

## New Indications & Dosage Forms for Existing Drugs

### 1. Tagrisso (osimertinib) Tablets

**New Indication Approved:** December 20, 2020

**Date of Original Approval:** November 13, 2015

Tagrisso approved in the US for the adjuvant treatment of patients with early-stage EGFR-mutated non-small cell lung cancer. Previously treated EGFR T790M mutation-positive metastatic NSCLC.

### 2. Xpovio (selinexor) Tablets

**New Indication Approved:** December 18, 2020

**Date of Original Approval:** July 3, 2019

Karyopharm Announces FDA approval of Xpovio (selinexor) as a treatment for patients with multiple myeloma after at least one prior therapy.

### 3. Ocrevus (ocrelizumab) Injection

**New Dosage Regimen:** December 14, 2020

**Date of Original Approval:** March 28, 2017

FDA approves Genentech's Ocrevus (ocrelizumab) shorter 2-hour infusion for relapsing and primary progressive multiple sclerosis.

### 4. Saxenda (liraglutide) Injection

**Patient Population Altered:** December 4, 2020

**Date of Original Approval:** December 23, 2014

FDA approves Saxenda (liraglutide) for the treatment of obesity in adolescents aged 12-17.

### 5. Gavreto (pralsetinib) Capsules

**New Indication Approved:** December 1, 2020

**Date of Original Approval:** September 4, 2020

Genentech announces FDA approval of Gavreto (pralsetinib) for people with advanced or metastatic RET-mutant and RET fusion-positive thyroid cancers.

### 6. Xolair (omalizumab) Subcutaneous Injection

**New Indication Approved:** December 1, 2020

**Date of Original Approval:** June 20, 2003

Genentech announces FDA approval of Xolair (omalizumab) for adults with nasal polyps.

### 7. Hetlioz (tasimelteon) Capsules

**New Indication Approved:** December 1, 2020

**Date of Original Approval:** January 31, 2014

FDA approves Hetlioz (tasimelteon) for the treatment of nighttime sleep disturbances in smith-magenis syndrome.

### 8. Xofluza (baloxavirmarboxil) Tablets and Granules for Oral Suspension

**New Indication Approved:** November 23, 2020

**Date of Original Approval:** October 24, 2018

Genentech announces FDA approval of Xofluza for the prevention of influenza following contact with an infected person.

### 9. Imfinzi (durvalumab) Injection

**New Dosage Regimen:** November 18, 2020

**Date of Original Approval:** May 1, 2017

For the treatment of adult patients with locally advanced or metastatic urothelial carcinoma.

### 10. Vimpat (Lacosamide) Tablets, Injection, Oral Solution

**New Indication Approved:** November 16, 2020

**Date of Original Approval:** October 28, 2008

Vimpat (lacosamide) now approved by FDA for primary generalized tonic-clonic seizures and expanded pediatric use for people living with epilepsy.

### 11. Keytruda (pembrolizumab) for Injection

**New Indication Approved:** November 13, 2020

**Date of Original Approval:** September 4, 2014

FDA Approves Merck's Keytruda (pembrolizumab) in combination with chemotherapy for patients with locally recurrent unresectable or metastatic

triple-negative breast cancer whose tumors express PD-L1 (CPS  $\geq$ 10).

### **12. Brilinta (ticagrelor) Tablets**

**New Indication Approved:** November 5, 2020

**Date of Original Approval:** July 20, 2011

Brilinta approved in the US to reduce the risk of stroke in patients with an acute ischemic stroke or high-risk transient ischemic attack.

### **13. Sklice (ivermectin) Lotion**

**Labeling Revision Approved:** October 27, 2020

**Date of Original Approval:** February 7, 2012

FDA approves Sklice (ivermectin) lotion for nonprescription use to treat head lice.

### **14. Venclexta (venetoclax) Tablets**

**New Indication Approved:** October 16, 2020

**Date of Original Approval:** April 11, 2016

Venclexta (venetoclax) is an oral B-cell lymphoma-2 (BCL-2) inhibitor indicated for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).

### **15. Keytruda (pembrolizumab) for Injection**

**Labeling Revision Approved:** October 14, 2020

**Date of Original Approval:** September 4, 2014

Keytruda (pembrolizumab) is a human PD-1 (programmed death receptor-1)-blocking antibody indicated for the treatment of melanoma, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell carcinoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, urothelial carcinoma, microsatellite instability-high cancer, gastric cancer, esophageal

cancer, cervical cancer, hepatocellular carcinoma, Merkel cell carcinoma, renal cell carcinoma, endometrial carcinoma, tumor mutational burden-high (TMB-H) cancer, cutaneous squamous cell carcinoma, and triple-negative breast cancer.

### **16. Wakix (pitolisant) Tablets**

**New Indication Approved:** October 13, 2020

**Date of Original Approval:** August 14, 2019

Wakix (pitolisant) is a histamine-3 (H<sub>3</sub>) receptor antagonist/inverse agonist for the treatment of excessive daytime sleepiness (EDS) or cataplexy in adult patients with narcolepsy.

### **17. Ultomiris (ravulizumab-cwvz) Injection**

**New Formulation Approved:** October 9, 2020

**Date of Original Approval:** December 21, 2018

Ultomiris (ravulizumab-cwvz) is a long-acting C5 complement inhibitor for the treatment of adult patients with paroxysmal nocturnal hemoglobinuria (PNH).

### **18. Opdivo (nivolumab) Injection**

**New Indication Approved:** October 2, 2020

**Date of Original Approval:** December 22, 2014

Opdivo (nivolumab) is a programmed death receptor-1 (PD-1) blocking antibody for the treatment of melanoma, non-small cell lung cancer, small cell lung cancer, malignant pleural mesothelioma, renal cell carcinoma, classical Hodgkin lymphoma, squamous cell carcinoma of the head and neck, urothelial carcinoma, MSI-H or dMMR metastatic colorectal cancer, hepatocellular carcinoma, and esophageal squamous cell carcinoma.

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*Source: [www.drugs.com/new-indications](http://www.drugs.com/new-indications)*