refractory B-cell ALL
  - Randomized to inotuzumab or standard intensive chemotherapy chosen at investigator's discretion

Outcome	Inotuzumab arm n=164	Control arm n= 162	
CR	80.7%	29.4%	p < 0.001
MRD -	78.4%	28.1%	p < 0.001

Kantarjian HM, et al. *N Engl J Med*. 2016;375(8):740-753

Adverse reactions

- **Hepatotoxicity, including veno-occlusive disease**
- **Higher post-HSCT non-relapse mortality rate**
- Infusion reactions
- Myelosuppression
- Infection and febrile neutropenia
- Fatigue
- Nausea
- Abdominal pain
- Headaches

Kantarjian HM, et al. *N Engl J Med*. 2016;375(8):740-753

Place in therapy and clinical pearls

- Treatment option for patients with relapsed or refractory ALL in patients with Ph – disease as well as Ph+ disease intolerant to tyrosine kinase inhibitors (TKIs)
- Patients with circulating blasts should receive cytoreductive therapy with goal peripheral blast < 10,000/m3 to minimize risk of reactions
- Concomitant use with other drugs that prolong QT interval may result in torsades de pointe

Audience response question #2

Inotuzumab ozogomicin has following black box warning:

a. Infusion reactions
b. Increased rich for JC virus infections
c. Hepatotoxicity, including VOD
d. Splenic rupture

Answer: C

Abemaciclib (Verzenio®)

- Approved in September 2017 for treatment of HR+, HER-2 negative metastatic breast cancer
  - Monotherapy
  - In combination with fluvestrant
  - In combination with an aromatase inhibitor

- MOA: inhibitor of cyclin dependent kinases 4 and 6 which blocks progression from G1 to S phase of the cell cycles leading to apoptosis

Verzenio (abemaciclib) [package insert]. Indianapolis, IN: Eli Lilly and Company; 2018

Dosage and administration

- Monotherapy
  - 200 mg by mouth twice daily
- In combination with fulvestrant or aromatase inhibitor
  - 150 mg by mouth twice daily
- May be taken with or without food

Verzenio (abemaciclib) [package insert]. Indianapolis, IN: Eli Lilly and Company; 2018

Clinical data

- MONARCH-3
  - Randomized , double blinded, placebo controlled trial
  - 493 patients with HR+, HER2- metastatic breast cancer
  - Abemaciclib or placebo plus either letrazole or anastrazole
- Median PFS was 28.2 months for combination group vs 14.8 months for control group. HR 0.540; 95% CI 0.418 – 0.698)
- ORR was 59% for combination group vs 44% for control (p< 0.004)

Goetz MP, et al. *J Clin Oncol*.2017;35(32):3638-3646.

Adverse events

- Diarrhea (81%)
- Neutropenia
- Fatigue
- Infections
- Nausea, vomiting and abdominal pain
- Anemia
- Alopecia
- Decreased appetite liver enzyme abnormalities

Goetz MP, et al. *J Clin Oncol*.2017;35(32):3638-3646.

Clinical pearls

- Unlike other CDK 4/6 inhibitors, abemaciclib is dosed continuously
- Higher incidence of diarrhea, but lower rates of hematologic toxicity (neutropenia)
- Inhibition of renal tubular secretion that results in creatinine elevations but no change in GFR
- Both parent drug and active metabolites cross blood brain barrier (BBB)

Lutetium Lu 177 dotatate (Luthatera®)

- Approved in January 2018 for treatment of somatostatin receptor positive neuroendocrine tumors in adults
- MOA: radiolabeled somatostatin analogue that induces cellular damage by formation of free radicals in somatostatin receptor positive cells
- Dose:
  - 200 mCi IV every 8 weeks for total of 4 doses

Lutathera [package insert]. Millburn, NJ: Advanced Accelerator Applications USA, Inc.; 2018.

Clinical data

- NETTER-1 trial
  - Randomized, open-label, active controlled trial
  - 229 patients with locally advanced or metastatic NET
  - Lutathera with long acting octreotide vs. high dose long acting octerotide
- Median PFS not reached for study group and was 8.5 months in control group; HR 0.21 95% CI 0.13-0.32
- Objective tumor responses observed in 18% of patients in study group vs 3% in the control group; $p<0.001$

Strosberg J, et al. *N Engl J Med*.2017; 376(2):125-135.

Adverse events

- Lymphopenia
- Nausea and vomiting
- Increased lever enzymes
- Hyperglycemia
- Hypokalemia
- Increased risk of myelodysplastic syndrome (MDS)
  - 2.7% patients in NETTER-1

Strosberg J, et al. *N Engl J Med*.2017; 376(2):125-135.

Place in therapy and clinical pearls

- Second line therapy for somatostatin receptor+ metastatic NET in patients inadequately controlled with somatostatin analogues
- Octreotide should be discontinued before starting lutathera
  - 24 hrs before for octriotide
  - 4 weeks before for octreotide, long acting release (LAR)
- Octreotide may be given during lutathera therapy for symptom management starting 4-24 hrs after the start of therapy
- All patients should receive amino acid solution 30 minutes before lutathera and continue during and x 3 hrs post infusion for renal protection

Audience response question #3

Administration of amino acid solution around Lutathera infusion provides a rescue for healthy tissues.

a. True
b. False

Answer: B

Apalutamide (Erleada®)

- Approved in February 2018 for patients with non-metastatic, castration resistant (NM-CR) prostate cancer
- MOA: androgen receptor inhibitor that impedes AR nuclear translocation, inhibits DNA binding and transcription resulting in increased apoptosis

- Dose: 240 mg by mouth once daily
  - Can be taken with or without food

Erleada (apalutamide) [package insert]. Horsham, PA: Janssen Biotech, Inc.; 2018.

Clinical data

- SPARTAN trial
  - Randomized, double-blind, placebo controlled
  - 1207 patients with NM-CR prostate cancer
  - Apalutamide + androgen deprivation therapy (ADT) (n=806) vs placebo + ADT (n=401)
- Median metastasis free survival:
  - 40.5 months in apalutamide arm
  - 16.2 months in placebo arm
  - HR 0.28, 95% CI 0.23 – 0.35
- 72% lower risk of metastasis or death in apalutamide group

Smith MR,et al. *N Engl J Med*. 2018;378:1408-1418

Adverse events

- Fatigue
- Hypothyroidism 8.1%
- Rash 23.8%
- Nausea and diarrhea
- Hot flashes
- Arthralgia
- Fractures 12%
- Peripheral edema

Smith MR,et al. *N Engl J Med*. 2018;378:1408-1418

Place in therapy and clinical pearls

- Treatment option for men with NM-CR prostate cancer who are at high risk for developing metastatic disease

- Dose adjustments are needed if used with strong CYP2C9 or CYP3A4 inhibitors/inducers
- Bone mineral density should be assessed for all patients receiving apalutemide
- Gonadotropin-releasing hormone analogue should be given concomitantly
  - Exception: patients s/p documented, bilateral orchiectomy

Daunorubicin and cytarabine liposome for injection (CPX351; Vyxeos®)

- Approved in August 2017 for treatment of adults with newly diagnosed, therapy-related AML (t-AML) or AML with myelodysplasia related changes (AML-MRC)

- MOA: Liposomal formulation of daunorubicin and cytarabine at a fixed 1:5 molar ratio. Intracellularly, liposomes undergo degradation releasing cytarabine and daunorubicin within the intracellular environment.

Vyxeos [package insert]. Palo Alto, CA. Jazz Pharmaceuticals, 2017

Dosage and administration

- Induction
  - Doxorubicin 44 mg/m2 and cytarabine 100 mg/m2 liposome given intravenously over 90 minutes on days 1,3 and 5 (and on days 1 and 3 for subsequent cycles if needed
- Consolidation
  - Doxorubicin 29 mg/m2 and cytarabine 65 mg/m2 liposome given intravenously over 90 minutes on days 1 and 3

Vyxeos [package insert]. Palo Alto, CA. Jazz Pharmaceuticals, 2017

Clinical data

- Phase 3, randomized, multicenter, open-label, active-controlled trial compared liposomal doxorubicin/cytarabine to standard 7+3 in 309 patients with newly diagnosed t-AML or AML-MRC

- Liposomal cytarabine and daunorubicin demonstrated superior OS (HR 0.69, p=0.005; median OS 9.56 versus 5.95 months), EFS (HR 0.74, p=0.021) and CR + Cri response (47.7% versus 33.3%, p=0.016)

- Adverse events were similar between treatment and control arms. Grade 3 thrombocytopenia with associated hemorrhagic events and grade 4 neutropenia were higher in patients treated with liposomal formulation

Lancet JE, et al. JCO. 2016;34:15. Abstr 7000.

Monitoring parameters

- Cardiac function evaluation
  - MUGA
- Hypersensitivity reactions
  - Routine premedication not recommended prior to first dose
- Copper overload
  - reconstituted liposomal daunorubicin and cytarabine contains 5mg/ml copper gluconate

Vyxeos [package insert]. Palo Alto, CA. Jazz Pharmaceuticals, 2017

Place in therapy and clinical pearls

- Should be considered in adults age 60 to 75 with T-AML or AML-MRC who are candidates for intensive chemotherapy

- Liposomal formulation is deep purple color and may alter color of patient's urine, sweat and tears

Gemtuzumab ozogamicin (Mylotarg®)

- Approved in September 2017 for the treatment of newly diagnosed CD-33+ AML in adults and for treatment of relapsed or refractory CD-33+ AML in adults and pediatric patients > 2 years old

- MOA: CD33 directed humanized monoclonal antibody drug conjugated to calicheamicin, which is a cytotoxic agent that is internalized by the cell and induces double strand DNA breaks, leading to cell cycle arrest and apoptotic cell death.

Mylotarg [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.;2017

Dosage and administration

- Newly diagnosed AML (single agent regimen)
  - Induction: 6 mg/m2 on day 1 and 3 mg/m2 on day 8
  - Continuation: 2 mg/m2 on day 1 every 4 weeks up to 8 cycles
- Newly diagnosed AML (combination regimen)
  - Induction: 3 mg/m2 (up to 4.5 mg) on day 1,4 and 7 in combination with daunorubicin and cytarabine
  - Consolidation
- Relapsed or refractory AML
  - 3 mg/m2 on days 1,4 and 7
- Administer over 2 hours and use in-line 0.2 micron polyetersulfone filter
  - Premedicate with acetaminophen, diphenhydramine and methylprednisolone

Mylotarg [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.;2017

Clinical data

- ALFA-0701 [1]
  - Newly diagnosed AML
  - “7+3” with or without gemtuzumab
  - Event free survival 17.3 months in gemtuzumab group vs 9.5 months in control group, HR 0.56 (95% CI 0.42 – 0.76)
- AML-19 [2]
  - Newly diagnosed AML
  - Gemtuzumab vs best supportive care
  - Median OS 4.9 months in gemtuzumab group vs 3.6 months in control group, HR 0.69 (95% CI 0.53 – 0.90)
- MyloFrance-1 [3]
  - AML in first relapse
  - Gemtuzumab induction followed by cytarbine consolidation
  - CR in 26% of patients after single course of gemtuzumab with median relapse free survival of 11.6 months

1. Castaigne S, et al. *Lancet*. 2012;379:1508-1516.
2. Amadori S, et al. *J Clin Oncol*. 2016;34:972-979.
3. Taksin AL, et al. *Leukemia*. 2017;21:66-71

Adverse events

- **Veno-occlusive disease (VOD)**
- Hemorrhage
- Infection and fever
- Nausea and vomiting headache
- Liver function tests elevation
- Rash
- Mucositis
- QT prolongation

Mylotarg [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.;2017

Place in therapy and clinical pearls

- Should be considered in AML patients with high CD33 expression and those with intermediate or favorable cytogenetics
- Patients with FLT3-ITD positive AML have a better response due to higher CD33 expression
- Monitor QTc and electrolytes

Audience response question #4

Gemtuzumab is indicated for treatment of patients with CD 33 positive AML in first relapse based on results of this trial

a. ALFA-0701
b. MyloFrance-1
c. AML-19
d. Zuma

Answer: B

Enasidenib (Idhifa®)

- Approved in August 2017 for patients with relapsed/refractory AML with and isocitrate dehydrogenase-2 (IDH2) mutation as detected by and FDA approved test

- MOA: Small molecule inhibitor of the IDH2 enzyme. Inhibition of the IDH2 enzyme results in lower levels of 2-hydroxyglutarate (2-HG) and induced myeloid differentiation with reduced blast counts and increased percentages of mature myeloid cells

- Dosing: 100 mg by mouth once daily until disease progression or unacceptable toxicity

IDHIFA [package insert]: Celgene Corp., Summit, NJ. 2017

Clinical data

- AG221-C-001
  - 199 adults with relapsed or refractory AML with IDH2 mutation
  - Enasidenib 100 mg once PO once daily
  - 19% patient achieved CR and 4% pf patients achieved CR with partial hematological recovery
  - Median response duration was 8.2 months
  - Median follow up was 6.6 months

Stein EM, et al. Blood. 2017;130(6):722-731.

Monitoring parameters

- Liver function tests
- **Differentiation syndrome**
- Leukocytosis and tumor lysis syndrome labs

IDHIFA [package insert]: Celgene Corp., Summit, NJ. 2017

Place in therapy and clinical pearls

- Option for patients with relapsed or refractory AML with IDH2 mutation
- Mutational testing required using companion device to test for IDH2 mutations, the Abbott RealTime™ IDH2 assay prior to initiation of therapy
  - Diagnostic test may be done on bone marrow sample or peripheral blood
- Minimum of 6 months of therapy needed before a clinical response is observed
- Patient assistance program available through Celgene Patient Support

New Drug Update

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August 4, 2018