New Drug Update 2016

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Disclosure

• Nothing to disclose.

Learning Objectives

• Name the major new chemical entities approved by the FDA in 2015 and early 2016
• Recognize the major therapeutic aspects of new drugs approved by the FDA in 2015 (e.g., indications, adverse reactions, drug interactions)
• Compare new agents to previously available therapies when possible
FDA Approvals
- In 2015 – FDA approved 45 novel drugs
- From 2006-2014 – average 28 per year

First in Class
- 16 of these 45 Novel Drugs are the first in their class
Cardiology/Vascular Diseases

- **Corlanor (ivabradine)**; Amgen; For the treatment of chronic heart failure, Approved April 2015
  - First in class HCN channel blocker that lowers the heart rate

- **Entresto (sacubitril and valsartan)**; Novartis; For the treatment of chronic heart failure, Approved July 2015
  - First in class angiotensin receptor-neprilysin inhibitor (ARNI)
  - PARADIGM-HF (NEJM)
  - > 8000 chronic heart failure patients
  - Entresto significantly reduced cardiovascular death or heart-failure hospitalizations by 20%
  - Compared with treatment with the ACE inhibitor enalapril alone
  - When studied with an ACE inhibitor – severe angioedema

- **Savaysa (edoxaban)**; Daiichi Sankyo; For the treatment of deep vein thrombosis, pulmonary embolism and risk of stroke and embolism due to atrial fibrillation, Approved January 2015
  - Factor Xa inhibitor
  - Non-vascular atrial fibrillation
  - Treatment of DVT/PE
  - Not for use in CrCl >95 mL/min
  - Reduce dose when CrCl < 50 mL/min
  - Must be started with parenteral agent
  - Once daily

- **Kengreal (cangrelor)**; The Medicines Company; For reducing periprocedural thrombotic events, Approved June 2015
  - First IV P2Y12 platelet inhibitor used with percutaneous coronary intervention (PCI) to reduce risk of periprocedural myocardial infarction, Repeat coronary recanalization, and stent thrombosis
  - For patients who have not been treated with a P2Y12 platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor
Cardiology/Vascular Diseases

- **Praluent (alirocumab)**; Sanofi Aventis; For the treatment of heterozygous familial hypercholesterolemia or atherosclerotic cardiovascular disease, Approved July 2015
  - First in class PCSK9 inhibitor
  - Pre-filled pens
  - Used along with diet and maximally tolerated statin therapy in adults with heterozygous familial hypercholesterolemia or atherosclerotic heart problems, who need additional lowering of LDL cholesterol
  - Repatha (evolocumab); Amgen; For the treatment of high cholesterol, Approved August 2015
    - PCSK9 inhibitor antibody
    - An adjunct to diet and maximally tolerated statin therapy for treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C)
    - An adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) in patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C

- **Kanuma (sebelipase alfa)**; Alexion; For the treatment of Lysosomal Acid Lipase (LAL) deficiency, Approved December 2015
  - First in class and only treatment of LAL deficiency
- **Prestalia (perindopril arginine and amlodipine besylate)**; Symplmed Pharmaceuticals; For the treatment of hypertension, Approved January 2015
- **Uptravi (selexipag)**; Actelion Pharmaceuticals; For the treatment of pulmonary arterial hypertension, Approved December 2015
  - Prostacyclin receptor agonist indicated for treatment of pulmonary hypertension to delay disease progression and reduce the risk of hospitalization for PAH

Dermatology

- **Cosentyx (secukinumab)**; Novartis; For the treatment of plaque psoriasis, Approved January 2015
  - First in class – selectively targets IL-17a
- **Enstilar (calcipotriene and betamethasone dipropionate)**; LEO Pharmaceuticals; For the treatment of psoriasis, Approved October 2015
  - Topical foam
- **Kybella (deoxycholic acid)**; Kythera Biopharma; For the treatment of submental fat, Approved April 2015
  - “Double Chin”
Dermatologic Oncology

• **Cotellic (cobimetinib)**: Genentech; For the treatment of BRAF V600E or V600K melanoma (in combination with Zelboraf (vemurafenib)), Approved November 2015

• **Imlygic (talimogene laherparepvec)**: Amgen; For the treatment of unresectable recurrent melanoma, Approved October 2015

• First in Class – Oncolytic Viral Therapy designed to destroy advanced melanoma

• **Odomzo (sonidegib)**: Novartis; For the treatment of locally advanced basal cell carcinoma, Approved July 2015

www.fda.gov
www.cotellic.com
www.imlygic.com
www.odomzo.com

Endocrineology

• **Addyi (flibanserin)**: Sprout Pharmaceuticals; For the treatment of premenopausal women with generalized hypoactive sexual desire disorder, Approved August 2015

• **Natpara (parathyroid hormone)**: NPS Pharmaceuticals; For the control hypocalcemia in patients with hypoparathyroidism, Approved January 2015

www.fda.gov
www.addyi.com
www.natpara.com
**Endocrinology**

- **Synjardy (empagliflozin and metformin hydrochloride)**; Boehringer Ingelheim; For the treatment of type II diabetes, Approved August 2015
- **Tresiba (insulin degludec injection)**; Novo Nordisk; For glycemic control in adults with diabetes mellitus, Approved September 2015

**Family Medicine**

- **Cosentyx (secukinumab)**, Enstilar (calcipotriene and betamethasone dipropionate); Kybella (deoxycholic acid); Savaysa (edoxaban);
- **Cresemba (isavuconazonium sulfate)**; Astellas; For the treatment of invasive aspergillosis and invasive mucormycosis, Approved March 2015
- **Otiprio (ciprofloxacin otic suspension)**; Otonomy; For the treatment of pediatrics with bilateral otitis media with effusion undergoing tympanostomy tube placement, Approved December 2015

**Family Medicine**

- **Viberzi (eluxadoline)**; Actavis; For the treatment of irritable bowel syndrome with diarrhea, Approved May 2015
- **Xifaxan (rifaximin)**; Salix Pharmaceuticals; For the treatment of irritable bowel syndrome with diarrhea, Approved May 2015
### Gastroenterology

- **Avycez (ceftazidime-avibactam)**: Actavis; For the treatment of complicated intra-abdominal and urinary tract infections, Approved March 2015.  
  - Use: In the treatment of complicated intra-abdominal infections.  
  - Contraindications: Hypersensitivity to any component of the formulation.  
  - Administration: Oral tablet or oral solution.  
  - Precautions: Use with caution in patients with reduced renal function.  
  - Interactions: None known.  
  - Side Effects: Common: Diarrhea, nausea, vomiting, abdominal pain; Rare: Urticaria, rash.  

- **Cholbam (cholic acid)**: Asklepion Pharmaceuticals; For the treatment of bile acid synthesis and peroxisomal disorders, Approved March 2015.  
  - Capsule must be taken with food, but separated from bile acid binding resins or aluminum-based antacids.  
  - For patients unable to swallow capsule, it may be opened and mixed with infant formula or soft food.  

- **Lonsurf (trifluridine and tipiracil)**: Taiho Oncology; For the treatment of metastatic colorectal cancer, Approved September 2015.  
  - Previously treated with fluoropyrimidine, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild type, an anti-EGFR therapy.  

- **Onivyde (irinotecan liposome injection)**: Merrimack; For the treatment of metastatic pancreatic cancer following gemcitabine-based therapy, Approved October 2015.  
  - In combination with fluorouracil and leucovorin.  

- **Varubi (rolapitant)**: Tesaro; For the prevention of delayed nausea and vomiting associated with chemotherapy, Approved September 2015.  
  - Substance P/neurokinin 1 (NK1) receptor antagonist.  

### Genetic Disease

- **Kanuma (sebelipase alfa)**: Alexion; For the treatment of hypophosphatasia, Approved October 2015.  
  - A tissue-nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).  

- **Strensiq (asfotase alfa)**: Alexion; For the treatment of hypophosphatasia.  
  - A tissue-nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).  

- **Xuriden (uridine triacetate)**: Wellstat Therapeutics; For the treatment of hereditary orotic aciduria, Approved September 2015.  

Hematology

- **Darzalex (daratumumab)**; Janssen Biotech; For the treatment of multiple myeloma, Approved November 2015
  - Human CD38-directed monoclonal antibody
  - Indicated for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy.
  - Including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double refractory to a PI and an immunomodulatory agent

- **Farydak (panobinostat)**; Novartis; For the treatment of multiple myeloma, Approved February 2015
  - A histone deacetylase inhibitor
  - In combination with bortezomib and dexamethasone
  - Indicated for the treatment of patients with multiple myeloma who have received at least 2 prior regimens, including bortezomib and an immunomodulatory agent
  - Accelerated approval based on progression free survival

- **Natpara (parathyroid hormone)**; NPS Pharmaceuticals; For the control hypocalcemia in patients with hypoparathyroidism, Approved January 2015
  - Parathyroid hormone used with calcium and vitamin D to control hypocalcemia in people with hypoparathyroidism

- **Nuwiq (recombinant Factor VIII)**; Octapharma; For the prophylaxis and treatment of hemophilia A, Approved September 2015
  - Human coagulation factor VIII (rDNA)
  - Simoctocog alfa is a purified protein
  - Produced by recombinant DNA technology in genetically modified human embryonic kidney (HEK) cells
  - No animal or human derived materials are added during the manufacturing process or to the final medicinal product

- **Veltassa (patiromer)**; Relypsa; For the treatment of hyperkalemia, Approved October 2015
  - Binds together with potassium in your gastrointestinal tract, primarily in the colon, or large intestine, where excess potassium is most common
  - Both the potassium and VELTASSA pass through and are removed by your body
  - VELTASSA is not absorbed by your body

- **Praxbind (idarucizumab)**; Boehringer Ingelheim; For the reversal of the anticoagulant effects of dabigatran, Approved October 2015
  - PRAXBIND is indicated in patients treated with Pradaxa® when reversal of the anticoagulant effects of dabigatran is needed:
    - For emergency surgery/urgent procedures
    - In life-threatening or uncontrolled bleeding
  - This indication is approved under accelerated approval based on a reduction in unbound dabigatran and normalization of coagulation parameters in healthy volunteers
### Hepatology (Liver, Pancreatic, Gall Bladder)

- **Cholbam (cholic acid)**
- **Daklinza (daclatasvir)**: Bristol-Myers Squibb; For the treatment of chronic HCV genotype 3, Approved July 2015
  - 12-week, all-oral (60 mg) treatment for chronic hepatitis C (hep C) genotype 3
  - In combination with Sovaldi (sofosbuvir)

- **Technivie, (ombitasvir, paritaprevir and ritonavir)**: Abbvie; For the treatment of chronic HCV genotype 4, Approved July 2015
  - In combination with ribavirin

### Immunology

- **Cosentyx (secukinumab)**
- **Envarsus XR (tacrolimus extended-release)**: Vittox, For the prophylaxis of organ rejection in kidney transplant patients, Approved July 2015
  - Once a day tacrolimus
  - Kidney transplant

- **Evotaz (atazanavir and cobicistat)**: Bristol-Myers Squibb; For the treatment of HIV-1 infection, Approved January 2015
  - Combination HIV medication

- **Genvoya (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide)**: Gilead Sciences; For the treatment of HIV-1 infection, Approved November 2015
  - Combination HIV medication

- **Prezembix (darunavir and cobicistat)**: Janssen; For the treatment of HIV-1 infection, Approved January 2015
  - Combination HIV medication
### Infections/Infectious Diseases

- **Avycaz (ceftazidime-avibactam)**; Cresemma (ciprofloxacin-mometasone furoate); Daklinza (daclatasvir); Evotaz (atazanavir and cobicistat); Genvoya (elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide); Prezcobix (darunavir and cobicistat); Technivie, (ombitasvir, paritaprevir and ritonavir)

- **Bexsero (Meningococcal Group B Vaccine)**; Novartis; For the treatment of invasive meningococcal disease caused by serogroup B, Approved January 2015
- The vaccine is indicated for active immunization to prevent invasive disease caused by Neisseria meningitidis serogroup B. BEXSERO is approved for use in individuals 10 through 25 years of age. For intramuscular use only. Administer two doses (0.5 mL each) of BEXSERO at least 1 month apart.

- **Fluad (trivalent influenza vaccine)**; Seqirus; For the prevention of influenza A and B, Approved November 2015
- The first seasonal influenza vaccine containing an adjuvant. Adjuvants are incorporated into some vaccine formulations to enhance or direct the immune response of the vaccinated individual.

### Musculoskeletal

- **Vivlodex (meloxicam)**; Iroko Pharmaceuticals; For the management of osteoarthritis pain, Approved October 2015
- The first low-dose SoluMatrix meloxicam for osteoarthritis (OA) pain.

### Oncology

- **Cotellic (cobimetinib)**; Dazaxel (daratumumab); Farydak (panobinostat); Imlygic (talimogene laherparepvec); Lonsurf (trifluridine and tipiracil); Odomzo (sonidegib); Onivyde (irinotecan liposome injection); Varubi (rolapitant)
- **Alecensa (alectinib)**; Roche; For the treatment of ALK-positive, metastatic non-small cell lung cancer, Approved December 2015
- Kinase inhibitor – Treatment of patients with anaplastic lymphoma kinase (ALK)-positive, metastatic non-small cell lung cancer (NSCLC) – Progresses on or are intolerant to crizotinib – Under accelerated approval based on tumor response rate and duration of response.
- **Empliciti (elotuzumab)**; Bristol-Myers Squibb; For the treatment of patients with multiple myeloma who have received prior therapies, Approved November 2015
- Monoclonal antibody that directly activates Natural Killer (NK) Cells to fight tumor cells
- In combination with revlimid (lenalidomide) and dexamethasone
- In patients who have received 1 to 3 previous multiple myeloma treatments.
Oncology

- **Ibrance (palbociclib)**: Pfizer; For the treatment of ER-positive, HER2-negative breast cancer, Approved February 2015
  - Kinase inhibitor
  - In combination with letrozole
- **Lenvima (lenvatinib)**: Eisai; For the treatment of thyroid cancer, Approved February 2015
  - Kinase inhibitor
- **Ninlaro (ixazomib)**: Millennium Pharmaceuticals; For the treatment of multiple myeloma, Approved November 2015
  - Proteasome inhibitor
  - In combination with lenalidomide and dexamethasone

- **Opdivo (nivolumab)**: Bristol-Myers Squibb; For the treatment of metastatic squamous non-small cell lung cancer, Approved March 2015
  - Programmed death receptor-1 (PD-1) blocking antibody
- **Portrazza (necitumumab)**: Eli Lilly; For the treatment of metastatic squamous non-small cell lung cancer, Approved November 2015
  - Epidermal growth factor receptor (EGFR) antagonist
  - In combination with gemcitabine and cisplatin, for first-line treatment of patients with metastatic squamous non-small cell lung cancer

- **Tagrisso (osimertinib)**: AstraZeneca; For the treatment of EGFR T790M mutation positive non-small cell lung cancer, Approved November 2015
  - Kinase inhibitor
- **Unituxin (dinutuximab)**: United Therapeutics; For the treatment of pediatrics with high-risk neuroblastoma, Approved March 2015
  - GD2-binding monoclonal antibody
  - In combination with granulocyte-macrophage stimulating factor (GM-CSF), Interleukin-2, and 13-cis-retinoic acid
  - Who achieved at lease a partial response to prior first-line multiagent, multimodality therapy
- **Yondelis (trabectedin)**: Janssen; For the treatment of liposarcoma or leiomyosarcoma, Approved October 2015
  - Alkylating drug
  - Received prior anthracycline-containing regimen
Envarsus XR (tacrolimus extended-release); Zurampic (lesinurad); AstraZeneca; For the treatment of hyperuricemia associated with gout, Approved December 2015

- URAT1 inhibitor
- In combination with Xanthine Oxidase Inhibitor
- In patients who have not achieved target serum uric acid levels with a Xanthine Oxidase Inhibitor alone

Duopa (carbidopa and levodopa enteral suspension); Abbvie; For the treatment of motor fluctuations in patients with advanced Parkinson’s disease, Approved January 2015

Rytary (carbidopa and levodopa extended-release capsules); Impax Labs; For the treatment of Parkinson’s disease, Approved January 2015

Aristada (aripiprazole lauroxil) extended-release injectable; Alkermes; For the treatment of schizophrenia, Approved October 2015

Belbuca (buprenorphine) Buccal film; Indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment, and for which alternative treatment options are inadequate

Vraylar (cariprazine) Atypical antipsychotic; Treatment of schizophrenia; Acute treatment of manic or mixed episodes associated with bipolar disorder

Neurology

Neurology

Neurology
Obstetrics/Gynecology (Women’s Health)

- **Addyi (flibanserin)**: Sprout Pharmaceuticals; For the treatment of premenopausal women with generalized hypoactive sexual desire disorder, Approved August 2015
- **Ibrance (palbociclib)**: Pfizer; For the treatment of ER-positive, HER2-negative breast cancer, Approved February 2015

Orthopedics/Orthopedic Surgery

- **Strensiq (asfotase alfa)**: Alexion; For the treatment of hypophosphatasia, Approved October 2015

Otolaryngology (Ear, Nose, Throat)

- **Otiprio (ciprofloxacin otic suspension)**: Otonomy; For the treatment of pediatrics with bilateral otitis media with effusion undergoing tympanostomy tube placement, Approved December 2015
  - Intratympanic administration only
  - Two 0.1 mL doses available in each vial
Pediatrics/Neonatology
- **Bexsero (Meningococcal Group B Vaccine)**: Cholera toxin abortus; Kanuma (sebelipase alfa); Otiprio (ciprofloxacin otic suspension); Strensiq (asfotase alfa); Unituxin (dinutuximab)
- **Orkambi (lumacaftor and ivacaftor)**: Vertex Pharmaceuticals; For the treatment of cystic fibrosis, Approved July 2015
  - A cystic fibrosis transmembrane conductance regulator (CFTR) potentiator
  - Treatment of CF in patients age 12 years and older
  - Homozygous for the F508del mutation in the CFTR gene
  - An FDA-cleared CF mutation test should be used to detect the mutation if unknown

Pharmacology/Toxicology
- **Bridion (sugammadex)**: Merck; For the reversal of neuromuscular blockade induced by rocuronium and vecuronium in adults undergoing surgery, Approved December 2015
- **Vistogard (uridine triacetate)**: BTG; For the emergency treatment of patients with a fluorouracil or capecitabine overdose, Approved December 2015

Psychiatry/Psychology
- **Aristada (aripiprazole lauroxil) extended-release injectable**, Vraylar (cariprazine)
- **Rexulti (brexpiprazole)**: Otsuka; For the treatment of depression and schizophrenia, Approved July 2015
  - Atypical antipsychotic
  - An adjunctive therapy to antidepressants for the treatment of major depressive disorder
  - Treatment of schizophrenia
Pulmonary/Respiratory Diseases

- **Alecensa (alectinib)**: Orkambi (lumacaftor and ivacaftor); **Opdivo (nivolumab)**; **Portrazza (necitumumab)**; **Tagrisso (osimertinib)**
- **Nucala (mepolizumab)**: GlaxoSmithKline; Approved November 2015
- **Stialto Respimat (tiotropium bromide and olodaterol)**: Boehringer Ingelheim; Approved May 2015
- **Utibron Neohaler (indacaterol and glycopyrrolate)**: Novartis; Approved October 2015

Urology

- **Avycaz (ceftazidime-avibactam)**: Actavis; Approved February 2015
- **Xuriden (uridine triacetate)**: Wellstat Therapeutics; Approved September 2015

Vaccines

- **Bexsero (Meningococcal Group B Vaccine)**: Novartis; Approved January 2015
- **Fluad (trivalent influenza vaccine)**: Seqirus; Approved November 2015
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