NEW DRUG UPDATE 2017
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Accreditation
• New Drug Update 2017 is accredited by ACPE for pharmacists and technicians:
  – Pharmacists
    • ACPE 0154-0000-17-012-101-P
  – Pharmacy technicians
    • ACPE 0154-0000-17-012-101-T

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Presentation Objectives

1. Discuss the basic pharmacology of the new drugs presented and how the pharmacologic actions relate to both therapeutic and adverse effects.
2. Discuss clinically significant adverse effects and drug interactions, and the appropriate dosing and monitoring of the new drugs presented.
3. Discuss the therapeutic role of the new drugs presented as compared to agents already marketed.

Top 10 Grossing Drug Patent Expirations in 2017

- Copaxone—$3.5 billion annual revenue
- Cialis—$1.4 billion annual revenue
- Viagra—$1.1 billion annual revenue
- Velcade—$1.1 billion annual revenue
- Sustiva—$900 million annual revenue
- Sandostatin LR—$850 million annual revenue
- Norditropin—$650 million annual revenue
- Viread—$600 million annual revenue
- Pristiq—$575 million revenue
- Strattera—$500 million revenue

FDA Drug Approvals in 2016/2017

- 2016
  - 22 new drug approvals
  - 60% approval rate
- 2017
  - 21 w/ novel MOA drugs approved so far!
GI DRUGS

SOFOSBUVIR/VELPATABSVIR
(EPCLUSA®-GILEAD)

Hepatitis C

- 150 million individuals infected worldwide
- Implicated in 500,000 deaths annually
- Seven confirmed genotypes
  - Genotype 1: 46%, genotype 3: 30%
  - Only one genotype 7 infection described
- Sofosbuvir/lepitasvir and elbasvir/grazoprevir most recommended in current VA guidelines
**Sofosbuvir/velpatasvir (Epclusa®)**

- **Indications**
  - Patients w/o cirrhosis or compensated cirrhosis
  - With ribavirin for decompensated cirrhosis
- **Dosing:** One tablet once daily (400mg S / 100mg V) for 12 weeks
  - Add ribavirin in decompensated cirrhosis
- **First “pangenotypic direct – acting” Hep C treatment**
- **Mechanism of Action**
  - Sofosbuvir: nucleotide inhibitor
  - Velpatasvir: NS5A inhibitor

**ASTRAL-1**
- Double blind, placebo-controlled
  - Genotypes 1-6 (except 3) +/- cirrhosis
  - Sustained Virologic Response (SVR) >97%
  - Randomized, open label, genotype 2 only +/- cirrhosis
  - Sofosbuvir/velpatasvir + sofosbuvir/ribavirin
  - SVR rates: 99% vs. 94%

**ASTRAL-2**
- Randomized, open label, genotype 3 only +/- cirrhosis
  - Sofosbuvir/velpatasvir + sofosbuvir/ribavirin
  - SVR rates: 95% vs. 80%

**ASTRAL-3**
- Randomized, open label, all genotypes, decompensated cirrhosis only
  - Sofosbuvir/velpatasvir/ribavirin + Sofosbuvir/velpatasvir
  - SVR rates: 94% vs. 83%

**Well tolerated, most common SEs:**
- Fatigue (28% vs. 21% placebo)
- Headache (29% vs. 20% placebo)
- Insomnia (14% vs. 6% placebo)

**Drug interactions**
- Very important in HCV treatment regimens
- Both V&S are substrates of P-glycoprotein
- Avoid amiodarone/digoxin
- Rosuvat/orvastatin levels may increase
- Separate from antacids (pH affects absorption)
- Run interaction check w/ HIV meds

**Pricing:** $890/tablet, $75k for entire treatment
BEZLOTOXUMAB
(ZINPLAVA®-MERCK)

Recurrent C. difficile infection
• First recurrence in 20 – 30% of patients after treatment of initial episode
• Subsequent recurrences at 40 – 60%
• May be due to reinfection or new infection
• Current treatment options:
  – Vancomycin tapers
  – Fidaxomicin ($2,200 for ten days)
  – Stool transplant

Bezlotoxumab (Zinplava®)
• Indicated for recurrent C. difficile infections (CDI) in adults who are receiving treatment for CDI and are at high risk for recurrence
• Dosing: Single dose 10 mg/kg IV infusion over one hour
• Mechanism of Action
  – Monoclonal antibody against C. difficile toxin B
  – Blocks binding of the toxin to host cells
  – 3 week half life

CJHP 2013;66(6)

NEJM 2017;376(4)

Lexi-Drugs
Bezlotoxumab (Zinplava®)

- Clinical Trial Data
  - Two Phase 2 RCT of bezlo + standard of care (SOC) versus SOC alone
  - 10% decrease in recurrence of CDI
  - Also studied in combo w/ actoxumab (antibody against toxin A)
- Adverse effects/warnings
  - Heart failure – 7% absolute increase in death
- Pricing: $4,560 for 1g vial

OBETICHOLIC ACID (OCALIVA®)
INTERCEPT

Obeticholic Acid (Ocaliva®)

- Primary biliary cholangitis
  - (previously primary biliary cirrhosis)
    - Autoimmune hepatic destruction
      - Progressive cholestasis; blockage & destruction of bile ducts
    - $>\alpha$
      - Typically diagnosed mid-life
- Signs & symptoms
  - Consistent with extent of hepatic damage
    - Often asymptomatic
    - Initial symptoms
      - Fatigue
      - Right upper quadrant pain
      - Pruritus
Obeticholic Acid (Ocaliva®)

- **PBC treatment**
  - Ursodeoxycholic acid (UDCA)
    - Most evidence
    - Slows disease progression
  - Other therapies
    - Methotrexate
    - Corticosteroids
    - Cyclosporine
    - Colchicine

Obeticholic Acid (Ocaliva®)

- **Mechanism**
  - Farnesoid X receptor (FXR) agonist
  - FXR regulates bile acid metabolism
    - Activation of FXR
      - Suppresses bile acid production
      - Increases flow of bile from hepatocytes
      - Limits hepatocellular exposure to bile acids
  - Once-daily oral dosing
    - Adverse effects
      - Itching
      - Fatigue
      - Abdominal pain
      - Dizziness
      - Constipation

Obeticholic Acid (Ocaliva®)

- **Indication**
  - PBC with ursodeoxycholic acid (UDCA) in adults
    - Inadequate response to UDCA
    - Unable to tolerate UDCA

- **Fast track designation & accelerated approval**
  - Surrogate endpoint
    - Alkaline phosphatase (ALP)
      - RCT n = 216 vs placebo
      - 12 months
        - Obeticholic acid group had a reduction in ALP vs placebo
  - Orphan drug status
    - Tax credits
    - Exclusivity rights
NALDEMEDINE (SYMPROIC®)
Purdue Pharma

Naldemedine (Symproic®)
- OIC
  - Opioids bind mu receptors in myenteric plexus
    - GI binding results in
      - Decreased peristalsis
      - Decreased colonic mucus production
      - Increased rectal sphincter tone
  - Chronic non-cancer pain
    - ~40-50%

- Mechanism of action
  - Peripheral opioid antagonist
    - Blocks GI mu opioid receptors
    - Removes opioid agonism
    - Restores peristalsis
  - Does not cross BBB

- Clinical trials
  - COMPOSE I & II
    - 12 week multicenter, RCTs
  - COMPOSE III
    - 52-week safety trial
Naldemedine (Symproic®)

- Once-daily oral dosing
  - Adverse effects (vs placebo)
    - Abdominal pain (8% vs 2%)
    - Diarrhea (7% vs 2%)
    - Nausea (4% vs 2%)
    - Gastroenteritis (2% vs 1%)
- Indication
  - OIC in adults with chronic non-cancer pain
  - C-II; structurally related to naltrexone
  - Petitioning for change in schedule

PLECANATIDE
(TRULANCE®-SYNERGY)

Chronic Idiopathic Constipation

- Symptoms
  - <3 defecations per week
  - Straining when defecating
  - Need for manual maneuvers to aid defecation
- Treatment options:
  - Dietary changes first (fiber/water) then laxatives
  - Linaclotide: guanylate cyclase – C agonist
  - Lubiprostone: chloride channel activator
  - Both agents cost ~$350/month
Plecanatide (Trulance®)
- Indicated for chronic idiopathic constipation (CIC) in adults
- Dosing: 3mg oral once daily
- Mechanism of Action
  - Guanylate cyclase – C receptor agonist
  - Binds receptor in intestine stimulating secretion of bicarbonate/chloride increasing fluid/transit
- Studies indicate 10% improvement over placebo (one extra BM per week)
- Adverse effects: diarrhea (5%)
- Cost ~ $350/month

LIXISENATIDE (ADLYXIN®)
SANOFI

Lixisenatide—Type 2 Diabetes
- Mechanism of action
  - GLP-1 agonist
- Efficacy/safety trials
  - N = 5400
    - Monotherapy
    - Combination therapy
      - Metformin
      - Sulfonylureas
      - Thiazolidinedione
      - Basal insulin
  - Outcomes
    - Decreased HbA1c
- Cardiovascular trials
  - N = 6000
    - Vs. placebo
    - No increase in CV events
Lixisenatide—Type 2 Diabetes

- Once-daily SC injection
  - Adverse effects
    - GI
      - Nausea
      - Vomiting
      - Diarrhea
    - Neuro
      - Headache
      - Dizziness
    - Hypersensitivity
      - Anaphylaxis
      - Anti-drug antibodies

TELOTRISTAT (XERMELO®)
LEXICON

Telotristat (Xermelo®)

- Carcinoid syndrome
  - Carcinoid tumors secrete vasoactive hormones
    - Serotonin, bradykinin, histamine, prostaglandins, polypeptide hormones
  - GI effects
    - Serotonin acts on smooth muscle to cause diarrhea, colic, malabsorption
  - Somatostatin analogs (SSA)
    - Decrease release of vasoactive hormones in GI tract
    - Limited effectiveness in controlling diarrhea
Telotristat (Xermelo®)

- Mechanism
  - Tryptophan hydroxylase (TPH) inhibitor
  - Rate-limiting step in serotonin production

- Oral TID dosing

- Adverse effects
  - GI
    - Nausea, ↑GGT, flatulence, decreased appetite
    - Steatorrhea, constipation
  - Headache, edema, depression

- Indication
  - Adults with carcinoid syndrome diarrhea
  - Not controlled with SSA alone

- Fast track designation & accelerated approval
  - 12-week RCT n = 90
    - Greater reduction in bowel movements vs. placebo
  - Orphan drug status

DERMATOLOGIC DRUGS

CRISBAROLE (EUCRISA®-PFIZER)
Atopic Dermatitis aka Eczema

- Chronic pruritic inflammatory skin condition
  - “itch that rashes”
- Common in infancy / early adolescents (10-30%)
- Affects flexural areas in older adults (2-10%)
- 90% present w/ mild – moderate disease
  - Treated w/ topical steroids / creams
  - Long term topical steroids → HPA suppression / Cushing
- Topical calcineurin inhibitors for severe or face – involving disease
  - Black box warning for lymphomas / skin malignancies
- Treatments unchanged in past 15 years

Crisbarole (Eucrisa®)

- Indicated for treatment of Atopic Dermatitis in patients ≥ 2 years old
- Dosing: thin layer to affected area twice daily
- Formulations: 60g & 100g 2% ointments
- Mechanism of Action
  - Phosphodiesterase – 4 (PDE-4) inhibitor
  - Increases cAMP → decreased cytokines
- Absorption: limited systemic absorption
- Adverse Effects: stinging/burning at application site
- Clinical trial: ~10% improvement in symptoms compared to placebo

DUPILUMAB
(DUPIXENT®-SANOFI)
**Dupilumab (Dupixent®)**

- Indicated for treatment of moderate/severe atopic dermatitis in adults who haven’t responded to topical therapies
- Dosing: two 300 mg SC injections (600 mg total) as initial dose, followed by 300 mg every other week
- Mechanism of Action
  - Fully human monoclonal antibody
  - Inhibits IL-4/IL-13

**Clinical trial data**

- 20-30% improvement in symptoms compared to placebo
- Improved severity when in combo w/ topical steroids compared to steroids alone

**Adverse effects:**

- Injection site reactions
- Ocular symptoms: conjunctivitis/keratitis/blepharitis
- Oral herpes virus infections

- One syringe (300mg) = $1,400
- $37,000 yearly cost
Brodalumab (Siliq®)

- **Plaque psoriasis**
  - Auto-immune disease
  - Thickened, inflamed skin with silvery plaques
- **Mechanism**
  - IgG2 monoclonal antibody
  - IL-17 receptor A antagonist
  - Blocks cytokine/chemokine activity
- **Dose**
  - Subcutaneous weeks 0, 1, 2, then Q2 weeks
- **Adverse effects**
  - Suicide & suicidal ideation
  - REMS program
  - Crohn’s disease exacerbation
  - Immune suppression/infection risk
  - Injection site reactions

**Indication**
- Plaque psoriasis
- Failed other therapies

LIFITEGRAST (XIDRA®)

- **Dry eye disease**
  - Reduced tear production; altered tear composition
  - Environmental, mechanical stresses, drugs
  - Increased risk in older, female population
- **Mechanism**
  - Lymphocyte function-associated antigen 1 (LFA-1) antagonist
  - Excessive LFA-1 leukocyte binding
    - Stimulates inflammation
  - Blockade decreases inflammation on ocular surface

- **Indication**
  - Plaque psoriasis
  - Failed other therapies
Lifitegrast (Xidra®)

- **Dose**
  - 1 drop in each eye Q12 hours

- **Adverse effects**
  - Dysgeusia
  - Eye irritation
  - Blurred vision

- **Indication**
  - Treat signs/symptoms of dry eye disease
  - 4 RCT n>1000
    - 12 week improvement

**ONCOLOGY DRUGS**

ATEZOLIZUMAB (TECENTRIQ®)
GENENTECH
Atezolizumab (Tecentriq®)

- **Mechanism**
  - Monoclonal antibody immune checkpoint inhibitor
    - Binds programmed-death ligand 1 (PD-L1)

- **Dose**
  - IV Q3 weeks until disease progression or unacceptable toxicity
  - Adverse effects
    - Fatigue, decreased appetite, nausea, urinary tract infection, fever, constipation
    - "immune-mediated" effects

- **Indication**
  - Non-small cell lung cancer
  - Urothelial carcinoma
    - Most common type of bladder cancer
    - Increased overall survival
    - PD-L1 + tumors had better response

AVELUMAB
(BAVENCIO®-MERCK/PFIZER)
Avelumab (Bavencio®)

- Approved for treatment of Merkel – cell carcinoma and bladder cancer
- Approved for those >12 years of age
- Mechanism of Action
  - PD L1 inhibitor: prevents tumor cells from using PD-L1 and escaping T-cells (Immunotherapy)
  - Unique trait: induced natural killer cell – mediated cytotoxicity in vitro
- Referred to as “checkpoint inhibitor”
- Dosing: 10 mg/kg every 2 weeks
  - Premedicate w/ APAP & antihistamine prior to at least first four doses

Clinical Data
- JAVELIN MERKEL 200
- JAVELIN Solid Tumor

Adverse effects
- Immune – mediated reactions (hepatitis/pneumonitis/acute kidney injury/Elevated LFTs)
- Minimal adverse events in Merkel trial
- AE – related deaths in 6% of bladder cancer trial (pneumonitis, respiratory failure, sepsis, GI AEs)

Cost ~ $13,000 / month

OLARATUMAB
(LARTRUVO®-ELI LILLY)
Olaratumab (Lartruvo®)
• Approved for treatment of soft tissue sarcoma
• Dosing: 15 mg/kg IV on days 1/8 of 21 day cycle
  – Given in combination with doxorubicin
  – Premedicate w/ diphenhydramine/dexamethasone
• Mechanism of Action
  – Platelet – derived growth factor (PDGF) receptor antibody → blocks tumor growth
• Adverse effects: infusion – related reactions (some severe hypotension, cardiac arrest)
• Concerning imbalances in primary Phase 2 study

 Ribociclib (Kisqali®-NOVARTIS)
• Approved for treatment of metastatic breast cancer
• Dosing: 600mg per day 3 weeks on / 1 week off
  – Given w/ letrozole in major phase 3 trial
• Mechanism of Action
  – Inhibitor of CDK-4 → reactivates tumor suppressors
  – When in combo, helps in “crosstalk” suppression and resultant synergistic action
• Adverse effects
  – Myelosuppression (mainly with first month)
  – 7% treatment discontinuation vs. 2% letrozole alone
VENETOCLAX
(VENCLEXTA®-GENENTECH/ROCHE)

Venetoclax (Venclexta®)

• Approved for CLL w/ 17p deletion who have been treated w/ at least one other agent
  – FDA first granted breakthrough designation in 2015
• Dosing: 20mg once daily to begin, increased gradually over 5 weeks to reduce risk of Tumor Lysis Syndrome (TLS)
• Mechanism of Action
  – Bcl-2 inhibitor leading to cell death in CLL cells
• Metabolized by CYP 3A4/5 / substrate of P-gp
• Adverse effects: TLS (5%), neutropenia (41%)
• Cost ~ $10k/month

RUCAPARIB (RUBRACA®)
CLOVIS
Rucaparib (Rubraca®)

• Mechanism
  – PARP inhibitor used as an anti-cancer agent
  – Targets DNA repair enzyme poly-ADP ribose polymerase-1

• Dose
  – Oral BID dosing until disease progression or unacceptable toxicity
  – Adverse effects
    • Fatigue, dizziness, weakness
    • Rash
    • Nausea, vomiting, constipation
    • Anemia, neutropenia
    • Increased AST/ALT, cholesterol
    • Dyspnea

• Indication
  – Advanced ovarian cancer
  – Treated with ≥2 chemotherapies
  – BRCA gene mutation
  – Identified by FDA-approved companion diagnostic test
  – N = 106
  – 54% complete or partial tumor shrinkage of their tumors
  – Median 9.2 months

NIRAPARIB (ZEJULA®)
TESARO
**Niraparib (Zejula®)**

- Same mechanism as rucaparib
- Indication
  - Maintenance treatment of adults with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer
  - Complete or partial response to platinum-based therapy
  - RCT n = 553
  - As above
  - BRCA mutation
    - Progression-free survival
      - 21 months vs 5 months
  - No BRCA mutation
    - Progression-free survival
      - 9.3 months vs 3.9 months
- Fast Track, priority review and breakthrough therapy designations
  - Orphan drug status

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**ETELCALCETIDE (PARSABIV®-AMGEN)**
Etelcalcetide (Parsabiv®)

- Approved for treatment of secondary hyperparathyroidism in dialysis patients
- Dosing: 5 mg intravenously three times/week
  - Administered after dialysis
  - Dose range individualized to PTH level (2.5 – 15 mg)
  - May be increased by 5 mg increments q4 weeks
- Mechanism of Action
  - Calcimimetic similar to cinacalcet (Sensipar®)
- Adverse effects
  - Hypocalcemia (D/C if serum calcium < 7.5 mg/dL)

SAFINAMIDE
(XADAGO®-NEWRON)

Safinamide (Xadago®)

- Approved for add on treatment in patients w/ Parkinson’s who are taking levodopa/carbidopa & experiencing “off” episodes
- Dosing: 50 mg once daily (may be increased to max of 100 mg after two weeks)
- Mechanism of Action
  - MAO-B inhibitor → increased dopamine
  - More selective for MAO-B than selegeline/rasagiline
  - Has glutamate increasing properties similar to amantadine
  - Selectivity bypasses dietary concerns w/ MAOIs
  - Also does not have BP/HR issues
Safinamide (Xadago®)
• Increased “on time” by ½ hour in a day
• Efficacy very similar to entacapone
• Adverse effects
  – Most common: dyskinesias, falls, nausea, insomnia
  – Warnings: HTN, serotonin syndrome, falling asleep, exacerbations of dyskinesias
• Contraindicated w/: SNRI, TCA, MAOI, opioids, dextromethorphan, cyclobenzaprine
• Avoid in severe hepatic disease
• Still recommended to avoid heavy – tyramine containing foods (e.g., aged cheese)

Obiltoxaximab (Anthim®)
• Approved for treatment of inhalational anthrax in adults and pediatrics. Also approved for prophylaxis if alternatives are not available.
• Dosing: (premedicate w/ diphenhydramine)
  • > 40 kg: 16 mg/kg single IV dose
  • 15 – 32 kg: 24 mg/kg single IV dose
  • < 15 kg: 32 mg/kg single IV dose
• Mechanism of Action
  – Monoclonal antibody against Bacillus anthracis (anthrax)
• Adverse effects
  – Hypersensitivity (11%)
  – Anaphylaxis (0.9%)
• Effectiveness evaluated only in animal studies
• Safety / PK in healthy volunteers
Brivaracetam (Brivact®)

- Mechanism
  - Listed as “unknown”
  - SV2A blocker
    - Bind & inhibit NT release from vesicle
      - Decrease glutamate, excitatory neurotransmitter
### Brivaracetam (Brivact®)

**Dose**
- Oral BID dosing; IV available

**Adverse effects**
- Drowsiness, dizziness, fatigue, nausea, vomiting
- Risks
  - Suicidal ideation/suicide attempts
  - Agitation, depression, panic attacks

**Indication**
- Ages ≥ 16 years
- Add-on therapy for partial onset seizures

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### Defibrotide (Defitelio®)

**Hepatic veno-occlusive disease (VOD)**
- After hematopoietic stem cell transplant (HSCT)
  - <2% of HSCT patients develop severe hepatic VOD
  - ~80% mortality
- Hepatocellular necrosis
- Hepatic vascular congestion
Defibrotide (Defitelio®)

- **Mechanism**
  - Hydrolyze fibrin clots
    - Increases
      - Tissue plasminogen activator (tPA) & thrombomodulin
    - Decreases
      - Von Willebrand factor
      - Plasminogen activator inhibitor -1

- **Dose**
  - IV Q6 hours X21-60 days

- **Adverse effects**
  - Bleeding
  - Hypotension
  - Allergic reactions

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Defibrotide (Defitelio®)

- **Indication**
  - Hepatic veno-occlusive disease (VOD)
  - After HSCT
  - Adults and children
  - Kidney or lung abnormalities

- **3 RCT n = 528**
  - 2 prospective, 1 expanded access
  - ~38-45% survival at 100 days

- **Priority review status**
  - Orphan drug designation

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**ETEPLIRSEN (EXONDYS 51®)**

SAREPTA
Eteplirsen (Exondys 51®)

- Duchenne muscular dystrophy (DMD)
  - Genetic disorder
    - Progressive muscle weakness
    - Affects primarily boys (X-linked recessive)
    - Onset ~4 years
  - Pathogenesis
    - Mutation in gene that encodes cytoskeletal protein dystrophin
      - Provides linking & structure in muscle tissue

- Mechanism
  - Antisense oligonucleotide
  - Binds to dystrophin mRNA exon 51
    - Allows exon skipping
    - Increase production of truncated dystrophin
      - Slows disease progression

- Dose
  - Weekly IV infusion
  - Adverse effects
    - Balance disorder
    - Vomiting

- Indication
  - DMD mutation amenable to exon 51 skipping
    - RCT n = 12; 24 weeks
      - Increase in dystrophin
        - “likely to provide benefit”
      - 6 minute walk test
    - FDA confirmatory trial
      - 48 week open-label phase III trial

- Fast track, priority review, orphan drug status & rare pediatric disease priority review voucher
Nusinersen (Spinraza®)

- Approved for treatment of muscular spinal atrophy
  - Genetic disorder causes deletion of motor neuron gene (SMN)
  - Muscle weakness / atrophy
- Dosing: 12 mg / 5 mL intrathecally
  - First three doses given 14 days apart
  - Fourth dose 30 days after third dose
  - Every 4 months maintenance after that
- Mechanism of Action
  - SMN2 antisense oligonucleotide
  - Increases gene production of motor neuron protein
- Adverse effects
  - Respiratory infections, LP effects
  - May cause growth retardation
- Only available through one specialty pharmacy.
- Cost: one vial = $125,000
Deflazacort (Emflaza®)

- Corticosteroid (CCS)
  - Approved for DMD
  - European approval other diseases
  - 6mg deflazacort = 5mg prednisone
- RCT N =196
  - Deflazacort, prednisone, placebo
  - Clinical improvements at week 12 vs. placebo
- Adverse effects
  - Less weight gain vs. prednisone; otherwise similar
- Fast track, priority review & orphan drug status, rare pediatric disease priority review voucher
- Anticipated cost/year
  - ~$89000
- Cost to import from Europe
  - ~$1200
- Cost of prednisone
  - ~50mg X100 tabs
  - ~$40.70…~$150/year

OCRELIZUMAB (OCREVUS®)
GENENTECH

- Multiple sclerosis
  - Relapsing & primary progressive
  - Immune-mediated disease; attacks myelin sheath that insulates CNS nerves
  - Multiple = number of lesions
  - Sclerosis = demyelinated lesions (plaques)
- Mechanism
  - Humanized monoclonal antibody
    - Binds CD20
  - Immunosuppressive
- Indication
  - MS
  - Relapsing & primary progressive forms
Questions?