OPTUMRx®

# RxHighlights

April 2019

## New drugs

Learn more

| Drug name<br>Manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|---|---|---|
| **Asceniv**™<br>(immune globulin intravenous, human – slra)<br>ADMA Biologics | Immune globulin | Treatment of primary humoral immunodeficiency in adults and adolescents (12 to 17 years of age) | 2H2019 |
| **Avaclyr**™ (acyclovir)<br>ophthalmic ointment†<br>Fera Pharmaceuticals | Antiviral | Treatment of acute herpetic keratitis (dendritic ulcers) in patients with herpes simplex (HSV-1 and HSV-2) virus | TBD |
| **Balversa**™ (erdafitinib)*<br>Janssen | Kinase inhibitor | Treatment of adult patients with locally advanced or metastatic urothelial carcinoma, that has: (1) susceptible FGFR3 or FGFR2 genetic alterations, and (2) progressed during or following at least one line of prior platinum-containing chemotherapy, including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy | TBD |
| **Dovato**™<br>(dolutegravir/lamivudine)<br>ViiV Healthcare | Integrase inhibitor/nucleoside analogue reverse transcriptase inhibitor | Complete regimen for the treatment of human immunodeficiency virus type 1 infection in adults with no antiretroviral treatment history and with no known substitutions associated with resistance to the individual components of Dovato | April 10, 2019 |

| Drug name<br>Manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|---|---|---|
| **Duobrii**™<br>(halobetasol propionate/ tazarotene)<br>Bausch Health | Corticosteroid/retinoid | Topical treatment of plaque psoriasis in adults | June 2019 |
| **Elcys**™ (cysteine hydrochloride)<br>Exela Pharma | Sulfur-containing amino acid | For use as an additive to amino acid solutions to meet the nutritional requirements of newborn infants requiring total parenteral nutrition (TPN) and of adult and pediatric patients with severe liver disease who may have impaired enzymatic processes and require TPN. It can also be added to amino acid solutions to provide a more complete profile of amino acids for protein synthesis. | TBD |
| **Eticovo**™ (etanercept-ykro)*§<br>Samsung Bioepis | Chronic inflammatory disease | For the treatment of rheumatoid arthritis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis | TBD |
| **Evenity**™ (romosozumab-aqqg)*<br>Amgen | Sclerostin inhibitor | Treatment of osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture; or patients who have failed or are intolerant to other available osteoporosis therapy | April 16, 2019 |
| **Selenious acid injection**<br>American Regent | Trace element | In adult and pediatric patients as a source of selenium for parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated | TBD |
| **Skyrizi**™ (risankizumab-rzaa)*<br>AbbVie | Interleukin-23 antagonist | Treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy | April 25, 2019 |

| Drug name Manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|---|---|---|
| **Welchol**® (colesevelam) chewable bars Daiichi Sankyo | Bile acid sequestrant | Adjunct to diet and exercise to reduce elevated low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia; to reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia who are unable to reach LDL-C target levels despite an adequate trial of dietary therapy and lifestyle modification; and as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus | TBD |

*New molecular entity †Orphan Drug §Biosimilar TBD: To be determined

## New generics

Learn more

| Drug name Manufacturer(s) | Generic manufacturer(s) | Strength(s) & dosage form(s) | Therapeutic use | Launch information |
|---|---|---|---|---|
| **Letairis**® (ambrisentan) Gilead Sciences | Sun†, Mylan†, Teva†, Zydus†, Par†, Sigmapharm† | 5 mg and 10 mg tablets | Pulmonary arterial hypertension | April 11, 2019Δ |
| **Proventil**® **HFA** (albuterol) Merck | Par* | 120 mcg inhalation aerosol (equivalent to 90 mcg of albuterol) per actuation | Bronchospasm | April 5, 2019 |
| **Valstar**® (valrubicin) Endo | Leucadia/Custopharm† | 200 mg/5 mL intravesical solution | BCG-refractory carcinoma *in situ* of the urinary bladder | April 22, 2019 |
| **Vesicare**® (solifenacin) Astellas | Teva† | 5 mg and 10 mg tablets | Overactive bladder | April 22, 2019 |

†A-rated generic manufacturer *Authorized generic
Δ Sun; other manufacturers pending

## Indications/label updates

Learn more

| Drug name<br>Manufacturer(s) | Type | Description |
|---|---|---|
| **Benlysta**® (belimumab)<br>GlaxoSmithKline | Expanded indication | Treatment of patients aged 5 years and older with systemic lupus erythematosus |
| **Corlanor**® (ivabradine)<br>Amgen | New orphan indication, new formulation approval | Treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate<br>A 5 mg/5 mL oral solution was also approved to support the new indication. |
| **Ibrance**® (palbociclib)<br>Pfizer | Expanded indication | Treatment of adults with hormone receptor -positive, human epidermal growth factor receptor 2-negative advanced or metastatic breast cancer in combination with: (1) an aromatase inhibitor as initial endocrine-based therapy in postmenopausal women or in men; or (2) in combination with Faslodex® (fulvestrant) in patients with disease progression following endocrine therapy |
| **Kalydeco**® (ivacaftor)<br>Vertex | Expanded indication | Treatment of cystic fibrosis in patients age 6 months and older |
| **Keytruda**® (pembrolizumab)<br>Merck | New and expanded indications | In combination with Inlyta® (axitinib), for the first-line treatment of patients with advanced renal cell carcinoma<br>As a single agent, for the first-line treatment of patients with stage III non-small cell lung cancer (NSCLC), who are not candidates for surgical resection or definitive chemoradiation, or metastatic NSCLC, and whose tumors express PD-L1, with no EGFR or ALK genomic tumor aberrations |
| **Mavyret™**<br>(glecaprevir/pibrentasvir)<br>AbbVie | Expanded indication | Treatment of patients 12 years and older or weighing at least 45 kg with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis; or HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor |
| **Praluent**® (alirocumab)<br>Regeneron, Sanofi | New and expanded indications | To reduce the risk of myocardial infarction, stroke, and unstable angina requiring hospitalization in adults with established cardiovascular disease<br>Adjunct to diet, alone or in combination with other lipid-lowering therapies, for the treatment of primary hyperlipidemia |

## Drug safety news

Learn more

| Drug name<br>Manufacturer(s) | Description |
|---|---|
| **Insomnia medications** | The FDA announced that a *Boxed Warning* will be added to the drug labels of certain common prescription insomnia medications [ie, Lunesta® (eszopiclone), zolpidem [Ambien®, Ambien CR®, Edluar®, Intermezzo®, Zolpimist®], and Sonata® (zaleplon)] due to rare but serious injuries occurring because of complex sleep behaviors, including sleepwalking, sleep driving, and engaging in other activities while not fully awake. |
| **Opioids** | The FDA announced that they are requiring changes to the prescribing information for opioids due to reports of serious harm in patients who are physically dependent on opioids suddenly having these medicines discontinued or the dose rapidly decreased. Reports include serious withdrawal symptoms, uncontrolled pain, psychological distress, and suicide. |

## Drug recalls/withdrawals/shortages/discontinuations

Learn more

| Drug name<br>Manufacturer(s) | Dosage form(s) | Type | Description |
|---|---|---|---|
| **Ceftazidime injection**<br>B. Braun Medical | Ceftazidime for injection (2 g) and dextrose injection (50 mL), duplex container | Recall | B. Braun Medical announced a user-level recall of one lot of ceftazidime injection because the recalled lot contained elevated high molecular weight polymers.<br>Ceftazidime for injection and dextrose injection is indicated for the treatment of certain infections caused by susceptible bacteria. |
| **Duzallo®** (lesinurad/allopurinol), **Zurampic®** (lesinurad)<br>Ironwood Pharmaceuticals | Duzallo (lesinurad/allopurinol): 200 mg/ 200 mg and 200 mg/ 300 mg tablets<br>Zurampic:<br>200 mg tablets | Discontinuation | Duzallo and Zurampic were discontinued as of February 1, 2019 due to business reasons and not due to safety, efficacy or quality issues.<br>Duzallo is indicated for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a medically appropriate daily dose of allopurinol alone.<br>Zurampic is indicated in combination with a xanthine oxidase inhibitor for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor alone. |

| Drug name<br>Manufacturer(s) | Dosage form(s) | Type | Description |
|---|---|---|---|
| **Fentanyl transdermal system**<br>Alvogen | 12 mcg/hr transdermal system | Recall | Alvogen announced a consumer-level recall of two lots of fentanyl 12 mcg/h patches because a small number of cartons labeled 12 mcg/h fentanyl transdermal system patches contained 50 mcg/h patches.<br>Fentanyl transdermal system is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. |
| **Lartruvo®** (olaratumab)<br>Eli Lilly | 190 mg and 500 mg injection | Market removal | Lartruvo injection will be removed from the market due the failure of a clinical trial, in which Lartruvo did not improve survival for patients. Eli Lilly is establishing a program to ensure current patients will have access to Lartruvo with limited interruption after it is withdrawn from the market.<br>Lartruvo was approved via the FDA's accelerated approval program in 2016 in combination with doxorubicin, for the treatment of adults with soft tissue sarcoma with a histologic subtype for which an anthracycline-containing regimen is appropriate and which is not amenable to curative treatment with radiotherapy or surgery. |
| **Losartan**<br>AvKARE | 25 mg and 50 mg tablets | Recall | AvKARE announced an expansion to a consumer-level recall of some lots of losartan tablets due to the detection of trace amounts of an unexpected impurity, N-Methylnitrosobutyric acid (NMBA), found in an active pharmaceutical ingredient (API) manufactured by Hetero Labs. This is an expansion to the recall that AvKARE announced on March 4, 2019.<br>Losartan tablets are used for the treatment of hypertension (HTN) and to reduce the risk of stroke in patients with HTN and left ventricular hypertrophy. Losartan tablets are also used for the treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in patients with type 2 diabetes and a history of HTN. |
| **Losartan**<br>Legacy Pharmaceutical Packaging | 50 mg tablets | Recall | Legacy Pharmaceutical Packaging announced an expansion to a consumer-level recall of three repackaged lots of losartan 50 mg tablets to include one additional lot due to NMBA. This is an expansion to the recall that Legacy announced on March 25, 2019 and prompted due to Torrent's recall of losartan tablets. |

| Drug name<br>Manufacturer(s) | Dosage form(s) | Type | Description |
|---|---|---|---|
| **Losartan**<br>Major | 25 mg, 50 mg and 100 mg tablets | Recall | Major announced a voluntary recall of losartan tablets due to the detection of an unexpected impurity NMBA. This recall was prompted due to Torrent's recall of losartan tablets. |
| **Losartan**<br>Teva/Golden State Medical Supply | 25 mg and 100 mg tablets | Recall | Teva announced a consumer-level recall of several lots of losartan tablets due to NMBA that is above the FDA's interim acceptable exposure limit. The finished product lots were sold by Teva in bulk containers exclusively to Golden State Medical Supply. |
| **Losartan-containing products**<br>Torrent | Losartan 25 mg, 50 mg and 100 mg tablets<br><br>Losartan/HCTZ 50 mg/12.5 mg, 100 mg/12.5 mg, and 100 mg/25 mg tablets | Recall | Torrent announced an expansion to the voluntary, consumer-level recall of several lots of losartan and losartan/hydrochlorothiazide (HCTZ) tablets due to an unexpected impurity, NMBA. This is an expansion to the recall announced in March 2019. |
| **Rebetol®** (ribavirin)<br>Merck | 40 mg/mL oral solution | Discontinuation | Rebetol was discontinued due to business reasons and not due to safety, efficacy or quality issues.<br><br>Brand Rebetol capsules will continue to be available. Generic ribavirin is currently available as a tablet and capsule.<br><br>Rebetol in combination with interferon alfa-2b is indicated for the treatment of chronic hepatitis C in patients ≥ 3 years of age with compensated liver disease. |

## Key guideline/literature updates

| Topic | Reference |
|---|---|
| American Urological Association - Recurrent Uncomplicated Urinary Tract Infections in Women | *American Urological Association Education and Research*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia – Version 1.2019 | *NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 3.2019 | *NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bone Cancer – Version 2.2019 | *NCCN Clinical Practice Guidelines in Oncology: Bone Cancer*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma – Version 1.2019 | *NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer – Version 4.2019 | *NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma – Version 2.2019 | *NCCN Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer – Version 4.2019 | *NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma – Version 2.2019 | *NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer – Version 2.2019 | *NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer*. April 2019 |

| Topic | Reference |
|---|---|
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer – Version 1.2019 | *NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities – Version 2.2019 | *NCCN Clinical Practice Guidelines in Oncology: Management of Immunotherapy-Related Toxicities*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Smoking Cessation – Version 2.2019 | *NCCN Clinical Practice Guidelines in Oncology: Smoking Cessation*. April 2019 |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology – Version 2.2019 | *NCCN Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology*. April 2019 |


**optum.com/optumrx**

OptumRx specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com.**



RxHighlights is published by the OptumRx Clinical Services Department.