KMCH INSTITUTE OF HEALTH SCIENCES AND RESEARCH

(A unit of Kovai Medical Centre and Hospital Limited)

Coimbatore,Tamilnadu

SERIES 2

SEP 2019

DEPARTMENT OF PHARMACOLOGY- NEW DRUG UPDATE

1. Istradefylline

- **Date of FDA Approval:** August 27, 2019
- **Indication**: Adjunctive treatment to levodopa/carbidopa in adult patients with **Parkinson's disease** experiencing "OFF" episodes.
- **Formulation**: Tablet
- **Dose:** 20 mg orally once daily; max of 40 mg orally once daily
- **Mechanism of action:** Adenosine A2A receptor Antagonist

2. Lefamulin

- **Date of FDA Approval:** August 19, 2019
- **Indication**: **Community-acquired bacterial pneumonia**
- **Formulation**: Tablet and Injection
- **Dose**: 150 mg IV / 600 mg orally twice daily x 5 -7 days
- **Mechanism of action**: First-in-class, semi-synthetic pleuromutilin antibiotic, Inhibits protein synthesis by binding to 50S of the bacterial ribosome.

3. Upadacitinib

- **Date of FDA Approval**: August 16, 2019
- **Indication:** Treatment of adult patients with **moderate to severe rheumatoid arthritis**.
- **Formulation**: Extended-Release Tablet
- **Dose**: 15 mg orally once daily
- **Mechanism of action**: Janus kinase (JAK) inhibitor

4. Fedratinib

- **Date of FDA Approval**: August 16, 2019
- **Indication**: Intermediate-2 or high-risk primary or secondary **myelofibrosis (MF)**
- **Formulation:** Capsule
- **Dose:** 400 mg orally once daily
- **Mechanism of action:** Highly selective Janus kinase 2 (JAK2) inhibitor

5. Entrectinib

- **Date of FDA Approval:** August 15, 2019
- **Indication:** ROS1-positive, metastatic **non-small cell lung cancer** (NSCLC) & neurotrophic tyrosine receptor kinase (NTRK) gene fusion-positive **solid tumors**.
- **Formulation**: Capsule
- **Dose:** 600 mg orally once daily
- **Mechanism of action:** Selective tyrosine kinase inhibitor

6. Pitolisant

- **Date of FDA Approval:** August 14, 2019
- **Indication**: **Excessive daytime sleepiness** in adult patients with narcolepsy.
- **Formulation**: Tablet
- **Dose**: Initiate with 8.9 mg orally once daily
- **Mechanism of action:** Histamine-3 (H_3) receptor antagonist/inverse agonist

7. Pretomanid

- **Date of FDA Approval**: August 14, 2019
- **Indication:** Part of a combination regimen with Bedaquiline & Linezolid for adults with **pulmonary extensively drug resistant (XDR),** treatment-intolerant or nonresponsive **multidrug-resistant (MDR) tuberculosis (TB)**
- **Formulation**: Tablet
- **Dose**: Pretomanid 200 mg orally once daily x 26 weeks
- **Mechanism of action**: It act as a bacterial respiratory poison and inhibits bacterial cell wall mycolic acid biosynthesis.

8. Pexidartinib

- **Date of FDA Approval**: August 2, 2019
- **Indication:** **Tenosynovial giant cell tumor (TGCT**) in adults.
- **Formulation:** Capsule
- **Dose:** 400 mg orally twice daily on an empty stomach
- **Mechanism of action:** Tyrosine kinase inhibitor

References

1.https://www.drugs.com/newdrugs.html
2.https://www.medscape.com/drugs