Specialty Pharmacy Pipeline

Drugs to Watch

Anticipated Launches | Q3–Q4 2017

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.
Hepatitis C Virus (HCV)	glecaprevir/ pibrentasvir oral AbbVie	The treatment of genotype (GT) 1, 2, 3, 4, 5 and 6 chronic HCV infection, including in patients with severe renal impairment, compensated cirrhosis and in those who have experienced a previous treatment failure with an oral direct-acting antiviral (DAA) regimen	Pending FDA approval	Hepatitis C is a viral disease that can lead to liver damage or failure, liver cancer and death. Chronic HCV infection is the most common reason for liver transplantation in the United States. Approximately 2.7 million people in the United States have chronic HCV infection; genotypes 1, 2, 3 and 4 HCV account for approximately 76%, 12%, 10% and 1% of these cases, respectively. Genotypes 5 and 6 are uncommon and account for less than 1% of cases of HCV in the United States.[4] It is estimated that 5% to 10% of patients experience DAA treatment failure and may be candidates for salvage therapy.[5]	**Oral Direct-Acting Antiviral Agents:** Daklinza (daclatasvir), Epclusa (sofosbuvir/ velpatasvir), Harvoni (ledipasvir/sofosbuvir), Olysio (simeprevir), Sovaldi (sofosbuvir), Technivie (ombitasvir/ paritaprevir/ritonavir), Viekira Pak/Viekira Pak XR (ombitasvir/ paritaprevir/ritonavir and dasabuvir), Zepatier (elbasvir/ grazoprevir)	The FDA is expected to review the applications for glecaprevir/ pibrentasvir and sofosbuvir/ velpatasvir/voxilaprevir by August 2, 2017, and August 8, 2017, respectively. Both agents have been granted Breakthrough Therapy Designation for the treatment of GT1 patients who experienced a previous DAA treatment failure and would provide the first treatment regimens for salvage therapy. It is expected that glecaprevir/ pibrentasvir will also offer an eight-week, pan-genotypic regimen for treatment-naïve patients without cirrhosis. Both agents will be included in Specialty Guideline Management subsequent to approval.
	sofosbuvir/ velpatasvir/ voxilaprevir oral Gilead	The treatment of GT 1, 2, 3, 4, 5 and 6 chronic HCV infection in patients who have experienced a previous treatment failure with an oral DAA regimen	Pending FDA approval			

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Hereditary Angioedema (HAE)	Haegarda (C1 esterase inhibitor, human) subcutaneous injection CSL Behring	The prevention of HAE attacks	Approved 06/22/2017	HAE is a rare, genetic disorder characterized by episodic attacks of edema (swelling) that can be life-threatening. The edema can affect the face, throat, abdomen and other areas. HAE is estimated to occur in 1 per 50,000-150,000 Americans.[6] Treatment modalities include routine prophylaxis to prevent attacks, management of acute attacks and limited prophylactic therapy in situations where attacks may occur (e.g., dental surgery, endoscopy).	**Prophylaxis:** Cinryze (C1 esterase inhibitor, human) intravenous (IV), danazol oral **Acute treatment:** Berinert (C1 esterase inhibitor, human) IV, Kalbitor (ecallantide) subcutaneous (SC), Firazyr (icatibant) SC, Ruconest (C1 esterase inhibitor, recombinant) IV	Haegarda is the first approved subcutaneously administered and self-administered product for the prophylaxis of HAE attacks. Haegarda has been added to Specialty Guideline Management.
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.[7] 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.[8] Of these patients, approximately 10% have a nonsense mutation.[9]	**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	Idhifa (enasidenib) oral Celgene/Agios Pharmaceuticals	The treatment of relapsed or refractory acute myeloid leukemia (AML) in patients with isocitrate dehydrogenase (IDH)-2 mutations	Pending FDA approval	AML is a type of blood cancer that starts in certain immature blood cells and progresses quickly.[10] The average lifetime risk for AML is less than 0.5%. It occurs most commonly in individuals 45 years of age and older. Approximately 9% of AML patients have an IDH2 mutation.[11]	None	The FDA is expected to review the application by August 30, 2017. If approved, enasidenib would offer the first targeted treatment option for AML patients with IDH mutations. Enasidenib will be included in Specialty Guideline Management subsequent to approval.
	Lynparza (olaparib) oral tablet *new formulation* AstraZeneca	The maintenance treatment of recurrent ovarian, fallopian tube, or primary peritoneal cancer in women who are in complete or partial response to platinum-based chemotherapy in women with BRCA mutations	Pending FDA approval	Ovarian cancer is the fifth leading cause of cancer death in women.[12] Approximately 12 new cases of ovarian cancer per 100,000 women occur yearly.[13] It is estimated that BRCA mutations occur in 15% of ovarian cancers.[11] Many patients receive platinum-based chemotherapy as the initial treatment for advanced ovarian cancer. Maintenance treatment is used to delay disease progression or relapse in patients who have responded to the initial treatment.	**Maintenance treatment:** Zejula (niraparib) **Relapsed or refractory disease:** Lynparza (olaparib) capsule, Rubraca (rucaparib)	The FDA is expected to review the application by July 28, 2017. If approved, Lynparza tablet would offer an additional option for the maintenance treatment of ovarian cancer in patients with BRCA mutations. The new formulation of Lynparza will be added to Specialty Guideline Management subsequent to approval.

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Oral Oncology (continued)	Nerlynx (neratinib) oral Puma Biotechnology	The extended adjuvant treatment of early-stage HER-2 positive breast cancer in patients who received prior trastuzumab therapy	Pending FDA approval	Breast cancer is the most common cancer among women in the United States.[14] 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. Adjuvant therapy is used to delay disease progression or relapse in patients who have responded to the initial treatment.	**Adjuvant treatment:** Herceptin (trastuzumab) intravenous (IV) **Advanced or metastatic disease:** Herceptin (trastuzumab) IV, Perjeta (pertuzumab) IV, Tykerb (lapatinib) oral, Kadcyla (ado-trastuzumab emtansine) IV	The FDA is expected to review the application by July 21, 2017. If approved, neratinib would offer an oral treatment option for the adjuvant treatment of HER-2 positive breast cancer. Neratinib will be included in Specialty Guideline Management subsequent to approval.
Psoriasis	Tremfya (guselkumab) subcutaneous injection Janssen/Johnson & Johnson	The treatment of moderate to severe plaque psoriasis	Pending FDA approval	Psoriasis is an immune disease primarily affecting the skin and joints.[15] 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.	**Injectable biologic agents:** Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Siliq (brodalumab), Stelara (ustekinumab), Taltz (ixekizumab) **Oral agent:** Otezla (apremilast)	The FDA is expected to review the application by July 17, 2017. If approved, guselkumab would offer another injectable option for those with persistent symptoms despite topical therapy. Guselkumab will be included in Specialty Guideline Management subsequent to approval.

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Rheumatoid Arthritis (RA)	Plevensia (sirukumab) subcutaneous injection GlaxoSmithKline/ Janssen/Johnson & Johnson	The treatment of moderate-to-severe RA	Pending FDA approval	RA is an autoimmune disorder in which the immune system attacks healthy tissues.[16] RA can cause pain, stiffness, and decreased function of the hands and feet as well as other joints. Other organs such as the lungs and eyes may be affected as well. RA is estimated to affect 1.2 million Americans; approximately 75% of those affected are women.	**Selected biologic injectable agents:** Actemra (tocilizumab), Cimzia (certolizumab pegol), Enbrel (etanercept), Humira (adalimumab), Kevzara (sarilumab), Kineret (anakinra), Orencia (abatacept), Simponi (golimumab) **Selected oral agents:** methotrexate (e.g., Trexall), Xeljanz/ Xeljanz XR (tofacitinib)	The FDA is expected to review the application by September 23, 2017. If approved, sirukumab would offer a highly effective treatment option for RA and will be included in Specialty Guideline Management.
Sickle Cell Disease (SCD)	Endari (L-glutamine) oral powder Emmaus Life Sciences	The treatment of SCD in adults and children 5 years and older	Approved 07/07/2017	SCD is a genetic blood disorder with chronic symptoms that can worsen over time.[17] Complications of SCD may include pain crisis, anemia, infections, acute chest syndrome, blood clots, stroke, and leg ulcers. The severity of these complications can vary from mild to life threatening. In the United States, approximately 100,000 Americans have SCD, with African Americans having an increased risk for inheriting the disease.	**Oral agent:** hydroxyurea (e.g., Hydrea)	L-glutamine is the first approved treatment for pediatric patients with sickle cell disease and the first new sickle cell treatment for adults in nearly 20 years. L-glutamine will be included in Specialty Guideline Management.

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Systemic Lupus Erythemato-sus (SLE)	Benlysta (belimumab) subcutaneous injection *new formulation* Human Genome Sciences/ GlaxoSmithKline	The treatment of autoantibody positive active SLE in adults	Pending FDA approval	SLE is an immune disease where the body attacks its own tissues leading to inflammation and damage. Symptoms can vary based on the affected body organs and may include fever, fatigue, rash, swollen joints, seizures, vision changes, and difficulty breathing. People with SLE may have active flares with periods of remission. In the United States, it is estimated that 1.5 million people have a form of lupus; SLE accounts for 70% of cases.[18] SLE occurs most often in women of childbearing age with an estimated 129 out of every 100,000 women being affected.[19]	**Existing formulation:** Benlysta (belimumab) intravenous injection Oral therapy options include corticosteroids and hydroxychloroquine (e.g., Plaquenil)	The FDA is expected to review the application by July 23, 2017. If approved, this would allow for self administration of belimumab, making it an alternative to the existing intravenous injection formulation. The new formulation of Benlysta will be included in Specialty Guideline Management subsequent to approval.

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