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3RD QUARTER 2019
PIPELINE REPORT

Be "in the know". Confidio is committed to helping clients anticipate pharmaceutical trends and potential shifts in medication cost management. Confidio remains informed of the latest FDA drug approvals, medications in development, and upcoming specialty/biosimilar pipeline therapies.

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Look for these Drug Pipeline Reports each quarter.

PIPELINE HIGHLIGHTS:

Recent Approvals

- **Zolgensma (onasemnogene abeparvovec-xioi)** – Spinal muscular atrophy (SMA)
- **Mayzent (siponimod)** – Secondary progressive multiple sclerosis (SPMS)
- **Mavenclad (cladribine)** – Relapsing-remitting multiple sclerosis
- **Vyndaqel (tafamidis)** – Cardiomyopathy of transthyretin mediated amyloidosis (ATTR-CM)
- **Evenity (romosozumab-aqqg)** – Osteoporosis
- **Skyrizi (risenkizumab-rzaa)** – Plaque psoriasis
- **Sunosi (solriamfetol)** – Excessive daytime sleepiness due to narcolepsy or sleep apnea

Anticipated FDA Approvals

- **Upadacitinib** – Moderate to severe rheumatoid arthritis 3Q2019
- **Fedratinib** – Myelofibrosis, polycythemia vera 9/3/2019
- **Polatuzumab vedotin** – Diffuse large B cell lymphoma (DLBCL); Follicular lymphoma; B-cell lymphoma 8/19/2019
- **Istradefylline** – Parkinson's disease 8/27/2019
- **Selinexor** – Multiple Myeloma 7/6/2019
- **Pexidartinib** – Pigmented villonodular synovitis (PVNS) 8/3/2019
- **Entrectinib** – NTRK fusion-positive, locally advanced or metastatic solid tumors 8/18/2019
- **Golodirsen** – Duchenne muscular dystrophy 8/19/2019
- **Quizartinib** – Relapsed/refractory FLT3-ITD acute myeloid leukemia
- **Zynquista (sotagliflozin)** – Type 1 diabetes patients who lack adequate blood sugar control on insulin therapy

Anticipated Biosimilars FDA Launch Dates

- **Ogivri (trastuzumab-dkst)** – Biosimilar for reference product Herceptin – FDA Approved 12/2017; Anticipated Launch Date June 2019
- **Mvasi (bevacizumab-awwb)** – Biosimilar for reference product Avastin – FDA Approved 9/2017; Anticipated Launch Date July 2019
- **Ontruzant (trastuzumab-dttb)** – Biosimilar for reference product Herceptin – FDA Approved 1/2019; Anticipated Launch Date 2019-2020
- **Hyrimoz (adalimumab-adaz)** – Biosimilar for reference product Humira – FDA Approved 10/2018; Anticipated Launch Date 2022-2023
- **Erelzi (etanercept-szzs)** – Biosimilar for reference product Enbrel – FDA Approved 8/2016; Anticipated Launch Date 2019-2029
- **Truxima (rituximab-abbs)** – Biosimilar for reference product Rituxan – FDA Approved 11/2018; Anticipated Launch Date Q1-2 2019

Recent FDA Approvals

Approval Date	Estimated WAC / Year & Benefit coverage	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Therapy Options Approximate WAC/Year
05/24/2019	**$2,125,000** (possible 5 year payment plan) **Pharmacy benefit**	**Zolgensma (onasemnogene abeparvovec-xioi)** AveXis Novartis	**Neuromuscular condition** Spinal muscular atrophy (SMA)	IV, once per lifetime Anticipated that it will be administered in hospital outpatient departments. Before Spinraza (pre-12/2016), SMA was usually fatal within 2 years	Gene therapy–1X curative treatment to be given ASAP after diagnosis.	**Therapy Options:** › Spinraza (nusinersen): up to $750,000 year 1; $375,000 after that
05/3/2019	**$225,000** **Pharmacy benefit**	**Vyndaqel (tafamidis meglumine)** **Vyndamax (tafamidis)** FoldRx/Pfizer	**Stiff heart syndrome** *due to abnormal protein build-up* Cardiomyopathy of transthyretin mediated amyloidosis (ATTR-CM)	Oral, once daily ATTR-CM is rare, fatal	Small studies so far; no drug-related side effects have been identified. Vyndaqel has 4 capsules per dose, will be launched immediately. Vyndamax will offer a one-tablet dose and be launched in 2h2019.	**Therapy Options:** › Heart or heart-liver transplant
03/26/2019	**$88,500** **Pharmacy benefit**	**Mayzent (siponimod)** Novartis	**Multiple Sclerosis (relapsing forms)** Including secondary progressive MS (SPMS)	Oral, once daily SPMS leads to progressive, irreversible disability	Sphingosine 1-phosphate (S1P) receptor modulator Mayzent can slow progression of SPMS. The other drug shown to slow progression, mitoxantrone, may cause heart failure and cancer.	**Therapy Options:** If still experiencing relapses : › Gilenya (fingolimod): $200,000 › Ocrevus (ocrelizumab): $65,000 › Lemtrada (alemtuzumab): $68,711 › Tysabri (natalizumab): $83,148 SPMS without relapses: › Mitoxantrone (generic): $1000
03/29/2019	**$85,000** (based on 70-kg person) **Pharmacy Benefit**	**Mavenclad (cladribine)** EMD Serono	**Multiple Sclerosis (relapsing forms)** Including secondary progressive MS (SPMS)	Oral Unique Dosing Regimen: 2 courses of multiple 10mg tablets given one month apart per year for 2 years	Nucleoside analog that depletes B and T lymphocytes (Immune cells)	**Therapy Options:** › Gilenya (fingolimod): $200,000 › Ocrevus (ocrelizumab): $65,000 › Lemtrada (alemtuzumab): $68,711 › Tysabri (natalizumab): $83,148

Recent FDA Approvals *(continued)*

Approval Date	Estimated WAC / Year & Benefit coverage	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Therapy Options Approximate WAC/Year
04/20/2019	**$22,000** **Pharmacy Benefit**	**Evenity (romosozumab-aqqg)** Amgen/UCB	**Osteoporosis:** Osteoporosis in postmenopausal women with high risk of fractures	SubQ injection monthly for 1 yr	First in class mechanism of action (sclerostin inhibitor) Reduces vertebral fracture risk, increases bone mineral density	**Therapy Options (AWP pricing):** › Tymlos (abaloparatide): $20,000 › Forteo (teriparatide): $41,000
04/23/2019	**$63,425** (based on 4.3 doses/ year) **Pharmacy Benefit**	**Skyrizi (risankizumab-rzaa)** AbbVie/BI	**Plaque Psoriasis** Moderate to Severe	SubQ injection every 12 weeks after induction	Interleukin-23 inhibitor	**Therapy Options:** › Cosentyx (secukinumab): $67,326 › Taltz (ixekizumab): $69,784 › Tremfya (guselkumab): $70,586
03/20/2019	**TBD following DEA scheduling and launch**	**Sunosi (solriamfetol)** Jazz SK Biopharma-ceuticals	**Sleep Disorders:** Excessive daytime sleepiness in obstructive sleep apnea or narcolepsy	Oral, once daily Estimated 65% excessive sleepiness persists in CPAP patients	Solriamfetol will offer alternative for intolerant CPAP patients New Chemical Entity, Orphan Drug	**Therapy Options:** › Positive Airway Pressure therapy or › Continuous Positive Airway Pressure (CPAP)

Anticipated FDA Approvals

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Options
3Q19	**Brand name TBD** upadacitinib (aka ABT-494) Abbvie	**Inflammatory conditions:** Moderate to severe rheumatoid arthritis	Oral	Janus kinase (JAK) inhibitor. FDA Priority Review status. Also being studied for atopic dermatitis (has FDA Breakthrough Therapy status for this), ulcerative colitis, Crohn's disease.	**Therapy Options:** › Humira (adalimumab) › Xeljanz (tofacitinib)
09/3/2019	**Brand name TBD** fedratinib Impact Biomedicines Celgene	**Bone Marrow Dysfunction:** Myelofibrosis; Polycythaemia Vera	Oral	Second generation Janus kinase (JAK) inhibitor, granted priority review by FDA Available through Expanded Access, which allows patients with **immediately life-threatening conditions or serious diseases or conditions** to receive an investigational drug outside of clinical trials when no alternatives are available.	**Therapy Options:** › Preferred: bone marrow replacement with hematopoietic cell transplant › Jakafi (ruxolitinib)

Anticipated FDA Approvals *(continued)*

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Options
08/19/2019	**Brand name TBD** polatuzumab vedotin(aka DCDS4501A) Genentech Roche Seattle Genetics	**Lymphoma (cancer):** Diffuse large B cell lymphoma (DLBCL); Follicular lymphoma; B-cell lymphoma	IV Patients with relapsed/ refractory DLBCL and those ineligible for stem cell/bone marrow transplant have limited treatment options, poor prognosis	First-in-class product, granted priority review status by FDA. Used in combination with bendamustine and rituximab.	**Therapy Options:** › Various combination drug regimens are used in these cancers, e.g. R-CHOP
08/27/2019	**Brand name TBD** istradefylline (aka KW-6002) Kyowa Hakko Kirin	**Parkinson's Disease (PD)**	Oral Used together with levodopa/ carbidopa for "off" episodes (where levodopa/carbidopa effect is decreased).	Istradefylline is the first drug of its type (adenosine A 2A receptor antagonist) for PD Current treatments fall into three categories; each drug in these categories has significant clinical limitations.	**Therapy Options:** › Dopamine agonists (pramipexole; ropinirole; apomorphine; rotigotine): › COMT inhibitors (entacapone; tolcapone) › MAO B inhibitors (rasagiline; safinamide; selegiline)
07/6/2019	**Brand name TBD** selinexor Karyopharm	**Bone Marrow Cancer:** Penta- Refractory Multiple Myeloma	Oral (twice weekly) FDA application for a topical product was withdrawn.	First in class, oral Selective Inhibitor of Nuclear Export compound In March 2019, the FDA extended its deadline to review this product by 3 months to allow review of new data.	**Therapy Options:** › Bortezomib (Velcade › Carflizomib (Kyprolis) › Ixazomib (Ninlaro)
08/3/2019	**Brand name TBD** pexidartinib (aka PLX3397) Plexxikon Daiichi Sankyo	**Rare, painful, nonmalignant joint condition:** Pigmented villonodular synovitis (PVNS), also known as TGCT	Oral PVNS is an uncommon, non-cancerous condition where cells within a joint multiply and cause pain, movement limitations and joint damage. Cause is unknown.	Tyrosine kinase inhibitor FDA has granted priority review status and Breakthrough Therapy designation. The American Society of Clinical Oncology (ASCO) selected pexidartinib as one of five significant advancements of the year in rare disease treatment.	**Therapy Options:** › Surgery
08/18/2019	**Brand name TBD** entrectinib (aka RG6268) Roche Genentech	**Cancer:** Solid tumors, including non-small cell lung cancer, that have specific genetic features	Oral	Tyrosine kinase inhibitor FDA has granted Breakthrough Therapy Designation (BTD) status for the treatment of NTRK fusion-positive cancers in some patients. Therapy is personalized.	**Therapy Options:** None for this patient population.
08/19/2019	**Brand name TBD** golodirsen (aka SRP-4053) Sarepta Therapeutics	**Duchenne Muscular Dystrophy (DMD)**	IV DMD is a fatal genetic neuromuscular disorder affecting one in 3,500 - 5,000 males born worldwide.	Golodirsen targets DMD with a specific genetic mutation that affects about 8% of DMD patients. It is not curative but may delay worsening of symptoms. Cost-effectiveness has been questioned.	**Therapy Options:** › Exondys (eteplirsen) › Emflaza (deflazacort) › Prednisone

Anticipated FDA Approvals *(continued)*

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Options
08/25/2019	**Brand name TBD** quizartinib Ambit Biosciences Corporation; Daiichi Sankyo	**Leukemia:** Relapsed/ refractory FLT3-ITD acute myeloid leukemia (AML)	Oral AML patients with FLT3-ITD gene mutations have a worse overall prognosis than those without.	FLT-3 inhibitor Quizartinib has been granted Breakthrough Therapy designation and Priority Review status by the FDA.	**Therapy Options:** › Salvage chemotherapy: Xospata (gilteritinib) › Azacitidine or Decogen (decitabine) + Nexavar (sorafenib)
CRL* issued on 03/22/2019	**Zynquista** sotagliflozin Lexicon Phamaceuticals; Sanofi	**Diabetes:** For patients with type 1 diabetes who lack adequate blood sugar control on insulin therapy.	Oral Used along with insulin	Diabetic ketoacidosis, a serious diabetes complication, was more frequent in those given sotagliflozin compared to insulin alone. In January 2019, the FDA Advisory Committee were evenly divided on whether the benefits of Zynquista outweighed the risks.	**Therapy Options:** None

*CRL (Complete Response Letter) is a communication to a drug's manufacturer from the FDA indicating that the application for the drug cannot be approved in its present form.

Biosimilar Pipeline

Approval Date	Launch Date	Biosimilar Name	Biosimilar WAC / Year Cost	Reference Product	Reference Product WAC / Year Cost	Interchangeable	Disease Category*
May 2018	June 2018	Retacrit™ ** (epoetin alfa-epbx)	Retacrit - $154	Epogen Procrit (Epoetin Alfa)	Biosimilar Retacrit -$154 Epogen - $232 Procrit - $360	No	**Hematopoietic:** Treatment of anemia due to chronic kidney disease, Zidovudine in HIV-infected patients, chemotherapy in cancer patients, and reduction of allogeneic red blood cell transfusion in patients' elective surgery
December 2017	Anticipated June 2019	Ogivri (trastuzumab-dkst)	TBD Upon Launch	Herceptin (trastuzumab)	$32,000	No	**Cancer:** Treatment of Human Epidermal growth factor Receptor 2 (HER2) adjuvant breast cancer, metastatic breast cancer, and metastatic gastric cancer
December 2018	To Be Determined	Herzuma (trastuzumab-pkrb)	TBD Upon Launch			Interchangeability is not anticipated	
January 2019	2019-2020	Ontruzant (trastuzumab-dtb)	TBD Upon Launch			Interchangeability is not anticipated	
March 11, 2019	To Be Determined	Trazimera [Pfizer] (trastuzumab-qyyp)	TBD Upon Launch			Interchangeability is not anticipated	
Expected FDA Review June 2019	To Be Determined	Kanjinti [Amgen Allergan] (trastuzumab)	TBD Upon Launch			Interchangeability is not anticipated	

Biosimilar Pipeline *(continued)*

Approval Date	Launch Date	Biosimilar Name	Biosimilar WAC / Year Cost	Reference Product	Reference Product WAC / Year Cost	Interchangeable	Disease Category*
Expected FDA Review TBD 2018	To Be Determined	Grastofil (filgrastim)	TBD Upon Launch	Neupogen (filgrastim)	$5,314	Interchangeability is not anticipated	**Hematopoietic:** To reduce the incidence of infection in patents receiving chemotherapy, reduce the duration and time to recovery from neutropenia caused by chemotherapy, mobilization of progenitor blood cells for collection by leukapheresis, and reducing the incidence and duration of complications due to severe neutropenia.
Expected FDA Review May 2018	To Be Determined	Filgrastim Adello [Adello Biologics Amneal AE Companies Kashiv] (filgrastim)	TBD Upon Launch			Interchangeability is not anticipated	
March 2015	September 2015	Zarxio® ** (filgrastim-sndz)	$4,390			No	
August 2012	2015	Granix® ** (tbo-filgrastim)	$3,999			No	
July 2018	October 2018	Nivestym™ ** (filgrastim-aafi)	$3,504			No	
September 2017	Anticipated July 2019	Mvasi (bevacizumab-awwb)	TBD Upon Launch	Avastin (bevacizumab)	$162,576	No	**Cancer:** Treatment of Metastatic colorectal cancer, Non-squamous non-small cell lung cancer, Glioblastoma, Metastatic renal cell carcinoma, Persistent, recurrent, or metastatic carcinoma of the cervix
Expected FDA Review 2Q2019	To Be Determined	PF-06439535 [Pfizer] (bevacizumab)	TBD Upon Launch			Interchangeability is not anticipated	
December 2017	No US Launch	Ixifi™ (infliximab-qbtx)	Not anticipated to be launched due to acquisition	Remicade (infliximab)	$49,340	No	**Immunological Agent:** Ankylosing spondylitis, Crohn's disease (fistulizing), adult, Crohn's disease, adult and pediatric (6 years or older), Plaque psoriasis, Psoriatic arthritis, Rheumatoid arthritis in combination with methotrexate, Ulcerative colitis, adult
Expected FDA Review December 20, 2019	To Be Determined	ABP 710 [Amgen] (infliximab)	TBD Upon Launch			Interchangeability is not anticipated	
April 2017	July 2017	Renflexis® ** (infliximab-abda)	$31,831			No	
April 2016	November 2016	Inflectra® ** (infliximab-dyyb)	$39,980			No	
August 2017	Anticipated 2023	Cyltezo™ (adalimumab-adbm)	TBD Upon Launch	Humira (adalimumab)	$63,336	No	**Immunosuppressant:** Treatment of rheumatoid arthritis, plaque psoriasis, Crohn's disease, and ulcerative colitis
Expected FDA Review 4Q 2019	To Be Determined	PF-06410293 [Pfizer] (adalimumab)	TBD Upon Launch			Interchangeability is not anticipated	
Expected FDA Review July 2019	To Be Determined	SB5 [Samsung Bioepis Merck & Co Biogen] (adalimumab)	TBD Upon Launch			Interchangeability is not anticipated	
September 2016	Anticipated 2023	Amjevita™ (adalimumab-atto)	TBD Upon Launch			No	
October 2018	Anticipated 2022-2023	Hyrimoz (adalimumab-adaz)	TBD Upon Launch			No	

Biosimilar Pipeline *(continued)*

Approval Date	Launch Date	Biosimilar Name	Biosimilar WAC / Year Cost	Reference Product	Reference Product WAC / Year Cost	Interchangeable	Disease Category*
August 2016	Anticipated 2019-2029	Erelzi® (etanercept-szzs)	TBD Upon Launch	Enbrel (etanercept)	$64,629	No	**Immunosuppressant:** Ankylosing spondylitis, Juvenile idiopathic arthritis (2 years or older), Plaque psoriasis adult, Psoriatic arthritis, Rheumatoid arthritis
April 25, 2019	To Be Determined	Eticovo [Samsung Bioepis] (etanercept-ykro)	TBD Upon Launch			Interchangeability is not anticipated	
November 2018	Anticipated Q 1-2 2019	Truxima™ (rituximab-abbs)	TBD Upon Launch	Rituxan (rituximab)	$40,712	Interchangeability is not anticipated	**Cancer:** Treatment of patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, rheumatoid arthritis, granulomatosis with polyangiitis and microscopic polyangiitis.
Expected FDA Review 3Q2019	To Be Determined	PF-05280586 [Pfizer] (rituximab)	TBD Upon Launch			Interchangeability is not anticipated	
June 2018	July 2018	Fulphila™ ** (pegfilgrastim-jmdb)	$4,175	Neulasta (pegfilgrastim)	$6,231	No	**Hematopoietic:** Reduce incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
November 2018	January 2019	Udenyca** (pegfilgrastim-cbqv)	$4,175			No	
Expected FDA Review October 2019	To Be Determined	LA-EP2006 [Sandoz] (pegfilgrastim)	TBD Upon Launch			Interchangeability is not anticipated	
Expected FDA Review September 2019	To Be Determined	TX01 [Tanvex] (pegfilgrastim)	TBD Upon Launch			Interchangeability is not anticipated	
Expected FDA Review 2018	To Be Determined	Lapelga™ CHS-1701 (pegfilgrastim)	TBD Upon Launch			Interchangeability is not anticipated	

**Green boxes above indicate launched products.

*Indications for the biosimilars may vary from the originator and from each other, and are continually evolving. Indications listed here are for the originator product.

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