AmWINS Rx®

# NEW DRUG REPORT: 2ND QUARTER 2020

## FIRST TIME GENERIC APPROVALS

**Metformin Hydrochloride Oral Solution:** The U.S. Food and Drug Administration recently approved Saptalis Pharmaceuticals, LLC to produce a generic alternative to Riomet™, indicated for improving glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus. Expected availability and cost are unknown.

**Thiotepa for Injection USP:** MSN Laboratories was approved by the FDA to produce the first generic thiotepa for injection USP, indicated for the treatment of tumors of the breast or ovary; controlling intracavitary fluid release or localized cancerous diseases of various membranous body cavities; treating superficial tumors of the urinary bladder. The TEPADINA® alternative is expected to be released to the public mid-2020, though the expected cost is unknown.

**Melphalan for Injection:** A generic alternative for EVOMELA® was approved for the treatment of patients with multiple myeloma for whom oral therapy is not appropriate. Actavis LLC has not yet released an expected availability date or expected cost for the medication.

**Prednisolone Sodium Phosphate Oral Solution:** Pharmaceutical Associates, Inc. was approved by the FDA to produce a generic alternative to ORAPRED® for the control of severe or incapacitating allergic conditions: allergic rhinitis (runny/itchy nose); asthma, inflammatory rashes, eczema, drug hypersensitivity reactions. Expected availability and cost are unknown.

**Carfilzomib for Injection:** Apotex Inc. was approved to produce a generic alternative to Kyprolis®, a medication indicated for the treatment of patients with relapsed or refractory multiple myeloma (cancer of the blood plasma cells) who have received one to three lines of therapy. Expected availability and cost are unknown.

**Esomeprazole Magnesium Delayed-Release for Oral Suspension:** Esomeprazole Magnesium Delayed-Release for Oral Suspension from Cipla Limited was approved by the FDA as a gastrointestinal agent indicated for the treatment of gastroesophageal reflux disease (GERD), risk reduction of NSAID associated gastric ulcer, to reduce the risk of small intestine ulcer recurrence, and conditions regarding abnormal, excessive secretions from the intestines. Expected availability and cost are unknown for the Nexium® alternative.

**Buprenorphine Transdermal System:** The FDA approved Amneal Pharmaceuticals to produce a generic alternative to the Butrans® Transdermal System. The generic buprenorphine transdermal system is an analgesic patch indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Expected availability and cost are unknown.

**Clocortolone Pivalate Cream USP, 0.1%:** Taro Pharmaceuticals was approved by the FDA to produce Clocortolone Pivalate Cream USP, 0.1%, a generic alternative to CLODERM® 0.1%, a topical corticosteroid indicated for the relief of the inflammatory and itchy manifestations of corticosteroid-responsive skin conditions. Expected availability and cost are unknown.

**Epinephrine Injection USP, 30 mL Multiple-Dose Vials:** International Medication Systems, Ltd. has been approved by the FDA to produce a generic alternative to Adrenalin® 30mL vial of epinephrine for injection for the emergency treatment of allergic reactions (Type 1), including anaphylaxis; to increase arterial blood pressure in adult patients with low blood pressure associated with septic shock. Expected availability and cost are unknown, though its brand name alternative costs approximately $400 per 30mL vial.

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# NEW DRUG REPORT: 1ST QUARTER 2020

## NEW BRAND NAME DRUG APPROVALS

**ZEPOSIA® (ozanimod):** Celgene International was approved by the FDA to produce ZEPOSIA®, a daily 0.92mg immunomodulator capsule used to treat relapsing forms of multiple sclerosis (MS), a disease in which the protective coverings on the nerves degenerate, making it harder for nerve signals to travel between cells. When compared to AVONEX®, ZEPOSIA® demonstrated a relative reduction in annualized relapse rate of 48% over one year. Expected price and availability are unknown.

**KOSELUGO™ (selumetinib):** The FDA approved AstraZeneca LP's KOSELUGO™ bi-daily oral capsule. Indicated to treat neurofibromatosis type 1 (NF1), a rare neurological disorder of the nervous system causing tumors to grow on the nerves, KOSELUGO™ is the first and only FDA-approved treatment for pediatric patients (2 years and older) who have tumors caused by NF1 that can't be completely removed by surgery. This condition is estimated to affect 11,000 children in the U.S. AstraZeneca expects to launch the medication mid to late 2020 at a price of $12,500 per month, with the goal that each eligible, commercially insured patient pays $0 out of pocket.

**TUKYSA™ (tucatinib):** The FDA recently approved Seattle Genetics to produce TUKYSA™, an oral tablet medication used to treat advanced, unresectable or metastatic (spreading) HER2-positive breast cancer. During clinical trials, 33% of patients taking TUKYSA™ (along with trastuzumab and capecitabine) had not had their cancer progress at 12 months, compared to the 12% of patients only taking trastuzumab and capecitabine. TUKYSA™ also helped patients live longer. Physicians can order the drug immediately. A median course (~5.8 months) of TUKYSA™ costs approximately $111,000.

**PEMAZYRE™ (pemigatinib):** Incyte Corporation has been approved by the FDA on an accelerated basis to produce PEMAZYRE™ oral tablets due to exceptional response rate and duration of responses in clinical trial. The medication is indicated for the treatment of certain patients with cholangiocarcinoma, a rare form of bile duct cancer that cannot be surgically removed. The medication is available immediately for an average cost of $17,000 per cycle. It is estimated that average treatment duration will last 6 months, for eight or nine cycles, making the total cost approximately $145,000 per patient.

**TRODELVY™ (sacituzumab govitecan-hziy):** The FDA recently approved TRODELVY™, the injectable medication from Immunomedics Inc., indicated for the treatment of adult patients with breast cancer that is estrogen, progesterone, and "HER2" receptor negative, and who received at least two prior therapies for the spreading of the disease. Clinical trials revealed a 33% response rate, compared to standard chemotherapy which typically has a response rate between 5% and 10% for this disease. Immunomedics Inc. anticipates releasing the drug mid-2020 at an approximate cost of $16,000 per 21-day cycle.

**ONGENTYS® (opicapone):** Neurocrine has been approved by the FDA to produce ONGENTYS®, a medication in the form of an oral capsule used to treat patients with Parkinson's disease experiencing "off" episodes as adjunctive treatment to levodopa/carbidopa. The medication's approval was supported by 38 clinical trials, ultimately showing that adding once daily ONGENTYS® to other Parkinson's therapies significantly reduces "off time", leading to improved and more consistent motor control. Neurocrine states ONGENTYS® will be priced "below the specialty tier" to favor patient access, and is expected to be available later in 2020.

**TABRECTA™ (capmatinib hydrochloride):** The FDA recently approved Novartis Pharmaceuticals to produce TABRECTA™, indicated to treat adults with NSCLC, a rare form of lung cancer, that has spread to other parts of the body, cannot be removed through surgery, and whose tumors have an abnormality in the MET gene. TABRECTA™ works by blocking the activity of specific proteins that can cause your cancer to grow, though it does affect both healthy cells and cancer cells. There is no clinical information available to show if patients treated with TABRECTA™ live longer or if their symptoms improve. TABCRECTA™ and its effects continue to be studied despite a launch date during the week of 5/10/2020 for $17,950 per 28-day supply.

**RETEVMO™ (selpercatinib):** Loxo Oncology Inc. has been approved by the FDA to produce RETEVMO™, the first oral tablet therapy specifically approved for people aged 12 and older with certain lung and thyroid cancers that test positive for abnormal RET genes. In clinical trials, RETEVMO™ shrank tumors in 64% of 105 patients that had already been treated with chemo, and 84% of 39 patients who hadn't received previous treatment. The selpercatinib capsules are available for physicians to order immediately. A 30-day supply costs approximately $20,600.

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# AmWINS Rx® NEW DRUG REPORT: 2ND QUARTER 2020

**QINLOCK™ (ripretinib):** QINLOCK™ is the FDA approved prescription medicine from Deciphera Pharmaceuticals used to treat adults with advanced gastrointestinal stromal tumor (GIST) who have received 3 or more prior treatments for their GIST. The oral tablet medication was approved 3 months ahead of schedule after showing it could cut the risk of disease progression or death by 85% in advanced GIST patients who had received prior therapies. The median progression-free survival was 6.3 months. However, the label warns that the medication could cause heart dysfunction, noting close monitoring is highly suggested, especially for patients with pre-existing heart disease and/or failure. QINLOCK™ is available immediately for a cost of $32,000 per month.

**CERIANNA™ (fluorodestradiol F18):** Zionexa USA has been approved by the FDA to produce CERIANNA™, the injectable diagnostic imaging agent for use in PET scans for the detection of specific estrogen lesions as an adjunct to biopsy in patients with recurring or metastatic (spreading) breast cancer. CERIANNA™ is the first F18 PET imaging agent specifically indicated for this use. It is expected to be available late 2020 or early 2021. Estimated cost is unknown at this time.

## KEY PIPELINE DRUGS WITH FDA APPROVAL DECISIONS EXPECTED BY THE END OF THE 3RD QUARTER 2020 (SS&C PIPELINE REVIEW 2020)

| DRUG NAME | MANUFACTURER | INDICATION/ USE | EXPECTED FDA DECISION DATE |
|---|---|---|---|
| Ofatumumab (SC) | Novartis | Multiple Sclerosis (a disease in which the immune system eats away at the protective covering of nerves) | 6/2020 |
| Abicipar pegol | Allergan | Neovascular age-related macular degeneration (vision loss due to abnormal blood vessel growth) | 6/2020 – 7/2020 |
| Triheptanoin | Ultragenyx Pharmaceutical | Long-chain fatty acid oxidation disorders (a rare genetic metabolism disorder) | 7/31/2020 |
| Fostemsavir | ViiV Healthcare/ GlaxoSmithKline | HIV-1 infection | 8/5/2020 |
| Viaskin Peanut | DBV Technologies | Peanut allergy | 8/5/2020 |
| KTE-X19 | Gilead Sciences/ Kite Pharma | Mantle cell lymphoma (an aggressive, rare cancer of white blood cells) | 8/10/2020 |
| Ripretinib | Deciphera Pharmaceuticals | Gastrointestinal tumors | 8/13/2020 |
| Belantamab mafodotin | GlaxoSmithKline | Multiple myeloma (cancer of blood plasma cells) | 8/14/2020 |
| Satralizumab | Roche/Genentech/ Chugai | Neuromyelitis optica spectrum disorder (an inflammatory disorder of the central nervous system) | 8/14/2020 |
| Tucatinib | Seattle | Breast cancer | 4/17/2020 (Approved) |
| Margetuximab | MacroGenics | Breast cancer | 8/19/2020 |
| Filgotinib | Gilead Sciences | Rheumatoid arthritis | 8/19/2020 |
| Valoctocogene roxaparvovec | BioMarin | Hemophilia A (a hereditary bleeding disorder caused by lack of blood clotting) | 8/21/2020 |
| Veverimer | Tricida | Metabolic acidosis associated with chronic kidney disease (a condition in which too much acid accumulates in the body) | 8/22/2020 |
| Tafasitamab | MorphoSys | Diffuse large B-cell lymphoma (a cancer of white blood cells that usually grows in lymph nodes) | 8/30/2020 |

**Resources**

*https://www.fda.gov/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-sacituzumab-govitecan-hziy-metastatic-triple-negative-breast-cancer*
*https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals*
*https://drugstorenews.com/novadoz-gets-fda-green-light-generic-thiotepa*
*https://www.drugs.com/generic-approvals-archive/february-2020.html*
*https://www.drugs.com/newdrugs/fda-approves-zeposia-ozanimod-relapsing-forms-multiple-sclerosis-5189.html*
*https://scrip.pharmaintelligence.informa.com/SC142060/Seattle-Genetics-Win-Early-US-FDA-Approval-For-Tukysa-Plans-Rapid-Launch*
*https://www.fiercepharma.com/marketing/incyte-scores-fda-nod-for-rare-bile-duct-cancer-therapy-pemazyre*
*https://www.thepharmaletter.com/article/fda-nod-for-pemazyre-for-metastatic-cholangiocarcinoma*
*https://www.fiercepharma.com/pharma/astrazeneca-merck-finally-grab-a-green-light-for-rare-disease-med-koselugo*
*https://www.biopharmadive.com/news/bristol-myers-zeposia-ozanimod-fda-approval/574577/*
*https://www.bioworld.com/articles/434610-immunomedics-sets-trodelvy-price-discusses-launch-plans-in-tnbc*
*https://www.fiercepharma.com/pharma/neurocrine-scores-fda-nod-for-parkinson-s-drug-ongentys-but-won-t-launch-amid-pandemic*
*https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/novel-drug-approvals-2020*
*https://www.fda.gov/news-events/press-announcements/fda-approves-first-targeted-therapy-treat-aggressive-form-lung-cancer*
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*http://www.pmlive.com/pharma_news/fda_clears_novartis_tabrecta_for_metex14_lung_cancer_1340092*
*https://www.fiercepharma.com/pharma/lilly-cashes-loxo-buyout-fda-approval-for-first-class-cancer-drug-retevmo*
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*https://www.fiercepharma.com/marketing/deciphera-fills-where-blueprint-falls-short-early-fda-nod-for-qinlock-rare-stomach-cancer*
*https://www.us.tabrecta.com/met-exon-14-skipping-mutation-nsclc/about-tabrecta/what-is-tabrecta/?site=MTX-1229341GK101532&source=01030&gclid=EAIaIQobChMIkufRgL_H6QIVIsDICh0MrgG9EAAYAiAAEgI5t_D_BwE&gclsrc=aw.ds*
*https://www.retevmo.com/*
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*https://www.zionexa.com/2020/05/27/zionexa-usa-and-petnet-solutions-announce-fda-approval-of-cerianna-fluoroestradiol-f18/*
*SS&C Quarter 2 Pipeline Review 2020*