Specialty Pharmacy Pipeline

Drugs to Watch

Anticipated Launches | Q2–Q3 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
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.[2] It is estimated that 5% to 10% of patients experience DAA treatment failure and may be candidates for salvage therapy.[3]	**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			
Hereditary Angioedema (HAE)	Haegarda (C1 esterase inhibitor, human) subcutaneous injection CSL Behring	The prevention of HAE attacks	Pending FDA approval	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.[4] 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, danazol oral **Acute treatment:** Berinert (C1 esterase inhibitor, human) intravenous, Kalbitor (ecallantide) subcutaneous, Firazyr (icatibant) subcutaneous, Ruconest (C1 esterase inhibitor, recombinant) intravenous	The FDA is expected to review the application by June 30, 2017. If approved, Haegarda would be the first subcutaneously administered and first self-administered product for the prophylaxis of HAE attacks. Haegarda will be included in Specialty Guideline Management subsequent to approval.

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Movement Disorders	Austedo (deutetrabenazine) oral Teva Pharmaceuticals	The treatment of chorea associated with Huntington's disease (HD)	Approved 04/03/2017; Launch is expected in April 2017	HD is a genetic neurodegenerative disorder. It can affect movement and thinking and may be associated with emotional problems.[5] Chorea (involuntary jerking or twitching of the fingers, feet, face or trunk) commonly occurs with HD and can lead to difficulty walking and an increased risk of falls. It is estimated that HD affects 4 to 8 per 100,000 people in the United States; chorea affects approximately 90% of these individuals.[6]	tetrabenazine products (i.e., Xenazine and generics)	Austedo offers an additional therapy option for HD with a longer dosing interval. Austedo will be included in Specialty Guideline Management.
		The treatment of tardive dyskinesia (TD)	Pending FDA approval	TD is characterized by involuntary movement of the lip, tongue, face, trunk and extremities.[7] TD most commonly occurs in patients who receive long-term treatment with antipsychotic medications (e.g., chlorpromazine, haloperidol, risperidone) but can occur with other medications (e.g., metoclopramide). The estimated risk of developing TD with long-term antipsychotic treatment is 30% to 50%.[8]	None	The FDA is expected to review the TD application for Austedo by August 30, 2017. Both products have been granted Breakthrough Therapy Designation, and would offer the first treatment options for TD. Both drugs will be included in Specialty Guideline Management.
	Ingrezza (valbenazine) oral Neurocrine Biosciences	The treatment of TD	Approved 04/11/2017; Launch is expected in April 2017			
	Radicava (edaravone) intravenous infusion Mitsubishi Tanabe Pharma	The treatment of amyotrophic lateral sclerosis (ALS; also known as Lou Gehrig's disease)	Pending FDA approval	ALS is a disorder characterized by progressive destruction of motor neurons, the nerves that control voluntary muscles. Patients may eventually lose the ability to eat, speak, walk and breathe on their own. Approximately 20,000 Americans have ALS.[9]	riluzole products (i.e., Rilutek and generics)	The FDA is expected to review the application by June 20, 2017. If approved, Radicava would offer a symptomatic treatment option for patients with early-stage disease. Radicava will be included in Specialty Guideline Management upon approval.

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Oral Oncology	brigatinib oral Ariad Pharmaceuticals	The treatment of metastatic ALK-positive non-small cell lung cancer (NSCLC) in patients who are resistant or intolerant to crizotinib	Pending FDA approval	Lung cancer is the second most common cause of cancer and is the leading cause of cancer death in the United States.[10] NSCLC is responsible for 80% to 85% of all lung cancer cases while the ALK mutation is present in approximately 5% of these cases. Nearly all patients treated with Xalkori (crizotinib) will eventually develop resistance.[11]	Alecensa (alectinib), Zykadia (ceritinib)	The FDA has granted Breakthrough Therapy Designation to brigatinib and is expected to review the application by April 29, 2017. If approved, brigatinib would provide an additional treatment for crizotinib-resistant, ALK-positive NSCLC. Brigatinib will be included in Specialty Guideline Management subsequent to approval.
	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.[12] 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 **Advanced or metastatic disease:** Herceptin (trastuzumab) intravenous, Perjeta (pertuzumab) intravenous, Tykerb (lapatinib) oral, Kadcyla (ado-trastuzumab emtansine) intravenous	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.

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Oral Oncology (continued)	Zejula (niraparib) oral Tesaro	The maintenance treatment of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in women who are in complete or partial response to platinum-based chemotherapy	Approved 03/27/2017; Launch is expected in April 2017	Ovarian cancer is the fifth leading cause of cancer death in women.[13] Approximately 12 new cases of ovarian cancer per 100,000 women occur yearly.[14] It is estimated that BRCA mutations occur in 15% of ovarian cancers.[16] 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:** None **Relapsed or refractory disease:** Lynparza (olaparib), Rubraca (rucaparib)	Zejula was granted Breakthrough Therapy Designation and is the first drug approved for the maintenance treatment of ovarian cancer. It will be included in Specialty Guideline Management.
	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			The FDA is expected to review the application by July 28, 2017. If approved, Lynparza would offer an additional option for the maintenance treatment of ovarian cancer in patients with BRCA mutations.

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Oral Oncology (continued)	enasidenib oral Celgene/Agios Pharmaceuticals	The treatment of relapsed or refractory 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.[15] 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.[16] Nearly one-third of patients diagnosed with AML have the FLT3 mutation which is associated with poorer outcomes. Mast cells are a type of blood cell involved in allergic reactions.[17] In systemic mastocytosis, an abnormal number of mast cells accumulate in organs throughout the body. Aggressive SM is a rare form of the disease that progresses rapidly and can lead to impaired organ function. ASM affects 1 in 250,000 to 400,000 individuals worldwide.[18] The average length of survival for ASM is two to four years after diagnosis.	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.
	midostaurin oral Novartis	The treatment of newly diagnosed FLT3-mutated acute myeloid leukemia (AML) in adults and the treatment of aggressive systemic mastocytosis (ASM)	Pending FDA approval		**FLT3-mutated AML:** None **ASM:** Gleevec (imatinib; only approved for small subset of patients); Symptomatic therapies (e.g., cromolyn, famotidine, ranitidine, omeprazole)	The FDA has granted Breakthrough Therapy Designation to midostaurin for the treatment of newly diagnosed FLT3-mutated AML in adults. The FDA is expected to review the applications for both indications by May 14, 2017. If approved, midostaurin would provide the first therapy targeting FLT3-mutated AML. Midostaurin would also provide an additional option for the treatment of ASM. Midostaurin will be included in Specialty Guideline Management subsequent to approval.

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Osteoporosis	abaloparatide subcutaneous injection Radius	The treatment of postmenopausal osteoporosis (PMO)	Pending FDA approval	Osteoporosis is a disease that causes thin, weakened bones and increases the risk of broken bones.[19] Nearly 54 million people in the United States have osteoporosis. It is estimated that one in two women 50 years of age and older will experience a fracture due to osteoporosis.	**Oral agents:** Bisphosphonates (e.g., alendronate, ibandronate, risedronate [e.g., Atelvia]), Evista (raloxifene) **Injectable/ infusion agents:** Forteo (teriparatide), Prolia (denosumab), Reclast (zoledronic acid)	The FDA is expected to review the applications by June 30, 2017 and July 19, 2017, respectively. If approved, these drugs would offer additional treatment options for PMO patients at high risk of fracture. Both products will be included in Specialty Guideline Management subsequent to approval.
	Evenity (romosozumab) subcutaneous injection Amgen/UCB	The treatment of PMO	Pending FDA approval			
Rheumatoid Arthritis (RA)	baricitinib oral Eli Lilly/Incyte	The treatment of moderate-to-severe RA	Pending FDA approval	RA is an autoimmune disorder in which the immune system attacks healthy tissues.[20] 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), Kineret (anakinra), Orencia (abatacept), Simponi (golimumab) **Selected oral agents:** methotrexate (e.g., Trexall), Xeljanz (tofacitinib)	The FDA is expected to review the baricitinib application by April 19, 2017, and the sirukumab application by September 23, 2017. It is anticipated that the FDA will review the sarilumab application in 2Q 2017. If approved, all three drugs would offer highly effective treatment options for RA and will be included in Specialty Guideline Management.
	Kevzara (sarilumab) subcutaneous injection Regeneron/ Sanofi	The treatment of moderate-to-severe RA	Pending FDA approval			
	sirukumab subcutaneous injection GlaxoSmithKline/ Janssen/Johnson & Johnson	The treatment of moderate-to-severe RA	Pending FDA approval			

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