New Drugs of 2017: Part 1
PharMEDium Lunch and Learn Series

LUNCH AND LEARN

New Drugs of 2017: Part 1
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NEW DRUGS OF 2017 - PART 1
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

Really....it was even bigger²

- This number does not include the first of a new wave of cell and gene therapies
  - Kymriah®
  - Luxturna®
  - Yescarta®
- Approved under separate category using a Biologic Licensing Agreement (BLA)
- These agents approved through FDA’s Center for Biologics Evaluation and Research (CBER)
Many Drugs Fast-Tracker

- **First in Class** 15 (33%)
- **Orphan drugs** 18 (39%)
- **Fast track** 18 (39%)
- **Breakthrough therapy** 17 (37%)
- **Priority review** 28 (61%)

Biosimilars

- 5 biosimilars approved in 2017
- Cyltezo® (adalimumab-adbm), biosimilar to Humira® (adalimumab)
- Ixifi® (infliximab-qbtx), biosimilar to Remicade® (infliximab)
- Mvasi® (bevacizumab-awwb), biosimilar to Avastin® (bevacizumab)
- Ogivri® (trastuzumab-dkst) biosimilar to Herceptin® (trastuzumab)
- Renflexis® (infliximab-abda), also biosimilar to Remicade® (infliximab)
New Drugs 2017

Delafloxacin (BAXDELA®)
Delafloxacin (Baxdela®)³

- Approved June 19, 2017
- Fluoroquinolone antibiotic
- Approved to treat acute skin and skin structure infections

Delafloxacin Pharmacology³

- Delafloxacin is a dual-targeting fluoroquinolone
- Equivalent affinity for DNA gyrase and topoisomerase IV
- Explains broad spectrum of in vitro activity against both Gram Negative and Gram Positive bacteria, including Methicillin-resistant Staphylococcus Aureus
Delafloxacin Pharmacokinetics

- IV and oral have same bioavailability
- 84% plasma protein bound, primarily albumin
- 60% excreted via urine, 30% in feces
- In moderate renal impairment, reduce IV dose to 200 mg every 12 hours
- Elimination half life: 4-8.5 hours

Delafloxacin Dosing

- Available in 300 mg vials, 450 mg oral tablets
- Intravenous: 300 mg every 12 hours over 60 minutes
- Oral: 450 mg every 12 hours
- May convert from IV to oral therapy when patient tolerates
- Duration of therapy is 5 to 14 days
- If Glomerular Filtration Rate (GFR) is 15-29 mL/min, reduce IV dose to 200 mg every 12 hours
Delafloxacin Compounding

- Reconstitute vial with 10.5 mL of 5% dextrose for injection or 0.9% sodium chloride for injection
- Dilute dose in 250 mL for IV administration
- Stable for 24 hours
- Infuse over 1 hour
- Avoid solutions in same IV line containing multivalent cations (calcium, magnesium)

Delafloxacin: PROCEED Trial 302

- Multicenter trial in ABSSSI- 660 patients
- Cellulitis, wound infection, abscess
- Clinical response at 48-72 hr with 20% reduction in lesion size
  - 78% (Delafloxacin) and 81% (Vancomycin/Aztreonam)
- Non-inferior, effective in obese patients
- Few non-Caucasians; few burn patients
Delafloxacin: PROCEED Trail 303<sup>5</sup>

- Multicenter trial in ABSSSI
- 850 patients – few non-Caucasian participants
- Clinical response at 48-72 hr with 20% reduction in lesion size
  - 84% (Delafloxacin) and 80% (Vancomycin/Aztreonam)
  - Non-Inferiority

Delafloxacin<sup>3</sup>

- Contraindications
  - Known hypersensitivity
- Black Box Warnings
  - Tendonitis, tendon rupture, peripheral neuropathy, CNS effects, exacerbation of Myasthenia Gravis
- *Clostridium difficile* Diarrhea
Delafloxacin Drug Interactions\(^3\)

- No CYP 450 interactions identified
- Wait at least 2 hr before or 6 hr after medications containing polyvalent cations such as antacids containing magnesium or aluminum, sucralfate, iron supplements, or multivitamins containing zinc or iron to avoid chelation

Delafloxacin- Common Adverse Effects\(^3\)

- Nausea (8%)
- Diarrhea (8%)
- Headache (3%)
- Elevated transaminase levels (3%)
- Vomiting (2%)
Delafloxacin-Place in Therapy

- Not a first line agent
- Most skin infections are caused by Gram + bacteria
- Side effects are still a concern
  - *Clostridium difficile-associated* diarrhea (CDAD)
  - Tendonitis and tendon rupture
  - Peripheral neuropathy, myasthenia gravis exacerbations

Pharmacist Clinical Points

- Not first line agent so review previous antibiotic orders
- No need to alter oral dose in renal disease
- Effective in obese patients with no dose adjustment
- Convert IV to PO as soon as feasible
Technician Points

- Follow instructions for reconstitution and dilution
- Use sterile technique
- Notify the pharmacist if the patient is taking oral medications so that IV dosage form can be switched to oral

Meropenem and Vaborbactam (Vabomere®)
Meropenem and Vaborbactam (Vabomere®)6

- Approved August 29, 2017
- Accelerated approval
- Penem antibiotic with a beta-lactamase inhibitor
- Indicated for the treatment of complicated urinary tract infections including pyelonephritis

Need for effective antibiotics7

- Gram-negative bacteria that produce beta-lactamase enzymes have spread in the US and Europe, particularly the Klebsiella pneumoniae carbapenemase (KPC) enzyme
- KPC-producing bacteria responsible for many carbapenem-resistant Enterobacteriaceae (CRE)
- CDC considers CRE to be an urgent antimicrobial resistance threat
Meropenem and Vaborbactam Pharmacology
- Meropenem inhibits cell wall synthesis and is bactericidal
- Vaborbactam is a beta-lactamase inhibitor that protects meropenem against degradation
- Vaborbactam has no antibacterial activity

Meropenem and Vaborbactam Pharmacokinetics
- Only 33% plasma protein bound
- Vaborbactam is not metabolized
- Both are primarily excreted in urine
- Dose reductions needed in renal failure
- Elimination half life: 2.5 hours
Meropenem and Vaborbactam Dosing

- 4 grams IV every 8 hours for 14 days
- Infuse dose over 3 hours: Concentration-time curve is optimized
- Dose reduction in renal disease (GFR mL/min/1.73m²)
  - 30-49: 2 grams every 8 hours
  - 15-29: 2 grams every 12 hours
  - < 15: 1 gram every 12 hours

Meropenem and Vaborbactam Preparation

- Reconstitute vial with 0.9% Sodium Chloride from infusion bag
- Final dilution must be made immediately
- 4 grams in 250 to 1000 mL 0.9% Sodium Chloride
- Infusion must be completed within 4 hours of dilution (room temperature) or 22 hours (if stored refrigerated)
Clinical Tango 1: Phase 3

- Complicated urinary tract infection including pyelonephritis
- 550 pts received Vabomere (V) or Piperacillin/tazobactam (P)
- Minimum 15 doses of IV therapy then switch to levofloxacin 500 mg PO Q 24 hr

Outcomes: TANGO 1

- Overall success of clinical outcome (cure or improvement) and microbiologic outcome of eradication
- Overall success
  - 183/186 patients (98.4%) in the V group
  - 165/175 patients (94.3%) in the P group
- Difference of 4.1% (95% CI: 0.3% to 8.8%)
- Most common adverse events for V included headache, infusion site reactions and diarrhea.
Clinical TANGO 2: Phase 3

- July 2017- enrollment in TANGO-2 stopped
- Statistically-significant differences in efficacy favor meropenem-vaborbactam
- Mortality rates were lower with meropenem-vaborbactam
- Clear difference in renal toxicity, with lower rates of renal adverse events and serum creatinine increases with meropenem-vaborbactam

Meropenem and Vaborbactam

Warning:

- Increased risk of seizures with Meropenem
- Breakthrough seizures – interaction with valproic acid
- Clostridium difficile-associated diarrhea
- Hypersensitivity-anaphylaxis and serious skin reaction
- Thrombocytopenia in patients with renal impairment
Meropenem and Vaborbactam

Adverse Effects

- Common Side effects (>3%)
  - Headache (8%)
  - Phlebitis/infusion site reactions (4.4%)
  - Diarrhea (3.3%)

Meropenem and Vaborbactam

Drug Interactions

- Valproic acid/Divalproex
  - Reduced valproic acid serum levels
  - Increased risk of seizures
- Probenecid
  - Increased plasma levels of Meropenem
Meropenem and Vaborbactam
Place in therapy

- Most likely a drug that will be reserved for CRE
- Highly active against carbapenem-resistant Enterobacteriaceae (CRE)
- Does not change coverage to carbapenem-resistant:
  - Acinetobacter baumannii, Pseudomonas aeruginosa, or Stenotrophomonas maltophilia

Pharmacist Clinical Points

- Reserve use to preserve it for when it is truly needed (e.g., CRE)
- Review patient history for potential risk of seizures
- Adjust dose for renal function
- Review drug interaction with valproic acid
Technician Points

- Short stability once mixed
- Complete infusion within 4 hours if stored at room temperature
- Complete infusion within 22 hours if stored under refrigeration

**Letermovir (Prevymis®)**
Letermovir (Prevymis®)

- Approved November 8, 2017
- Cytomegalovirus (CMV) DNA terminase complex inhibitor
- Indicated for prophylaxis of CMV infection in CMV-positive recipients [R+] of Allogeneic Stem Cell Transplant

Letermovir Pharmacology

- Antiviral drug against CMV
- Inhibits CMV DNA terminase complex
- Penetrates the cell wall of both gram positive/negative organisms
Letermovir Pharmacokinetics

- 99% plasma protein bound
- Not metabolized
- 97% excreted as unchanged parent compound
- 93% excreted in feces
- Elimination half life: 12 hours

Letermovir Dosing

- 480 mg once a day through 100 days post-transplant
- May administer intravenously or orally
- Infuse IV dose over 1 hour
- Dose reduction with cyclosporine
  - Reduce to 240 mg once a day with both dosage forms
  - No dose adjustment in renal disease
Letermovir Preparation

- Do not shake letermovir vial
- Add one single dose vial (480 mg/24 mL) into a 250 mL bag of 0.9% Sodium Chloride or Dextrose 5% in Water
- Compatible with polyvinyl chloride (PVC) IV administration tubing
- Stable for 24 hours at room temperature or 48 hours refrigerated

Letermovir Infusion Incompatibility

- Amiodarone
- Amphotericin B liposomal
- Aztreonam
- Cefepime
- Cyclosporine
- Diltiazem
- Fluoroquinolone
- Filgrastim
- Gentamicin
- Linezolid
- Lorazepam
- Midazolam
- Mycophenolate
- Ondansetron
- Palonosetron
Clinical Trial: Phase 3\textsuperscript{10}

- Multicenter, Double-blind, placebo controlled study
- 495 CMV seropositive individuals
- 325 patients received study drug and 170 placebo
- 38% failed prophylaxis with Letermovir, 61% failed prophylaxis with placebo

Clinical Trial: Phase 3\textsuperscript{10}

<table>
<thead>
<tr>
<th>Reasons for failure</th>
<th>L</th>
<th>P</th>
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<td>CMV infection</td>
<td>18%</td>
<td>42%</td>
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<tr>
<td>PET therapy</td>
<td>16%</td>
<td>40%</td>
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<td>CMV end organ</td>
<td>2%</td>
<td>2%</td>
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<tr>
<td>Discontinued study</td>
<td>17%</td>
<td>16%</td>
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<tr>
<td>Missing data</td>
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<td>3%</td>
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</table>

PET = Pre-Emptive Therapy
L = Letermovir
P = Placebo
Letermovir Drug Interactions

Letermovir inhibits CYP3A

- Pimozide
  - Increased pimozide levels
  - QT prolongation and torsades
- Ergot alkaloids
  - Increased ergot levels
  - Ergotism
- Simvastatin, pitavastatin
  - With cyclosporine
  - Increased statin levels and myopathy

Letermovir Adverse Effects

<table>
<thead>
<tr>
<th>Adverse effect</th>
<th>Letermovir</th>
<th>Placebo</th>
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<tbody>
<tr>
<td>Nausea</td>
<td>27%</td>
<td>23%</td>
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<tr>
<td>Diarrhea</td>
<td>26%</td>
<td>24%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>19%</td>
<td>14%</td>
</tr>
<tr>
<td>Edema</td>
<td>14%</td>
<td>9%</td>
</tr>
<tr>
<td>Cough</td>
<td>14%</td>
<td>10%</td>
</tr>
<tr>
<td>Headache</td>
<td>14%</td>
<td>9%</td>
</tr>
<tr>
<td>Fatigue</td>
<td>13%</td>
<td>11%</td>
</tr>
<tr>
<td>Tachycardia</td>
<td>4%</td>
<td>2%</td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>3%</td>
<td>1%</td>
</tr>
</tbody>
</table>
Letermovir Cardiac effects

- Event rate was 13% in studies (6% in placebo)
- Usually mild or moderate effect
- Most common reports were tachycardia (4%) and atrial fibrillation (3%)
- Contact physician if this occurs

Letermovir: Place in Therapy

- Does not have significant hematologic toxicity like valganciclovir
- Low risk of cross-resistance
- May be treatment of choice for ganciclovir-resistant CMV
Pharmacists Clinical Points

- Verify CMV status
- Only for allogeneic stem cell transplant
- CYP3A inhibitor
- Use oral drug when possible
- Counsel patient about need to take for 100 days post transplant
- Discuss need for adherence to regimen

Technician Points

- Compound IV product using sterile technique
- Do not shake vial
- Verify IV tubing is compatible
- Confirm when patient can take oral medications in order to convert to PO therapy
- Monitor for patient adherence and notify pharmacist if non-adherent
Brodalumab (Siliq®)

- Approved February 15, 2017
- Human interleukin-17 Receptor A antagonist (IL17-RA)
- Indicated for moderate-to-severe plaque psoriasis
Brodalumab Pharmacology

- Human IgG 2 antibody
- Binds to IL 17-RA
- Inhibits cytokines IL-17A, 17C, 17F, 17A/F and IL-25
- These cytokines are elevated in plaque psoriasis
- Reduces pro-inflammatory cytokines

Brodalumab Pharmacokinetics

- 55% bioavailable after SQ injection
- Metabolic pathway not characterized
- Patients with higher body weight have lower trough concentrations
- Elimination is nonlinear; clearance increases with decreasing doses
Brodalumab Dosing\textsuperscript{11}

- Available only through a restricted distribution program: Siliq® Risk Evaluation and Mitigation Strategies (REMS)
- 210 mg SQ at weeks 0, 1, and 2, followed by 210 mg every 2 weeks
- If adequate response not obtained after 12-16 weeks, consider discontinuing the drug

Brodalumab Efficacy\textsuperscript{12}

- 3 Randomized, Placebo-controlled trials
- 4,373 patients with moderate-to-severe plaque psoriasis for 6 months
- Change from baseline to week 12
  - 75% reduction in Psoriasis Area and Severity Index (PASI 75)
  - Static Physicians Global Assessment (sPGA) of 0 or 1 (2 point improvement)
Clinical Trial Results

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<tr>
<th></th>
<th>Trial 1</th>
<th>Trial #2</th>
<th>Trial #3</th>
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<tbody>
<tr>
<td>PASI 75</td>
<td>B 83% P 3%</td>
<td>B 86% U 70% P 8%</td>
<td>B 85% U 69% P 6%</td>
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<tr>
<td>sPGA</td>
<td>B 76% P 1%</td>
<td>B 79% U 61% P 4%</td>
<td>B 80% U 57% P 4%</td>
</tr>
</tbody>
</table>

B= Brodalumab  
P= Placebo  
U= Ustekinfumab

Brodalumab Contraindications and Warnings

- Contraindicated in Crohn’s Disease
- Because of risk of suicidality, available only through a restricted distribution program under a REMS
- Evaluate patient for tuberculosis infection before treatment
- Increased risk of serious infection
- Avoid live vaccines if taking brodalumab
Brodalumab Adverse Effects\textsuperscript{11}

Common adverse effects
- Arthralgia (4.7%)
- Headache (4.3%)
- Fatigue (2.6%)
- Diarrhea (2.2%)

Serious side effects
- Suicidal ideation and behavior
- Depression, anxiety, or other mood changes

Brodalumab Drug Interactions\textsuperscript{11}

- Avoid LIVE Vaccines
- CYP450 substrates, particularly those with a narrow therapeutic index
- Monitor for
  - effect (warfarin)
  - drug concentration (cyclosporine)
  - consider dosage modification of the CYP450 substrate
Brodalumab Place in Therapy

- TNF-alpha drugs (Humira® and Enbrel®) first line therapy
- 2 IL-17 inhibitors (Cosentyx® and Taltz®) already on market
- Black box warning with brodalumab
- Reserve for patients who have failed on all other regimens

Pharmacist Clinical Points

- Discuss the serious risk of suicide ideation
- Advise patients that brodalumab is available only through a restricted distribution program
- Discuss the risk of serious infection. Brodalumab may lower the ability of their immune system to fight infection.
- Advise patients to inform a clinician if they experience signs and symptoms of Crohn's disease (e.g., abdominal pain, diarrhea, weight loss).
Technician Points

- Alert pharmacist if prescription for LIVE vaccine is received for a patient on brodalumab
- Alert the pharmacist of any new prescription or non-prescription medications to screen for interactions

**ANGIOTENSIIN II**
**(GIAPREZA®)**
Angiotensin II (Giapreza®)

- Approved December 21, 2017
- Synthetic human angiotensin II
- Vasoconstrictor
- Priority review
- Indicated to increase blood pressure in adults with septic or other distributive shock

Angiotensin II Pharmacology

- Angiotensin II raises blood pressure by vasoconstriction and increased aldosterone release
- Angiotensin II receptor type 1 on vascular smooth muscle cells causes smooth muscle contraction
Angiotensin II Pharmacokinetics

- The plasma half-life of IV administered angiotensin II is less than one minute
- Metabolized in the plasma and major organs
- Clearance is not dependent on liver or kidney

Angiotensin II Dosing

- This drug is dosed in nanograms (ng)
- Starting dose is:
  - 20 ng/kg/min via continuous infusion
- Titrate every 5 minutes by increments of up to 15 ng/kg/min
Angiotensin II Dosing\textsuperscript{13}

- Do not exceed 80 ng/kg/min during the first 3 hours of treatment
- Maintenance doses should not exceed 40 ng/kg/min
- Once shock has improved, down-titrate every 5 to 15 minutes by increments of up to 15 ng/kg/min

Angiotensin II Compounding\textsuperscript{13}

- Administer as an intravenous infusion
- Use 0.9% Sodium Chloride ONLY as diluent
- Dilute one vial (2.5 mg or 5 mg) in 0.9% Sodium Chloride
- Final concentration: 5,000 ng/mL or 10,000 ng/mL respectively
- Discard prepared solution after 24 hours at room temperature or under refrigeration
Angiotensin II Efficacy: ATHOS-3

- 321 patients with shock and hypotension
- Titrate to mean arterial pressure (MAP) of $\geq 75$ mm Hg
- MAP $\geq 75$ mm Hg or a $\geq 10$ mm Hg increase in MAP at 3 hrs
- Endpoint achieved in 70% of angiotensin II compared to 23% of placebo; $p < 0.0001$

ATHOS 3 Concerns

- The primary outcome not in accordance with current guidelines
- The median baseline MAP of 66.3 mm Hg was within guidelines
- No statistically significant difference in arrhythmias
- Majority were septic shock
Angiotensin II Warnings\textsuperscript{13}

- Risk of arterial and venous thromboembolic events
  - ATHOS-3 study (13\% Angiotensin II vs. 5\% placebo)
  - The major imbalance was in deep venous thromboses
  - Use concurrent venous thromboembolism (VTE) prophylaxis

Angiotensin II Adverse Effects\textsuperscript{13}

- Thromboembolic events 12.9\%
- Thrombocytopenia 9.8\%
- Tachycardia (8.6\%)
- Fungal infection (6.1\%)
- Delirium (5.5\%)
- Acidosis (5.5\%)
- Hyperglycemia (4.3\%)
- Peripheral ischemia (4.3\%)
Angiotensin II Drug Interactions

- Angiotensin converting enzyme (ACE) inhibitors may increase response
- Angiotensin II blockers (ARBs) may decrease the response

Angiotensin II Place in Therapy

- Probably third line option
  - After norepinephrine and vasopressin or epinephrine
- Increased rates of thromboembolism, delirium, and infection
Pharmacist Clinical Points

- Review risks for Deep Vein Thrombosis (DVT)/Embolism
- Calculate dose and determine if dose should be in 250 mL or 500 mL (fluid restriction)
- Most costly vasopressor agent at $2550
  - 6 times the price of vasopressin
- Develop protocols for role of Angiotensin II

Technician Points

- Compound immediately before use in 0.9% Sodium Chloride
- Verify final volume to prevent compounding errors
- Discard solution after 24 hours
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

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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<tr>
<td>Plecanatide</td>
<td>Trulance</td>
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<td>Chronic idiopathic constipation</td>
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<td>Parsabiv</td>
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<td>Secondary hyperparathyroidism in chronic kidney disease</td>
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<td>Brodalumab</td>
<td>Siliq</td>
<td>2-15-2017</td>
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<td>Xermelo</td>
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<td>Carcinoid syndrome diarrhea</td>
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<td>Atopic dermatitis</td>
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<td>Relapsing and primary progressive forms of multiple sclerosis</td>
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<td>Edaravone</td>
<td>Radicava</td>
<td>5-5-2017</td>
<td>Amyotrophic lateral sclerosis</td>
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<td>Sarilumab</td>
<td>Kevzara</td>
<td>5-22-2017</td>
<td>Rheumatoid arthritis</td>
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<td>Delafloxacin</td>
<td>Baxdela</td>
<td>6-19-2017</td>
<td>Bacterial skin infections</td>
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<tr>
<td>Betrixaban</td>
<td>Bevyxxa</td>
<td>6-23-2017</td>
<td>Venous thromboembolism prophylaxis</td>
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<tr>
<td>Guselkumab</td>
<td>Tremfya</td>
<td>7-13-2017</td>
<td>Plaque psoriasis</td>
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<tr>
<td>Neratinib maleate</td>
<td>Nerlynx</td>
<td>7-17-2017</td>
<td>Reduce risk of breast cancer recurrence</td>
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<tr>
<td>Sofosbuvir, velpatasvir and voxilaprevir</td>
<td>Vosevi</td>
<td>7-18-2017</td>
<td>Hepatitis C</td>
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<tr>
<td>Enasidenib</td>
<td>Idhifa</td>
<td>8-1-2017</td>
<td>Relapsed or refractory acute myeloid leukemia</td>
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<td>Glecaprevir and pibrentasvir</td>
<td>Mavyret</td>
<td>8-3-2017</td>
<td>Hepatitis C</td>
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<td>Inotuzumab and ozogamicin</td>
<td>Besponsa</td>
<td>8-17-2017</td>
<td>Relapsed or refractory acute lymphoblastic leukemia</td>
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<td>Meropenem and vaborbactam</td>
<td>Vabomere</td>
<td>8-29-2017</td>
<td>Complicated urinary tract infection</td>
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<td>Benznidazole</td>
<td>Benznidazole</td>
<td>8-29-2017</td>
<td>Chagas disease</td>
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<tr>
<td>Copanlisib</td>
<td>Aliqopa</td>
<td>9-14-2017</td>
<td>Relapsed follicular lymphoma</td>
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<td>Secnidazole</td>
<td>Solosec</td>
<td>9-15-2017</td>
<td>Bacterial vaginosis</td>
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<td>Abemaciclib</td>
<td>Verzenio</td>
<td>9-28-2017</td>
<td>Metastatic or advanced breast cancers</td>
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<td>Acalabrutinib</td>
<td>Calquence</td>
<td>10-31-2017</td>
<td>Mantle cell lymphoma</td>
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<td>Latanoprostene bunod</td>
<td>Vyzulta</td>
<td>11-2-2017</td>
<td>Open-angle glaucoma or ocular hypertension</td>
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<td>Letermovir</td>
<td>Prevymis</td>
<td>11-8-2017</td>
<td>Prevent infection after bone marrow transplant</td>
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<td>Benralizumab</td>
<td>Fasenra</td>
<td>11-14-2017</td>
<td>Severe asthma</td>
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<td>Vestrotronidase alfa-vjbk</td>
<td>Mepsevii</td>
<td>11-15-2017</td>
<td>Mucopolysaccharidosis type VII</td>
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<td>Emicizumab</td>
<td>Hemlibra</td>
<td>11-16-2017</td>
<td>Hemophilia A</td>
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<tr>
<td>Generic Name</td>
<td>Brand Name</td>
<td>Approval Date</td>
<td>Indication</td>
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<tr>
<td>Semaglutide</td>
<td>Ozempic</td>
<td>12-5-2017</td>
<td>Type 2 diabetes</td>
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<tr>
<td>Ozenoxacin</td>
<td>Xepi</td>
<td>12-11-2017</td>
<td>Impetigo</td>
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<td>Netarsudil</td>
<td>Rhopressa</td>
<td>12-18-2017</td>
<td>Glaucoma or ocular hypertension</td>
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<tr>
<td>Ertugliflozin</td>
<td>Steglatro</td>
<td>12-19-2017</td>
<td>Type 2 diabetes</td>
</tr>
<tr>
<td>Macimorelin acetate</td>
<td>Macrilen</td>
<td>12-20-2017</td>
<td>Growth hormone deficiency</td>
</tr>
<tr>
<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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</tbody>
</table>
New Drugs of 2017: Part 1

1. The FDA approved ___ new drugs in 2017.
   a. 46
   b. 29
   c. 33
   d. 53

2. What percent of NMEs approved in 2017 qualified for priority review?
   a. 45%
   b. 50%
   c. 70%
   d. 61%

3. The intravenous dose of delafloxacin is
   a. 200 mg every 24 hours
   b. 100 mg every 12 hours
   c. 300 mg every 12 hours
   d. 400 mg every 24 hours

4. A patient has been diagnosed with an abscess and the physician calls you to ask about dosing delafloxacin. The patient is obese and the physician wants to know if they need to adjust the dose to the patient’s lean body mass?
   a. Yes, the dose should be reduced by 10% in obese patients.
   b. There is no need to adjust the dose of delafloxacin in obese patients. The IV dose remains at 300 mg every 12 hours.
   c. Yes the dose should be reduced by 25% in obese patients.
   d. Yes the dose should be increased by 20% in obese patients.

5. The dose of meropenem-vaborbactam is
   a. 4 grams every 8 hours for 14 days.
   b. 3 grams every 8 hours for 10 days.
   c. 2 grams every 6 hours for 14 days.
   d. 4 grams every 12 hours for 10 days.

6. When probenecid is given with meropenem-vaborbactam:
   a. There is no change in meropenem plasma levels.
   b. There is an increase in probenecid levels.
   c. There is an increase in plasma level of meropenem
   d. There is a decrease in plasma levels of meropenem.

7. Letermovir is dosed:
   a. 640 mg once a day for 100 days post-transplant.
   b. 320 mg once a day for 50 days post-transplant.
   c. 220 mg once a day for 50 days post-transplant.
   d. 480 mg once a day for 100 days post-transplant.

8. Brodalumab is approved for use in:
   a. Plaque psoriasis
   b. Rheumatoid arthritis
   c. Skin and soft tissue infection
   d. Heart failure
9. A major warning with the use of angiotensin II is:
   a. Atrial fibrillation
   b. Pancreatic cancer
   c. Arterial and venous thromboembolic events
   d. Renal failure

10. A patient presents a new prescription for brodalumab at the pharmacy. When discussing the prescription with the patient, what should the pharmacist check for?
    a. Did your doctor complete a blood test for low potassium?
    b. Has your doctor talked to you about the risk of suicide that has been reported with this drug? Do you know what signs to look for?
    c. Did your doctor check your HgA1c?
    d. Did your doctor complete a Cat Scan?