New Drugs of 2017: Part 2
PharMEDium Lunch and Learn Series

LUNCH AND LEARN

New Drugs of 2017: Part 2
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Code will be provided at the end of today’s activity
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Ask a Question

- Submit your questions to your site manager.
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Your question...?
Resources

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  - Handouts
  - Activity information
  - Upcoming live webinar dates
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NEW DRUGS OF 2017-
PART 2
Learning Objectives - Pharmacists

- Describe the new drugs approved by the Food and Drug Administration in 2017
- Discuss the role of these agents in therapy
- Summarize the adverse effects and potential drug interactions of these new agents

Learning Objectives - Technicians

- Describe the new drugs approved by the Food and Drug Administration in 2017
- Discuss any unique preparation and/or dispensing requirements for these agents
- Summarize the adverse effects and potential drug interactions of these new agents that may require pharmacist intervention
2017 was a BIG Year...¹

- U.S. drug approvals hit a 21-year high in 2017
- 46 novel medicines approved
  - More than double the previous year
- One third are first in class mechanisms
- See handout
Abaloparatide (Tymlos™)

- Approved April 28, 2017
- A synthetic peptide analog of hPTHrP (human parathyroid hormone-related protein)
- Treatment of postmenopausal women with osteoporosis and high fracture risk
  - history of osteoporotic fracture
  - multiple risk factors for fracture
  - patients who have failed or are intolerant to other available osteoporosis therapy
- First new bone-building agent since Eli Lilly's Forteo® in 2002
Abaloparatide Pharmacology

- Abaloparatide acts as an agonist at the PTH1 receptor (PTH1R)
- It has anabolic properties, increases bone mineral density (BMD)
- Correlates with an increase in bone strength

Abaloparatide Pharmacokinetics

- Subcutaneous bioavailability is 36%
- 70% plasma protein bound
- Primarily excreted in the urine
- Elimination half life: 1.7 hours
Abaloparatide Dosing

- 3120 mcg/1.56 mL (2000 mcg/mL) pen
- Administer 80 mcg subcutaneously once daily
- Cumulative use of abaloparatide and parathyroid hormone analogs for greater than 2 years is not recommended
- Supplemental calcium and vitamin D may be required
- Administer as a subcutaneous injection into periumbilical region of abdomen

Abaloparatide Administration

- Administer dose subcutaneously in the abdomen
- Administer the first few doses while patient is sitting or lying down
  - Risk of orthostatic hypotension
- Rotate the site of administration each day
- Administer at the same time each day
ACTIVE Clinical Trial\(^3\)

- Multicenter, double blind, randomized trial for 18 months
- 2,463 postmenopausal women
  - Abaloparatide 80 mcg
  - Teriparatide 20 mcg
  - Placebo
- Primary endpoint: Percent of patients with new vertebral fractures (versus placebo)
- Secondary endpoint: Changes in BMD

ACTIVE Clinical Trial\(^3\)

- Significant reductions in total fractures
  - 86% reduction in vertebral fractures
  - 43% reduction in non-vertebral fractures
Abaloparatide Warnings

- Black Box Warnings
  - Dose dependent increase in osteosarcoma in rats
  - Avoid use in patients at risk for osteosarcoma
    - Paget disease of bone
    - Unexplained elevations of alkaline phosphatase
    - Bone metastases
    - Skeletal malignancies
  - Avoid cumulative use with parathyroid hormone analogs > 2 years during patient’s lifetime

Abaloparatide Adverse Effects

- Redness at injection site (58%)
- Hypercalciuria (11%)
- Dizziness (10%)
- Injection site edema (10%)
- Nausea (8%)
- Orthostatic hypotension (4%)
- Hypercalcemia (2%)
Place in Therapy

- Approved for women at high risk for fracture
  - history of osteoporotic fracture
  - multiple risk factors for fracture
  - patients who have failed or are intolerant to other therapy
- Avoid in patients at risk for osteosarcoma
- Cost impact $20,000 vs $33,000 (Forteo®)

Pharmacist Clinical Points

- Alert for orthostatic hypotension
- Not first line agent so review previous orders
- Avoid in patients at risk for osteosarcoma
- Counsel regarding supplemental calcium and vitamin D
Technician Points

- Store multidose pen in refrigerator before first use
- After first dose, store at room temperature for 30 days
- Discard after 30 days
- Ensure patient has sharps container for disposal of needles

OCRELIZUMAB (OREVUS®)
Ocrelizumab (Ocrevus)\(^4\)

- Approved March 28, 2017
- Humanized monoclonal antibody
- Selectively targets CD20 positive B cells
  - Contributes to myelin and axonal nerve cell damage
- Indicated for relapsing or primary progressive forms of multiple sclerosis

Ocrelizumab Pharmacology\(^4\)

- Mechanism is unclear
- Presumed to involve binding to CD20, a cell surface antigen present on pre-B and mature B lymphocytes.
- Results in antibody-dependent cellular cytolysis and complement-mediated lysis
Ocrelizumab Dosing

- Premedicate with methylprednisolone and antihistamine (diphenhydramine)
- Start dose: 300 mg intravenous infusion (IV), followed two weeks later by a second 300 mg IV
- Subsequent doses: 600 mg IV every 6 months
- Monitor for at least 1 hour after infusion

Ocrelizumab Dosing- Initial 2 infusions

- Dilute 300 mg in 250 mL 0.9% sodium chloride (final concentration 1.2 mg/mL)
- Use infusion pump to administer
- Start infusion at 30 mL per hour
- Increase by 30 mL per hour every 30 minutes
- Maximum rate: 180 mL per hour
- Duration: 2.5 hours or longer
Ocrelizumab Dosing - Subsequent doses\(^4\)

- Dilute 600 mg in 500 mL 0.9% sodium chloride
- Use infusion pump to administer
- Start infusion at 40 mL per hour
- Increase by 40 mL per hour every 30 minutes
- Maximum rate: 200 mL per hour
- Duration: 3.5 hours or longer

Oratorio - Clinical Trial\(^5\)

- Total of 732 patients with primary progressive multiple sclerosis
- Primary endpoint: Significant reduction in progression of clinical disability; 24% compared to placebo (p=0.0321)
- Ocrelizumab also reduced the time required to walk 25 feet by 25%
- Decreased the volume of brain lesions
Opera I and II-Clinical Trials\(^6\)

- Phase III randomized, double-blind, double-dummy trials in relapsing disease
- Compared ocrelizumab 600 mg every 6 months to 44 mcg of interferon beta-1a given SQ three times per week
- 1,656 patients enrolled
- Primary outcome was annualized relapse rate (ARR)

OPERA I and II-Results\(^6\)

- 46% and 47% reduction in annualized relapse rate compared to interferon beta 1-A (p< 0.0001 and p< 0.0001)
- 40% reduction in confirmed disability progression sustained for 12 weeks (p=0.0006)
- 77% and 83% reduction in total number of new or enlarged brain lesions (p< 0.0001 and p< 0.0001)
Ocrelizumab Contraindications

- Active hepatitis B virus infection
- History of life-threatening infusion reaction to ocrelizumab

Ocrelizumab Warnings

- Infusion reactions
- Increased risk of cancer, including breast cancer
- Infections: Delay administration in patients with an active infection until infection resolves
- Use of live vaccines is not recommended
- Progressive multifocal leukoencephalopathy (PML) may occur
Ocrelizumab Adverse Effects

- Common side effects (> 10%)
- Upper respiratory tract infections (40%)
- Infusion reactions (34%)
- Skin infections (14%)

Ocrelizumab Drug Interactions

- Immunosuppressants
  - High dose corticosteroids
- Use caution when switching from other immunosuppressive therapies
  - Daclizumab
  - Fingolimod
  - Natalizumab
  - Teriflunomide
  - Mitoxantrone
Ocrelizumab - Place in Therapy

- Only agent approved for progressive disease
- Reserved for patients who have failed initial therapy
- Studies underway to determine its role earlier in disease process
- Concern about risk for cancer

Pharmacist Clinical Points

- Stop infusion if life-threatening reaction and permanently discontinue
- Advise patient to complete any required vaccination at least 6 weeks before treatment
- Discuss need for standard breast cancer screening
- Monitor for PML: Clumsiness, vision changes, confusion
Pharmacist Clinical Points

- If a dose is missed, give as soon as possible. Do not wait until next dose.
- Reset the schedule so subsequent doses are 6 months later.
- Doses must be separated by at least 5 months.

Technician Points

- Do not shake vial.
- Only dilute in 0.9% sodium chloride.
- Stable for 8 hours at room temperature, (including infusion time).
- Must use infusion set with 0.22 micron in-line filter to reduce risk of infection.
Dupilumab (Dupixent)\(^7\)

- Approved March 28, 2017
- Interleukin-4 receptor alpha antagonist
- Indicated for moderate to severe atopic dermatitis in patients who have failed topical therapy
Dupilumab Pharmacology

- Inhibits IL-4 and IL-13 signaling
- Blocks release of pro-inflammatory cytokines, IgE and chemokines

Dupilumab Pharmacokinetics

- 64% bioavailable
- Median time to non-detectable levels is 10-13 weeks
- Elimination has not been characterized
- Trough levels were lower in patients with higher body weight
Dupilumab Dosing

- Available as 300 mg/2 mL pre-filled syringe
- 600 mg SQ as a one time dose (2 syringes) then
- 300 mg SQ every other week
- Administer dose into thigh or abdomen
- May combine with topical corticosteroids

Dupilumab Preparation

- Sterile and preservative free - discard unused product immediately after injection
- Store in refrigerator and protect from light
- May store at room temperature for maximum of 14 days
- Ensure patient is trained to administer this drug
SOLO 1 and 2- Clinical Trials

- Multicenter, double-blind, placebo controlled trials compared dupilumab alone to placebo
- Primary endpoint - Improvement in Investigators Global Assessment (IGA) at 16 weeks
  - 38% of dupilumab patients in SOLO 1 and 36% of dupilumab patients in SOLO 2 achieved clear or almost clear skin as measured by the 5-point IGA scale compared to 10% of placebo patients in SOLO 1 and 9% of placebo patients in SOLO 2

CHRONOS Clinical Trial

- 740 patients received dupilumab and topical corticosteroids versus placebo
- Primary endpoint: Skin improvement at 16 weeks
  - 39% of dupilumab patients achieved clear or almost clear skin based on IGA compared to 12% of placebo patients
  - Secondary endpoint: 36% of dupilumab patients were still clear at 52 weeks
Dupilumab Drug Interactions

- Avoid use with live vaccines
- Non-live vaccines - response was similar to patients not receiving dupilumab
- No other interactions noted

Dupilumab Adverse Effects

Common Side effects
- Injection site reaction (10%)
- Conjunctivitis (10%)
- Oral herpes (4%)
- Keratitis (4%)
- Eye pruritus (2%)
- Dry eye (2%)
Dupilumab - Place in Therapy

- Do not use first line for atopic dermatitis
- Reserve for patients who have failed topical treatment
- May use in combination with topical corticosteroids
- Investigations are ongoing to determine the role of dupilumab in asthma

Pharmacist Clinical Points

- Verify failure with topical therapy
- Ensure patient has been trained on how to self-administer
- Counsel patient to avoid live vaccines
- If a dose is missed within 7 days from the missed dose, resume normal schedule. If more than 7 days, wait for the next dose
Technician Points

- Do not shake
- Dose should be stored in refrigerator
- May be stored at room temperature if used within 14 days

**SARILUMAB (KEVZARA®)**
Sarilumab (Kevzara®)10

- Approved May 22, 2017
- Human interleukin-6 receptor antagonist
- Indicated for use in moderate to severe rheumatoid arthritis in patients who have failed one or more disease-modifying antirheumatic drugs (DMARD)

Sarilumab Pharmacology10

- IL-6 receptor antagonist
- Blocks IL-6 signals
- Reduces pro-inflammatory cytokines in the joint fluid and other parts of the body
Sarilumab Pharmacokinetics

- Volume of distribution is 7.3 L
- Metabolic pathway not characterized
- Not eliminated through renal or liver pathways
- Elimination half life is 10 days

Sarilumab Dosing

- 200 mg injected SQ every two weeks
- May administer with or without methotrexate
- Dose is reduced to 150 mg in patients with neutropenia, thrombocytopenia or elevated liver function tests (LFTs)
- Do not use if LFTs > 3X normal, absolute neutrophil count (ANC)< 2,000/mm³ or platelets are <150,000 mm³
MOBILITY Clinical Trial

- Sarilumab 150 mg, 200 mg or placebo every 2 weeks
- Inadequate response to methotrexate
- Proportion of patients achieving American College of Rheumatology (ACR 20) improvement and improved Health Assessment Questionnaire (HAQ) at 16 weeks

MOBILITY Clinical Trial Results

- Sarilumab 150 mg and 200 mg showed statistically significant improvements in ACR 20 in 58% and 66% of patients compared to 33% with placebo (each P < 0.0001)
- Least squares mean change in HAQ disability index at week 16 was -0.53 and -0.55, respectively for sarilumab and -0.29 for placebo (P < 0.0001)
Sarilumab Contraindications\textsuperscript{10}

- Contraindicated in patients with known hypersensitivity to sarilumab or any of its components
- Black box warning: Serious infection and death may occur when taking sarilumab
- Monitor for signs and symptoms of infection during treatment with sarilumab

Sarilumab Warnings\textsuperscript{10}

- Potential for serious infection
- Laboratory abnormalities (neutropenia, thrombocytopenia, increased LFTs)
- Gastrointestinal perforation
- Avoid live vaccines
Sarilumab Adverse Effects\textsuperscript{10}

Common adverse effects
- Upper respiratory infection (4%)
- Urinary tract infection (3%)
- Hypertriglyceridemia (3%)
- Leukopenia (0.9%)

Sarilumab Drug Interactions\textsuperscript{10}

- Use with caution when given together with CYP substrates with narrow therapeutic index (warfarin)
- Use with caution with oral contraceptives or statins, the effects may be reduced
Sarilumab Place in Therapy

- TNF-alpha drugs (Humira® and Enbrel®) first line therapy
- Use only after failure with a DMARD
- Black box warning-Increased risk of infection

Pharmacist Clinical Points\textsuperscript{10}

- Counsel patient to be alert for infection, stop medication if infection occurs
- Confirm patient has been screened for tuberculosis
- Counsel patient regarding risk for gastrointestinal bleeding
- Avoid use of live vaccines
Technician Points

- Alert pharmacist if new prescription for live vaccine
- Do not shake vial
- Store at room temperature for no more than 14 days

Conclusions

- 46 new drugs approved
- Twice as many approved as last year
- 50% first in class
- Some of these agents could impact your compounding business
References

# New Drugs of 2017

<table>
<thead>
<tr>
<th>Generic Name</th>
<th>Brand Name</th>
<th>Approval Date</th>
<th>Indication</th>
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</thead>
<tbody>
<tr>
<td>Plecanatide</td>
<td>Trulance</td>
<td>1-19-2017</td>
<td>Chronic idiopathic constipation</td>
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<td>Etelcalcetide</td>
<td>Parsabiv</td>
<td>2-7-2017</td>
<td>Secondary hyperparathyroidism in chronic kidney disease</td>
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<td>Emflaza</td>
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<td>Duchenne muscular dystrophy</td>
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<td>Brodalumab</td>
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<td>Moderate-to-severe plaque psoriasis</td>
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<td>2-28-2017</td>
<td>Carcinoid syndrome diarrhea</td>
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<td>Ribociclib</td>
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<td>Advanced breast cancer</td>
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<td>Safinamide</td>
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<td>Parkinson’s disease</td>
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<td>Naldemedine</td>
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<td>Opioid-induced constipation</td>
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<td>Niraparib</td>
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<td>Recurrent epithelial ovarian, fallopian tube or primary peritoneal cancers</td>
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<td>Dupilumab</td>
<td>Dupixent</td>
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<td>Atopic dermatitis</td>
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<td>Ocrelizumab</td>
<td>Ocrevus</td>
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<td>Relapsing and primary progressive forms of multiple sclerosis</td>
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<td>Deutetrabenazine</td>
<td>Austedo</td>
<td>4-3-2017</td>
<td>Chorea associated with Huntington’s Disease</td>
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<td>Tardive dyskinesia</td>
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<td>Brigatinib</td>
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<td>Abaloparatide</td>
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<td>Imfinzi</td>
<td>5-1-2017</td>
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<td>Nerlynx</td>
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<td>Reduce risk of breast cancer recurrence</td>
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<td>Angiotensin II</td>
<td>Giapreza</td>
<td>12-21-2017</td>
<td>To increase blood pressure in septic shock</td>
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1. Which of the following drugs was approved in 2017 for use in the treatment of osteoporosis in postmenopausal women?
   a. Abaloparatide
   b. Ocrelizumab
   c. Dupilumab
   d. Sarilumab

2. Sarilumab dosing should be reduced in patients with:
   a. Renal failure
   b. Heart failure
   c. Plaque psoriasis
   d. Neutropenia or thrombocytopenia

3. Which agent is approved for use in primary progressive multiple sclerosis?
   a. Abaloparatide
   b. Dupilumab
   c. Ocrelizumab
   d. Sarilumab

4. A 27 year old women comes into your pharmacy with a prescription for sarilumab. She has been taking oral contraceptives for about 8 months. What should you tell her about taking sarilumab and oral contraceptives?
   a. She should reduce the dose of sarilumab by 50%
   b. The effectiveness of the oral contraceptive may be reduced when combined with sarilumab. She may want to consider an additional type of birth control (condoms) or talk to her physician about an alternative agent.
   c. Space the drugs at least 2 hours apart
   d. There is no drug interaction between oral contraceptives and sarilumab

5. The starting dose of ocrelizumab is
   a. 300 mg IV followed 2 weeks later by 300 mg IV
   b. 600 mg IV once a month. This answer is not correct, try again
   c. 300 mg IV once a month. This answer is not correct, try again
   d. 600 mg IV every 2 weeks. This answer is not correct, try again

6. A patient calls the pharmacy and tells you that they missed their dose of dupilumab. It was supposed to be taken 3 days ago and she just remembered. What do you advise her to do?
   a. Hold this dose and take the next dose in 3 weeks
   b. Hold this dose and resume normal dosing in 4 weeks
   c. She should go ahead and take her dose today and resume her normal schedule
   d. Take the dose today and then re-schedule next dose to 2 weeks from today

7. Dupilumab blocks:
   a. IL-2
   b. IL-6 and IL-12
   c. IL-3
   d. IL-4 and IL-13
8. Abaloparatide should not be used in patients at risk for:
   a. Osteosarcoma
   b. Rheumatoid arthritis
   c. Renal failure
   d. Heart failure

9. A patient has a new prescription for abaloparatide. She is having the first few doses administered in
   the doctor’s office and she asks you if you know why they are making her do that. What do you
   advise her?
   a. Risk of rapid heart rate (Atrial fibrillation)
   b. Allergic reaction
   c. Orthostatic hypotension risk (serious low blood pressure)
   d. Renal problems

    a. 46
    b. 29
    c. 33
    d. 53