Specialty Pharmacy Pipeline

Drugs to Watch

Anticipated Launches | Q4 2017-Q1 2018

CVSHealth

Therapeutic Category	Product Name, Route of Administration and Manufacturer[1]	Proposed Indication[1]	Phase of Study[1]	Disease Prevalence and Background	Select Available FDA-Approved Therapies	Comments — CVS Health Initial Recommendations
Allergic Asthma	benralizumab subcutaneous injection Medimmune/ AstraZeneca	The treatment of severe uncontrolled asthma with eosinophilic inflammation in patients 12 years and older	Pending U.S. Food and Drug Administration (FDA) approval	Asthma is a long-term respiratory disease caused by both genetic and environmental factors. Eosinophilic asthma is a severe subtype characterized by persistent inflammation and allergic reactions that can be life threatening.[2] Asthma affects approximately 7.6% of American adults and 8.4% of children; less than 10% of these patients have severe asthma that does not respond sufficiently to treatment.[3]	**Injectable biologic agents for severe asthma:** Cinqair (reslizumab), Nucala (mepolizumab), Xolair (omalizumab) Numerous inhaled and oral treatment options for asthma are also available	The FDA is expected to review the application by December 1, 2017. If approved, benralizumab will offer an additional therapy option for patients who are still poorly controlled despite treatment. Benralizumab will be included in Specialty Guideline Management subsequent to approval.
Cystic Fibrosis (CF)	tezacaftor/ivacaftor oral Vertex	The treatment of CF in patients 12 years of age and older with two copies (homozygous) of the F508del mutation	Pending FDA approval	CF is a genetically inherited disease; there are ~30,000 Americans with CF.[4] CF is caused by a mutation of the cystic fibrosis transmembrane conductance regulator (CFTR) gene, which is involved in the transportation of electrolytes and water.[4] The most common CFTR mutation is F508del, with 86.5% of CF patients having at least one copy of this mutation.[5]	**Homozygous F580del mutation:** Orkambi (ivacaftor/ lumacaftor)	The FDA is expected to review the application by February 26, 2018. If approved, tezacaftor/ivacaftor will offer an additional therapy option for CF patients with targeted mutations; it has been granted a breakthrough therapy designation for the homozygous population. Tezacaftor/ivacaftor will be included in Specialty Guideline Management subsequent to approval.
		The treatment of CF in patients 12 years and older with one copy of F508del-CFTR mutation and a second mutation that results in residual CFTR function.			**F508 del/residual function mutations:** Kalydeco (ivacaftor)	

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Hemophilia, Von Willebrand Disease and Related Bleeding Disorders	emicizumab subcutaneous injection Roche/Chugai Pharmaceutical	Routine prophylaxis of bleeding in adults and pediatric patients who have hemophilia A with inhibitors.	Pending FDA approval	Hemophilia A is a genetic bleeding disorder caused by a deficiency in blood clotting factor VIII levels, and it occurs in ~1 in 5,000 male births.[6] Guidelines recommend prophylaxis regardless of severity, to prevent bleeding symptoms and organ damage, most notably to the joints. However, only about half of U.S. children use prophylactic treatment.[7] The current standard of care is IV factor VIII replacement. However, formation of factor VIII-neutralizing antibodies (inhibitors) occurs in ~30% of hemophilia A patients. Inhibitors may inactivate factor VIII activity and counteract replacement therapy.[8]	**IV bypass therapy:** FEIBA (plasma-derived anti-inhibitor coagulant complex), NovoSeven RT (coagulation factor VIIa, recombinant; for treatment of bleeding episodes and perioperative management) **IV immune tolerance induction therapy:** High dose factor VIII, Human-plasma derived von Willebrand factor (containing factor VIII)	The FDA is expected to review the application by February 23, 2018. If approved, emicizumab will be the first once-weekly subcutaneously injected agent for hemophilia A and is not expected to be susceptible to inhibitors due to its unique mechanism of action. Emicizumab has been granted a breakthrough therapy designation for this population and will be included in Specialty Guideline Management subsequent to approval.

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Human Immuno-deficiency Virus (HIV) Medications	ibalizumab intravenous injection Theratechnologies/ TaiMed Biologics	The treatment of multi-drug resistant (MDR) HIV, in combination with other antivirals	Pending FDA approval	HIV is a lifelong viral infection that affects CD4 T cells, a type of white blood cell. As the infection progresses, the immune system becomes compromised and is no longer able to effectively fight off infection and disease. There are currently ~1.1 million Americans living with HIV. Though there is no cure for HIV, antiretroviral therapy can effectively control the disease for many years. Today, patients with HIV can have near-normal life spans.[9]	**Agents for MDR HIV:** Aptivus (tipranavir) oral, Fuzeon (enfuvirtide) SC injection, Intelence (etravirine) oral *Other antiretroviral agents may be considered depending on the results of patient-specific drug resistance testing.*	The FDA is expected to review the application for ibalizumab by January 3, 2018. Ibalizumab has been granted Breakthrough Therapy Designation. If approved, ibalizumab will offer another salvage therapy option for patients with MDR disease. The FDA is expected to review the applications for dolutegravir/ rilpivrine and bictegravir/ emtricitabine/TAF by December 1, 2017 and February 12, 2018, respectively. Both products will offer additional oral complete regimen options. All agents will be evaluated for inclusion in utilization management strategies subsequent to approval.
	Juluca (dolutegravir/ rilpivirine) oral Janssen/Viiv Healthcare	The maintenance treatment of adult patients with HIV	Pending FDA approval		**Oral complete regimen fixed-dose combination agents:** Atripla (efavirenz/ emtricitabine/tenofovir disoproxil fumarate [TDF]), Complera (rilpivirine/ emtricitabine/TDF), Genvoya (elvitegravir/ cobicistat/ emtricitabine/TAF), Odefsey (rilpivirine/ emtricitabine/TAF), Stribild (elvitegravir/ cobicistat/ emtricitabine/TDF), Triumeq (dolutegravir/ abacavir/lamivudine)	
	bictegravir/ emtricitabine/ tenofovir alafenamide (TAF) oral Gilead	The treatment of HIV in adults	Pending FDA approval			

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Inflammatory Bowel Disease, Psoriasis, and Rheumatoid Arthritis	infliximab intravenous injection Pfizer	Biosimilar of Remicade (infliximab)	Pending FDA approval	Remicade is approved for:[10] • Crohn's disease • Ulcerative colitis • Rheumatoid arthritis in combination with methotrexate • Ankylosing spondylitis • Psoriatic arthritis • Plaque psoriasis The infliximab biosimilar may or may not be approved for all indications.	**Originator agent:** Remicade (infliximab) **IV biosimilar agents:** Inflectra (infliximab-dyyb), Renflexis (infliximab-abda)	The FDA is expected to review the application by February 1, 2018. A biosimilar is a biological product that has no clinically meaningful differences in safety, purity, and potency from the reference product.[11] If approved, infliximab will offer another biosimilar option to Remicade. Infliximab will be included in Specialty Guideline Management subsequent to approval.
Muscular Dystrophy	Translarna (ataluren) oral PTC Therapeutics	The treatment of Duchenne muscular dystrophy (DMD) due to a nonsense mutation	Pending FDA approval	Muscular dystrophy is a group of genetic disorders characterized by progressive muscle weakness and degeneration.[12] Heart and respiratory muscle wasting can be life threatening. DMD and a milder form, Becker muscular dystrophy, typically only affect males. Males with DMD typically live into their twenties. In the United States, approximately 14 per 100,000 males from 5-24 years of age are reported to have DMD.[13] Of these patients, approximately 10% have a nonsense mutation.[14]	**Disease-modifying:** Exondys 51 (eteplirsen) for mutations amenable to exon 51 skipping **Symptomatic:** Emflaza (deflazacort)	The FDA is expected to review the application by October 24, 2017. If approved, Translarna would provide the first disease-modifying therapy for patients with DMD and a nonsense mutation. Translarna will be included in Specialty Guideline Management subsequent to approval.

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Oral Oncology	acalabrutinib oral AstraZeneca/ Acerta Pharma	The treatment of relapsed refractory mantle cell lymphoma (MCL) in patients who have received at least one prior therapy	Pending FDA approval	Non-Hodgkin's lymphoma (NHL) is a cancer that starts in a type of white blood cells called lymphocytes. Approximately 2.1% of Americans will be diagnosed with NHL in their lifetime.[15] MCL is an aggressive type of NHL and represents approximately 6% of new NHL cases in the United States.[16]	**Oral agents:** Imbruvica (ibrutinib), Revlimid (lenalidomide) **IV or SC agents:** Velcade (bortezomib) *Various IV chemotherapy regimens may be used off-label for treatment of MCL.*	The FDA is expected to review the application for acalabrutinib by February 2, 2018. If approved, acalabrutinib will offer an additional oral therapy option for MCL. Abemaciclib offers an additional therapy option for hormone receptor positive, HER2 negative advanced breast cancer. Both agents were granted Breakthrough Therapy designation and will be included in Specialty Guideline Management subsequent to approval.
	Verzenio (abemaciclib) oral Eli Lilly	The treatment of hormone receptor positive, HER2 negative advanced or metastatic breast cancer • in combination with fulvestrant in patients with disease progression following endocrine therapy • as monotherapy in patients who have received prior endocrine therapy and chemotherapy	Approved 09/28/2017	Breast cancer is the most common cancer among women in the United States.[17] Approximately 12% of women will develop breast cancer during their lifetime. Certain hormones (estrogen, progesterone) or proteins (HER2) can promote the growth of breast cancer. Approximately 20% of breast cancers are HER-2 positive.	**Oral CDK 4/6 inhibitors:** Ibrance (palbociclib), Kisqali (ribociclib)	

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Psoriasis	tildrakizumab subcutaneous injection Sun Pharma/ Merck	Treatment of moderate-to-severe chronic plaque psoriasis	Pending FDA approval	Psoriasis is an immune disease primarily affecting the skin and joints.[18] The most common form, plaque psoriasis, causes irritated scale covered patches on the skin. Psoriasis is estimated to affect 7.5 million Americans, or about 2.2% of the population, with the plaque psoriasis subtype accounting for 80%-90% of cases.	**Oral Agent:** Otezla (apremilast) **SC injectable biologic agents:** Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Siliq (brodalumab), Stelara (ustekinumab), Taltz (ixekizumab), Tremfya (guselkumab)	The FDA is expected to review the application by March 24, 2018. If approved, tildrakizumab will offer another SC option for plaque psoriasis. Tildrakizumab will be included in Specialty Guideline Management subsequent to approval.

[1] RxPipeline, September 2017.
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