Specialty Pharmacy Pipeline

Drugs to Watch

Anticipated Launches | Q1–Q2 2017

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Anticipated Launches – 1st Quarter 2017 to 2nd Quarter 2017

Therapeutic Category	Product Name, Route of Administration and Manufacturer[1]	Proposed Indication[1]	FDA Phase of Study[1]	Disease Prevalence	Select Available FDA-Approved Therapies	Comments — CVS Health Initial Recommendations
Atopic Dermatitis	Dupixent (dupilumab) Subcutaneous injection Regeneron Pharmaceuticals/Sanofi	The treatment of moderate-to-severe atopic dermatitis (AD) in adults	Pending U.S. Food and Drug Administration (FDA) approval	AD is a type of eczema characterized by itchy lesions and is often associated with allergic disorders (e.g., asthma, rhinitis or hay fever).[2] Open or crusted sores and skin infections may also occur. AD affects 2 to 10% of adults in the United States; of those, ~32% have moderate symptoms and ~15% have severe symptoms.[3]	Traditional therapy includes emollients, topical steroids (e.g., Cloderm [clocortolone], Locoid lotion [hydrocortisone]) and topical calcineurin inhibitors (Elidel [pimecrolimus], Protopic [tacrolimus])	The FDA has granted Breakthrough Therapy designation to Dupixent and is expected to review the application by March 29, 2017. If approved, Dupixent would be the first biologic agent for the treatment of AD. Dupixent will be included in Specialty Guideline Management subsequent to approval.
Movement Disorders	Austedo (deutetrabenazine) Oral Teva Pharmaceuticals	The treatment of chorea associated with Huntington's disease (HD)	Pending FDA approval	HD is a genetic disorder that leads to the deterioration of the brain. HD can affect movement and thinking and may be associated with emotional problems.[4] 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 falling. It is estimated that HD affects 4 to 8 per 100,000 people in the United States, while chorea affects approximately 90% of these individuals.[5]	tetrabenazine products (e.g., Xenazine and generics)	The FDA is expected to review the application by April 3, 2017. If approved, Austedo offers an additional therapy option with a less frequent dosing interval. Austedo will be included in Specialty Guideline Management subsequent to approval.
	Ingrezza (valbenazine) Oral Neurocrine Biosciences	The treatment of tardive dyskinesia (TD)	Pending FDA approval	TD is characterized by involuntary movement of the lip, tongue, face, trunk and extremities.[6] TD most commonly occurs in patients who receive long-term treatment with antipsychotic medications (e.g., chlorpromazine, haloperidol, risperidone) but can occur with various other medications (e.g., amitriptyline, fluoxetine, metoclopramide, sertraline). The estimated risk of developing TD with long-term antipsychotic treatment is 30 to 50%.[7]	None	The FDA has granted Breakthrough Therapy Designation to Ingrezza and is expected to review the application by April 11, 2017. If approved, Ingrezza would be the first FDA-approved treatment for TD. Ingrezza will be included in Specialty Guideline Management subsequent to approval.

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Multiple Sclerosis	Ocrevus (ocrelizumab) Intravenous injection Biogen/Genentech	The treatment of primary progressive multiple sclerosis (PPMS) and the treatment of relapsing-remitting multiple sclerosis (RRMS)	Pending FDA approval	MS is a chronic disease that damages the protective covering of nerves leading to a variety of symptoms ranging from numbness in the arms/legs to paralysis or loss of vision.[8] In RRMS, attacks (relapses) are followed by periods of recovery (remissions). In PPMS, relapses can occur but periods of remission do not. The risk of developing MS is approximately 1 in 750 but rises to 1 in 40 to 1 in 80 for individuals with a close relative with MS. MS is at least 2 to 3 times more common in women than in men. RRMS is the most common form accounting for ~85% while PPMS accounts for ~15% of cases.	**IV infusion agents:** Lemtrada (alemtuzumab), Tysabri (natalizumab) **IM/SC injection agents:** Avonex, Rebif (interferon beta 1a); Betaseron, Extavia (interferon beta-1b); glatiramer (Copaxone and generic); Plegridy (peginterferon beta 1a), Zinbryta (daclizumab) **Oral agents:** Aubagio (teriflunomide) Gilenya (fingolimod) Tecfidera (dimethyl fumarate)	The FDA is expected to review the application by March 28, 2017. Ocrevus was granted Breakthrough Therapy designation for the treatment of PPMS and, if approved, would provide the first disease modifying therapy for PPMS. Ocrevus will be included in Specialty Guideline Management subsequent to approval.
Muscular Dystrophy	deflazacort Oral Marathon Pharmaceuticals	The treatment of Duchenne muscular dystrophy (DMD)	Pending FDA approval	Muscular dystrophy is a group of genetic disorders characterized by progressive muscle weakness and degeneration.[9] 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 20s. In the United States, approximately 15 per 100,000 males from 5 to 24 years of age are reported to have DMD.[10]	Corticosteroids (e.g., prednisone) may be offered Exondys 51 (eteplirsen) may be considered for patients with mutations amenable to exon 51 skipping	The FDA is expected to review the application for deflazacort by February 9, 2017. If approved, deflazacort would provide a symptomatic therapy for DMD. Deflazacort will be included in Specialty Guideline Management subsequent to approval.

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Oral Oncology	binimetinib Oral Array Biopharma	The treatment of advanced NRAS mutation-positive melanoma	Pending FDA approval	Cancer of the skin is the most common form of cancer in the United States.[11] Melanoma is a type of skin cancer that accounts for 1% of all skin cancer cases. The NRAS mutation is present in 13 to 25% of cases of melanoma.[12] Some studies have noted poorer overall survival with the presence of the NRAS mutation.[13]	None	The FDA is expected to review the application for binimetinib by June 30, 2017. If approved, binimetinib would provide the first therapy specifically targeting NRAS-mutant melanoma. Binimetinib will be included in Specialty Guideline Management subsequent to approval.
	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.[14] 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 crizotinib will eventually develop resistance.[15]	Alecensa (alectinib), Xalkori (crizotinib), 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.
	ribociclib Oral Astex Pharmaceuticals/ Novartis	The treatment of hormone receptor positive, HER2 negative advanced or metastatic breast cancer in postmenopausal women, in combination with letrozole	FDA approval pending	Breast cancer is the most common cancer among women in the United States.[16] Approximately 12% of women will develop breast cancer during her lifetime. Certain hormones (estrogen, progesterone) or proteins (HER2) can promote the growth of breast cancer. Two of three breast cancers are hormone receptor positive while four of five cases are HER2 negative.	Ibrance (palbociclib)	The FDA has granted Breakthrough Therapy designation to ribociclib and is expected to review the application by May 1, 2017. If approved, ribociclib will provide an additional treatment option for hormone receptor positive, HER2 negative breast cancer. Ribociclib will be included in Specialty Guideline Management subsequent to approval.

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Oral Oncology (continued)	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	AML is a type of blood cancer that starts in certain immature blood cells and progresses quickly.[17] The average lifetime risk for AML is less than 0.5%. It occurs most commonly in individuals 45 years of age and older. 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.[18] 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.[19] The average length of survival for ASM is two to four years after diagnosis.	**FLT3-mutated AML:** None **ASM:** Gleevec (imatinib); Symptomatic therapies (e.g., antihistamines, corticosteroids, cromolyn, famotidine, montelukast, 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.
	telotristat Oral Lexicon Pharmaceuticals	The treatment of carcinoid syndrome	Pending FDA approval	Carcinoid tumors are a rare type of cancer that begins in certain cells (typically in the intestinal tract, lungs, stomach or pancreas) that produce hormones.[20] These tumors may stimulate overproduction of the hormones and can lead to carcinoid syndrome which is characterized by flushing and diarrhea. Approximately 10% of patients with carcinoid tumors develop carcinoid syndrome.	octreotide (generic, Sandostatin, Sandostatin LAR), Somatuline Depot (lanreotide)	The FDA is expected to review the application by February 28, 2017. If approved, telotristat will provide an oral agent for patients with insufficient response to an injectable product. Telotristat 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.[21] 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, risendronate [e.g., Atelvia]), Evista (raloxifene) **Injectable/infusion agents:** Forteo (teriparatide), Prolia (denosumab), Reclast (zoledronic acid)	The FDA is expected to review the application by March 30, 2017. Abaloparatide will be included in Specialty Guideline Management subsequent to approval.
Psoriasis	Siliq (brodalumab) Subcutaneous injection Valeant Pharmaceuticals	The treatment of moderate-to-severe plaque psoriasis	Pending FDA approval	It is estimated that approximately 2.2% of the U.S. population has psoriasis.[22] Plaque psoriasis is the most common form of psoriasis and is characterized by elevated, inflamed, scaly skin. These plaques are most often visible on the elbows, knees and scalp.	**SC injectable biologic agents:** Cosentyx (secukinumab), Enbrel (etanercept), Humira (adalimumab), Stelara (ustekinumab), Taltz (ixekizumab) **Selected oral agents:** methotrexate (e.g., Trexall), Otezla (apremilast)	The FDA is expected to review the application by February 16, 2017. Siliq will be included in Specialty Guideline Management subsequent to approval.
Rheumatoid Arthritis	baricitinib Oral Eli Lilly/Incyte	The treatment of moderate-to-severe rheumatoid arthritis (RA)	Pending FDA approval	RA is an autoimmune disorder in which the immune system attacks healthy tissues.[23] RA can cause pain, stiffness, 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), Orencia (abatacept), Simponi (golimumab) **Selected oral agents:** methotrexate (e.g., Trexall), Xeljanz (tofacitinib)	The FDA is expected to review the application for baricitinib by April 19, 2017. Baricitinib will be included in Specialty Guideline Management subsequent to approval.

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