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1ST 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

- **Lorbrena® (Lorlatinib)** – 2nd line ALK Positive Metastatic Non-Small Cell Lung Cancer
- **Vizimpro® (Dacomitinib)** – 1st line metastatic Non-Small Cell Lung Cancer with verified EGFR-activating mutations
- **Vitrakvi® (Larotrectinib)** – Unresectable local or metastatic solid cancer tumors with neurotrophic tyrosine receptor kinase gene mutation
- **Xospata® (Gilteritinib)** – Relapsed or refractory Acute Myeloid Leukemia with a verified FLT3 mutation
- **Talzenna® (Talazoparib)** – Advanced or metastatic Breast Cancer with inherited BRCA positive, HER-2 negative breast cancer

Anticipated FDA Approvals

- **Cal-PEG (Calaspargase-Pegol)** – Acute Lymphoblastic Leukemia (ALL) 12/2018
- **Romosozumab** – Osteoporosis in postmenopausal women with high risk of fractures 1/2019
- **Sacituzumab govitecan** – 3rd line metastatic Triple-negative breast cancer 1/2019

Market Launched Biosimilar Approvals

- **Retacrit (epoetin alfa-epbx)** – 57% Savings over reference product Epogen Procrit (Epoetin Alfa)
- **Zarxio (filgrastim-sndz)** – 17% Savings over reference product Neupogen (filgrastim)
- **Granix (tbo-filgrastim)** – 25% Savings over reference product Neupogen (filgrastim)
- **Nivestym (filgrastim-aafi)** – 34% Savings over reference product Neupogen (filgrastim)
- **Renflexis (infliximab-abda)** – 35% Savings over reference product Remicade (infliximab)
- **Inflectra (infliximab-dyyb)** – 19% Savings over reference product Remicade (infliximab)
- **Fulphiila (pegfilgrastim-jmdb)** – 33% Savings over reference product Neulasta (pegfilgrastim)

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
- **Erelzi (etanercept-szzs)** – Biosimilar for reference product Enbrel – FDA Approved 9/2016; Anticipated Launch Date 2019-2029
- **Amjevita (adalimumab-atto)** – Biosimilar for reference product Humira – FDA Approved 9/2016; Anticipated Launch Date 2023

Recent FDA Approvals

Approval Date	Estimated WAC / Year	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Therapy Options Approximate WAC/Year
Approved 9/14/2018	**$112,499.82** for 6 cycles based on 80kg weight, 0.04mg/kg on days 1, 3, 5 in a 28 day cycle **Anticipated Coverage: Medical**	**Lumoxiti™ (moxetumomab pasudotox)** MedImmune	**Blood & Bone Marrow Cancer:** Relapsed or refractory hairy cell leukemia (HCL) who have received 2 standard treatments, including treatment with a purine nucleoside analog	Lumoxiti: first treatment approved for HCL patients that relapses or fail other therapy 30% of trial patients showed complete disappearance of their cancer (complete response) with few adverse effects, 75% of patients in the trial had either a partial response or complete response	Offers treatment option to patients with shortened remissions and other therapy toxicities Promising nonchemotherapeutic treatment for HCL	Lumoxiti - First in class CD-22 inhibitor **Therapy Options:** › Imbruvica (Ibrutinib) - $148, 189 › Venclexta (venetoclax) - $135,665 › Rituximab – $40,712
Approved 08/29/2018	**$567,648** based on 60kg patient dosed at 40 u/kg twice weekly **Anticipated Coverage: Medical**	**Jivi® (damoctocog alfa pegol)** Bayer	**Hemophilia A:** Hemophilia A in adults and adolescents 12 years of age and over	Initial dosage once weekly or every 5 days via IV infusion to prevent bleeding episodes Can be used on-demand and prophylactically	Offers an extended half-life which may result in decreased frequency of infusions for hemophilia A patients Offers ability to tailor administration frequency based on patient bleeds	**Coagulation Factor VIII Therapy Options:** › Advate – $492,960 › NovoEight – $662,688 › Xyntha – $492,960 › Nuwiq – $562,094 › Recombinate – $369,720
Approved 08/23/2018	**$573,820** **Anticipated Coverage: Pharmacy**	**Takhzyro™ (lanadelumab-flyo)** Shire	**Hereditary Angioedema (HAE):** Prevention of hereditary angioedema attacks in patients 12 years and older	Initial dosage every 2 weeks SubQ injection, may extend to every 4 weeks Offers potential to change the HAE treatment guidelines, First monoclonal antibody treatment for angioedema attack prevention	No contraindications Less frequent dosing intervals relative to current treatment options of once or twice monthly; Poised to reduce acute attack treatment utilization	**Prevention Treatment Options:** › Danazol – $990 - $7,511 › Cinryze – $686,400 › Haegarda – $586,560 depending on weight-based dosing
Approved 11/02/2018	**$195,346** **Anticipated Coverage: Pharmacy**	**Lorbrena® (lorlatinib)** Pfizer Inc.	**Lung Cancer:** 2nd line ALK Positive Metastatic Non-Small Cell Lung Cancer (NSCLC)	Oral tablets administered daily, inhibits ALK inhibitor therapy is usually continued until disease progression 5% of NSCLC patients are ALK-positive	Lorlatinib is poised to treat NSCLC resistant to 1st & 2nd generation ALK-targeted treatment Research continues to determine 1st line therapy for metastatic ALK-positive NSCLC (Lorlatinib vs Crizotinib)	**First-line ALK Tyrosine Kinase Inhibitors:** › Alecensa (alactinib) - $176,561 › Zykadia (certinib) - $201,889 › Xalkori (crizotinib) - $195,346
Approved 9/27/2018	**$150,867** **Anticipated Coverage: Pharmacy**	**Vizimpro® (dacomitinib)** Pfizer	**Lung Cancer:** 1st line metastatic Non-Small Cell Lung Cancer (NSCLC) with EGFR-activating mutations as detected by an FDA-approved test	Once daily oral therapy Dacomitinib inhibits several receptors compared to first generation EGFR inhibitors which are limited to a single receptor	Improved efficacy over first-generation EGFR inhibitor gefitinib (Iressa), however with greater toxicity. Dacomtinib use may be limited by the more effective and better tolerate Osimertinib	**First Generation EGFR Inhibitors:** › Tarceva (erlotinib) - $102,825 › Iressa (gefitinib) - $93,827 › Gilotrif (afatinib) - $99,216 **Third Generation EGFR Inhibitor:** › Tagrisso (osimertinib) - $177,834

Recent FDA Approvals *(continued)*

Approval Date	Estimated WAC / Year	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Therapy Options Approximate WAC/Year
Approved 11/26/2018	**$399,067** **Anticipated Coverage: Pharmacy**	**Vitrakvi® (larotrectinib)** Array BioPharma Bayer Loxo Oncology	**Solid Tumor Cancer:** Unresectable local or metastatic solid cancer tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion mutation as detected by an FDA-approved test	Once daily oral therapy Larotrectinib inhibits tropomyosin receptor kinases (TRK), resulting in reduced tumor growth when the NTRK gene fusion is present	FDA granted a priority review in May 2018 Orphan Drug, Breakthrough Therapy, Rare pediatric disease designations	Larotrectinib is the only selective TRK inhibitor in clinical development Bayer and Loxo Oncology will collaborate in development and promotion.
Approved 11/28/2018	**$273,250** **Anticipated Coverage: Pharmacy**	**Xospata® (gilteritinib)** Astellas Pharma	**Blood & Bone Marrow Cancer:** Relapsed or refractory (resistant to treatment) Acute Myeloid Leukemia (AML) with a FLT3 mutation as detected by an FDA-approved test	Once daily oral therapy Gilteritinib inhibits 2 types of FLT3 mutations in AML patients FLT3 mutation patients often do not respond or relapse to currently available treatments, New AML treatment options greatly needed	Gilteritinib is poised to be the only drug approved for relapsed or refractory FLT3 mutation-positive (FLT3mut+) AML 30% of AML patients have FLT3 mutations and are associated with poor survival outcomes.	**Treatment Options:** › Iclusig (ponatinib hydrochloride) - $201,492 › Vyxeos (cytarabine; daunorubicin) - $79,825 › Mylotarg (gemtuzumab ozogamicin) - $106,600 › Daurismo (glasdegib) - $205,921
Approved 11/21/2018	**$205,921** **Anticipated Coverage: Pharmacy**	**Daurismo® (glasdegib)** Pfizer	**Blood & Bone Marrow Cancer:** Newly diagnosed acute myeloid leukemia (AML) in combination with low-dose cytarabine (LDAC) in patients >75 year of age or in whom intense induction chemotherapy is not indicated.	Once daily oral therapy Glasdegib inhibits the smoothened (SMO) receptor and the hedgehog pathway, which is overexpressed in many types of cancer	Potential chemotherapy alternative therapy for AML patients ineligible for intense induction chemotherapy Offers greatly needed new AML treatment options for patients with limited options	**Treatment Options:** › Iclusig (ponatinib hydrochloride) - $201,492 › Vyxeos (cytarabine; daunorubicin) - $79,825 › Mylotarg (gemtuzumab ozogamicin) - $106,600 › IDHIFA (enasidenib) - $205,921
Approved 10/16/2018	**$177,390** **Anticipated Coverage: Pharmacy**	**Talzenna® (talazoparib tosylate)** Pfizer	**Breast Cancer:** Advanced or metastatic inherited germline BRCA mutated HER-2 negative breast cancer as detected by an FDA-approved test	Once daily oral therapy, poly ADP ribose polymerase (PARP) inhibitor Dual mechanism of action - tumor cell death by: 1) blocking PARP cancer cell repair activity, and 2) trapping PARP on DNA damage	Considered more potent compared to other PARP inhibitors due to the dual mechanism of action Current PARP inhibitors only inhibit the PARP repair enzyme and do not offer the dual action of Talzenna	**PARP Inhibitors Currently Approved:** › Olaparib (Lynparza) – Breast cancer, HER2-negative, germline BRCA-mutated disease › Niraparib (Zejula) – Not indicated for BC - $200,718 › Rucaparib (Rubraca) – Not indicated for BC - $176,424

Recent FDA Approvals *(continued)*

Approval Date	Estimated WAC / Year	Drug Name / Manufacturer	Treatment Indication	Disease or Administration Comments	Clinical Comments	Therapy Options Approximate WAC/Year
Approved 09/28/2018	**$154,700** **Anticipated Coverage: Medical**	**Libtayo® (cemiplimab)** Sanofi	**Skin Cancer:** Locally advanced / metastatic cutaneous squamous cell carcinoma (CSCC)	350 mg IV infusion (every 3 weeks) until disease progresses or not tolerated. Advanced CSCC is the deadliest non-melanoma skin cancer, 7,000 US deaths / year	Offers option to locally advanced CSCC patients who are not candidates for curative surgery or curative radiation. Only PD-1 inhibitor approved for this indication.	First drug and only approved treatment for advanced CSCC. FDA designated Breakthrough Therapy
Approved 10/24/2018	**$150** **Anticipated Coverage: Pharmacy**	**Xofluza™ (Baloxavir marboxil)** Roche	**Flu:** Treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours	Single-dose, oral treatment would require less frequent dosing compared to existing therapy. It is not known if Xofluza is safe and effective in children younger than 12 years of age or weighing less than 88 lbs.	May reduce duration of flu symptoms by about a day. Advantage of single oral dose	**Treatment Options:** › Tamiflu (oseltamivir) - $190 › Oseltamivir generic - $60 › Relenza (zanamivir) inhaled - $59

Anticipated FDA Approvals

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Options
12/20/2018	**Solriamfetol** Jazz SK Biopharmaceuticals	**Sleep Disorders:** Excessive daytime sleepiness in obstructive sleep apnea or narcolepsy	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)
12/22/2018	**Cal-PEG (calaspargase Pegol)** Shire Baxalta	**Blood & Bone Marrow Cancer:** Acute lymphoblastic leukemia (ALL)	Every 2 week IV infusion, component of a multi-agent chemotherapeutic regimen	Calaspargase pegol requires less frequent dosing than Oncaspar (pegaspargase). ALL – 75% of American childhood leukemia and 78% in Europe	**Treatment Options:** › Oncaspar (pegaspargase) › L-asparaginase
01/12/2019	**romosozumab** Amgen/UCB	**Osteoporosis:** Osteoporosis in postmenopausal women with high risk of fractures	SC injection once monthly for 1 yr. Express Scripts excluded Forteo and made Tymlos the preferred agent.	Compared to alendronate alone, Phase III trials showed reduced vertebral fracture risk and increased bone mineral density. Reports of cardiovascular safety concerns in 2.5% trial patients	First in class mechanism of action (sclerosin inhibitor) **Treatment Options:** › Actonel (risedronate) › Boniva (ibandronate) › Tymlos (abaloparatide) › Forteo (teriparatide)
01/18/2019	**sacituzumab govitecan** Immunomedics	**Breast Cancer:** Triple-negative breast cancer (TNBC) who have failed at least 2 prior metastatic disease therapies	IV infusion (day 1 & 8 of each 21-day cycle). 10-20% of all breast cancer cases are "triple negative".	Antibody + drug conjugate allows specific targeting of cancer TROP-2 antigen. Orphan Drug	**Treatment Options:** › Numerous non-targeted chemotherapy agents.

Anticipated FDA Approvals *(continued)*

Expected FDA Review Date	Drug Name / Manufacturer	Indication	Disease or Administration Comments	Clinical Comments	Therapy Options
02/21/2019	**tagraxofusp** Stemline	**Rare Blood Cancer:** Blastic plasmacytoid dendritic cell neoplasm (BPDCN)	Diphtheria toxin conjugated to human Interleukin-3 (IL-3) protein, causing cell death	IV infusion (every 4 weeks) Elzonris is being evaluated in clinical trials for other types of leukemia	**Treatment Options:** › None, Blastic plasmacytoid dendritic cell neoplasm currently has no approved standard therapies available
02/27/2019	**turoctocog alfa pegol** Novo Nordisk	**Hemophilia A**	PEGylated recombinant human Factor VIII Long acting formulation of NovoEight (Turoctocog Alfa)	IV infusion (twice weekly or every 4 days to prevent bleeding episodes) Short acting Factor VIII (NovoEight) is currently approved for use in Germany, EU, Japan, and the US.	**Coagulation Factor VIII Therapy Options:** › Advate – $492,960 › NovoEight – $662,688 › Xyntha – $492,960 › Nuwiq – $562,094 › Recombinate – $369,720
03/30/2019	**Cladribine** EMD Serono	**Multiple Sclerosis:** Relapsing-remitting multiple sclerosis Approved in UK	Oral (2 courses of 5 tablets one month apart for 2 years), based on body weight Nucleoside analog that deplete B and T lymphocytes	Unique Dosing Regimen Recent study showed cladribine reduced relapse rate 96 weeks after start of treatment	**Treatment Options:** › Gilenya (Novartis) › Ocrevus (Roche) › Lemtrada (Sanofi) › Tysabri (Biogen)
04/6/2019	**Selinexor** Karyopharm	**Bone Marrow Cancer:** Penta- Refractory Multiple Myeloma	Oral (twice weekly) option for patients battling highly resistant, refractory myeloma	First in class, oral Selective Inhibitor of Nuclear Export compound	**Treatment Options:** › Bortezomib (Velcade) › Carflizomib (Kyprolis) › Ixazomib (Ninlaro)
04/25/2019	**risankizumab** AbbVie/BI	**Plaque Psoriasis Moderate to Severe** Being reviewed for Crohn's & Ulcerative Colitis	SC injection (every 12 weeks after induction) Interleukin-23 inhibitor	2017 study results show promising results compared to Stelara and Humira As more competitor products become available, price competition and formulary exclusivity present challenges to Humira and Enbrel.	**Treatment Options:** › Humira (adalimumab) › Enbrel (etanercept) › Stelara (ustekinumab) › Cosentyx (secukinumab) › Taltz (Ixekizumab) › Siliq (brodalumab) › Tremfya (guselkumab)

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

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 December 2018	To Be Determined	Herzuma (trastuzumab)	TBD Upon Launch	Herceptin (trastuzumab)	$32,000	Interchangeability is not anticipated	**Cancer:** Treatment of Human Epidermal growth factor Receptor 2 (HER2) adjuvant breast cancer, metastatic breast cancer, and metastatic gastric cancer
Expected FDA Review October 2018	June 2019	SB3 (Trastuzumab)	TBD Upon Launch			Interchangeability is not anticipated	
Expected FDA Review December 2018	To Be Determined	Ontruzant (trastuzumab)	TBD Upon Launch			Interchangeability is not anticipated	
December 2017	June 2019	Ogivri (trastuzumab-dkst)	TBD Upon Launch			No	
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.
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	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
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
April 2017	July 2017	Renflexis® ** (infliximab-abda)	$31,831			No	
April 2016	November 2016	Inflectra® ** (infliximab-dyyb)	$39,980			No	
August 2017	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
September 2016	2023	Amjevita™ (adalimumab-atto)	TBD Upon Launch			No	
October 2018	To Be Determined	Hyrimoz (adalimumab)	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	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
Expected FDA Review November 2018	To Be Determined	Truxima™ (rituximab)	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.
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. **Note: Biosimilar approval does not extend to Radiation Induced Neutropenia.**
November 2018	To Be Determined	Udenyca (pegfilgrastim)	TBD Upon Launch			No	
Expected FDA Review 2018	To Be Determined	Lapelga™ TPI-120 CHS-1701 (pegfilgrastim)	TBD Upon Launch			Interchangeability is not anticipated	

** Green boxes above indicate launched products.

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