KMCH INSTITUTE OF HEALTH SCIENCES AND RESEARCH

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SERIES 4

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DEPARTMENT OF PHARMACOLOGY- NEW DRUG UPDATE

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Innovation drives progress.

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- *Newer drugs*
- *Existing drugs with change in formulation*

1. DIROXIMEL FUMARATE

DIROXIMEL FUMARATE is similar to dimethyl fumarate, in efficacy, but its unique chemical structure is less likely to cause GI irritation. It acts by regulating cell signalling pathways causing beneficial immune & neuroprotective effects.

DIROXIMEL FUMARATE used in **relapsing forms of multiple sclerosis (MS)** in adults with active secondary progressive disease, clinically isolated syndrome & relapsing-remitting MS

Dosage & administration: Available as delayed release capsule 231 mg to be taken orally twice daily for 7 days. Maintenance dose of 462mg twice daily for 7days.

Adverse effects: Flushing, abdominal pain, diarrhea and nausea.

Date of FDA Approval: Oct 29,2019

2.ELEXACAFTOR+TEZACAFOR+ IVACAFTOR & IVACAFTOR

ELEXACAFTOR,TEZACAFTOR & IVACAFTOR combined therapy ↑quantity & function of F508del-Cystic fibrosis transmembrane conductance regulator (CFTR) protein at the cell surface, resulting in ↑CFTR activity as measured by CFTR mediated chloride transport.

ELEXACAFTOR+TEZACAFTOR+ IVACAFTOR & IVACAFTOR is indicated in **cystic fibrosis**

Dosage & administration: Per orally 2 fixed-dose tablets (Elexacaftor100 mg, Tezacaftor 50 mg and Ivacaftor 75 mg) once in the morning, one Ivacaftor 150-mg tablet in the evening, 12 hours apart. Should be taken orally with fat-containing food

Adverse effects: Headache, upper respiratory tract infection , diarrhea

Date of FDA Approval: Oct 21, 2019

3. PHENYLEPHRINE HYDROCHLORIDE

PHENYLEPHRINE HYDROCHLORIDE is an alpha-1 adrenergic receptor agonist causing vasoconstriction, used for the treatment of **hypotension** during anesthesia

Dosage & administration: **PHENYLEPHRINE** is available as a ready to use injection. IV bolus: 40-100 mcg. If BP < target, start a continuous IV infusion at a dose of 10-35 mcg/min; not to exceed 200 mcg/min

Adverse effects: Nausea, vomiting, headache, exacerbation of angina, heart failure, pulmonary arterial hypertension, peripheral & visceral ischemia, skin & subcutaneous necrosis, bradycardia

Date of FDA Approval: Oct 21, 2019

4. MINOCYCLINE

MINOCYCLINE, a broad spectrum antibiotic, acts topically by an unknown mechanism and it is indicated in **inflammatory lesions of non-nodular moderate-to-severe acne vulgaris**

Dosage & administration: Topical Foam 4%. Apply to acne-affected areas once daily at night, repeat until it resolves.

Adverse effects: Headache, rarely systemic side effects similar to oral minocycline

Date of FDA Approval: Oct 18, 2019

5. LASMIDITAN

LASMIDITAN is a serotonin (5-HT) 1F receptor agonist, indicated for **Acute migraine with or without aura in** adults

Dosage & administration: 50 mg, 100 mg, or 200 mg tablet

Adverse effects: Dizziness, fatigue, paresthesia, sedation, nausea and/or vomiting, and muscle weakness

Date of FDA Approval: Oct 11, 2019

6. ASENAPINE

ASENAPINE acts by an unknown mechanism, probably via combined antagonist activity at dopamine D_2 and serotonin type 2 ($5\text{-}HT_2$) receptor, indicated in **Schizophrenia**

Dosage & administration: Transdermal System. Apply 3.8 mg/24 hours patch initially & ↑ 5.7 mg/24 hr or 7.6 mg/24 hr after 1 week

Adverse effects: Restlessness, difficulty moving, muscle stiffness, tremors, skin irritation, weight gain

Date of FDA Approval: Oct 11, 2019

7. AFAMELANOTIDE

AFAMELANOTIDE is a First-in-class. Selective agonist of the melanocortin 1 receptor (MC1R), acts by ↑the levels of melanin in the skin & shields against UV radiation and sunlight, used to Prevent **Phototoxicity in Erythropoietic Protoporphyria**

Dosage & administration: Available as a Subcutaneous Implant - 16mg implanted SC every 2 months

Adverse effects: Implant site reaction, nausea, oropharyngeal pain, cough, fatigue, dizziness, skin hyperpigmentation, somnolence, melanocytic nevus, respiratory tract infection, non-acute porphyria, skin irritation.

Date of FDA Approval: Oct 8, 2019

8. BROLUCIZUMAB- dbll

BROLUCIZUMAB- dbll, binds to Human vascular endothelial growth factor - A (e.g., VEGF110, VEGF121 and VEGF165), thereby prevents the interaction with receptors VEGFR-1 and VEGFR-2 & suppresses endothelial cell proliferation, neovascularization and vascular permeability

BROLUCIZUMAB- dbll is used to treat **Neovascular (wet) age-related macular degeneration (AMD).**

Dosage & administration: Available as an Intravitreal Injection. 6 mg monthly for the first three doses, followed by one dose of 6 mg every 8-12 weeks

Adverse effects: Blurred vision, cataract, conjunctival hemorrhage, vitreous floaters, eye pain, endophthalmitis, retinal detachment, ↑ intra-ocular pressure & arterial thromboembolic events

Date of FDA Approval: Oct 7, 2019

9. TERIPARATIDE

TERIPARATIDE is a Parathyroid hormone analog (PTH 1-34)

TERIPARATIDE is used in **postmenopausal osteoporosis,**↑ bone mass in men with primary **hypogonadal osteoporosis**, sustained systemic **glucocorticoid therapy induced osteoporosis**

Dosage & administration: Single-patient-use pen for subcutaneous injection at a dose of 20 mcg subcutaneously once a day

Adverse effects: Arthralgia, pain and nausea

Date of FDA Approval: Oct 4, 2019

10. TRIFAROTENE

TRIFAROTENE is an agonist of retinoic acid receptors (RARγ), stimulation of RAR results in modulation of target genes which are associated with cell differentiation and mediation of inflammation. The exact process by which trifarotene ameliorates acne is unknown

TRIFAROTENE is used to treat **Acne vulgaris** in patients aged 9 years and above

Dosage & administration: 0.005% Topical Cream. Apply a thin layer of cream to the affected areas of the face and/or trunk once a day, in the evening, on clean and dry skin

Adverse effects: Site irritation, application site pruritus (itching), and sunburn

Date of FDA Approval: Oct 4, 2019

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