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
New Drug Approvals

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

16. Wakix (pitolisant) Tablets
New Indication Approved: October 13, 2020
Date of Original Approval: August 14, 2019
Wakix (pitolisant) is a histamine-3 (H₃) 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

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Source: www.drugs.com/new-indications