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NEWS LETTER OF CLINICAL PHARMACY

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Vision

St.Peter's is committed to generate, disseminate and preserve knowledge and work with pioneers of this knowledge, and to be the most sought after institute globally in the field of pharmaceutical sciences by creating world class pharmacy professionals and researchers.

Mission

To achieve academic excellence with integrity and creating opportunities for leadership and responsibilities through groundbreaking performance in the field of Pharmaceutical Sciences by educating students with pharmaceutical needs of the society and to advance the knowledge through research and to serve the profession and community.

2020(JANUARY TO MARCH) FDA APPROVED DRUG LIST

Date of approval	Name	Active ingredient	Category	MOA	Indications

09-01-2020	Ayvakit	Avapritinib	Antineoplastic agents	negatively modulates the action of cell transporters to resensitize them to other chemotherapies.	Indicated for the treatment of systemic mastocytosis (AdvSM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).
21-01-2020	Tepezza	teprotumumab	Monoclonal antibody	Inhibits the downstream effects of IGF-1R signaling	To treat thyroid eye disease
23-01-2020	Tazverik	Tazemetostat	EZH2 inhibitor or histone methyl transferase inhibitor	Inhibitor of EZH2 enzymatic activity. EPZ6438 induces apoptosis	To treat epithelioid sarcoma.
12-02-2020	Pizensy	Lactitol	osmotic laxative	Pizensy (lactitol) cause influx of water into the small intestine leading to a laxative effect in the colon.	To treat chronic idiopathic constipation (CIC) in adults.
21-02-2020	Nexletol	bempedoic acid	Lipid-Lowering Agents, ACL Inhibitors	Adenosine triphosphatecitrate lyase (ACL) inhibitor that lowers LDL-C by inhibiting cholesterol synthesis in the liver	To treat adults with heterozygous familial hypercholesterolemia or established atherosclerotic cardiovascular disease
21-02-2020	Vyepti	eptinezumabjjmr	Antimigraine Agents	Vyeptiis an humanized monoclonal antibody that binds to calcitonin generelated peptide (CGRP) ligand and blocks its binding to the	For the preventive treatment of migraine in adults.
				receptor	

26-02-2020	Barhemsys	Amisulpride	Antiemetic Agents	amisulpride blocks presynaptic autoreceptors, which facilitates dopamine release and thus resolves dopaminergic hypoactivity and the symptoms of depression	To help prevent nausea and vomiting after surgery.
27-02-2020	Nurtec ODT	Rimegepant	Antimigraine Agents	binds to CGRP receptor, which is thought to be causally involved in migraine pathophysiology	To treat migraine
02-03-2020	Sarclisa	Isatuximab	monoclonal antibodies	binds to the CD38 receptor on multiple myeloma cells. It induce programmed tumor cell death (apoptosis)	To treat multiple myloma.
06-03-2020	Isturisa	Osilodrostat	Steroidogenesis Inhibitors	inhibitor of 11betahydroxylase, an enzyme that catalyzes the final step of cortisol synthesis in the adrenal cortex	To treat adults with Cushing's disease

MONOGRAPH ON AVAPRITINIB

Brand name: Ayvakit
Class: Antineoplastic Agents
Category: Selective tyrosine **; Indication:** Indicated for the treatment of adult patients with advanced systemic mastocytosis (AdvSM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).

Mechanism of action : Avapritinib is a selective kinase inhibitor that negatively modulates the action of cell transporters to resensitize them to other chemotherapies.

Pharmacokinetics-

Absorption- Tmax- 2 to 4 hours and Cmax- 813ng/dL

Distribution- mean apparent volume of distribution- 1200L

Metabolism: metabolized mainly by CYP3A4 and CYP2C9 in vitro.

Elimination- 81% eliminated in feces and 18% as unchanged in urine

Half-life- 32-57h

Clarence- apparent oral clearance – 19.5L/h

Administration: Orally (i.e., ≥1 hour before or 2 hours after a meal). **Warnings/Precautions**

- Intracranial Hemorrhage
- CNS effects
- Fetal/Neonatal Morbidity and Mortality
- Impairment of Fertility **Specific Populations**

1. Pregnancy - May cause fetal harm.
2. Lactation Not known
3. Pediatric Use Safety and efficacy not established.

Common Adverse Effects

Edema, nausea, fatigue, asthenia, cognitive impairment, vomiting, decreased appetite, diarrhea, hair color changes, increased lacrimation, abdominal pain, constipation, rash, dizziness, decreased hemoglobin concentration, leukopenia, neutropenia, thrombocytopenia, elevated INR, elevated bilirubin concentration, hypophosphatemia, hypokalemia, hypoalbuminemia, hypomagnesemia, elevated serum creatinine concentration, hyponatremia

TREATMENT GUIDELINES FOR COVID-19 IN PREGNANCY

COVID-19 is acquired following infection with the severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) pathogen. Pregnant women do not appear to be more likely to contract SARS-CoV-2 than the general population, and most women who are infected during pregnancy will only ever experience mild to moderate symptoms. Reported cases of COVID-19 pneumonia in pregnancy are milder and with good recovery. Pregnant women with heart disease are at highest risk (congenital or acquired). **Antenatal Care**

Women should be advised to attend routine antenatal care at the discretion of the maternal care provider at 12, 20, 28 and 36 weeks of gestation, unless they meet current self-isolation criteria.

For women who have had symptoms, appointments can be deferred until 7 days after the start of symptoms, unless symptoms (aside from persistent cough) become severe. Foetal Kick count to be maintained.

For women who are self-quarantined because someone in their household has possible symptoms of COVID-19, appointments should be deferred for 14 days.

Any woman who has a routine appointment delayed for more than 3 weeks should be contacted.

Intrapartum Care- Once settled in an isolation room, a full maternal and foetal assessment should be conducted to include:

Assessment of the severity of COVID-19 symptoms, which should follow a multidisciplinary team approach including an infectious diseases or medical specialist.

Delivery should be preferably at tertiary care centre. Maternal observations including temperature, respiratory rate & oxygen saturations.

Confirmation of the onset of labour, as per standard care.

Care in Labour- Aim to keep oxygen saturation >94%, titrating oxygen therapy accordingly.

If the woman has signs of sepsis, investigate and treat as per guidance on sepsis in pregnancy, but also consider active COVID-19 as a cause of sepsis and investigate according to guidance.

There is currently no evidence to favour one mode of birth over another. Mode of birth should not be influenced by the presence of COVID-19, unless the woman's respiratory condition demands urgent delivery.

There is no evidence that epidural or spinal analgesia or anaesthesia is contraindicated in the presence of coronaviruses

In case of deterioration in the woman's symptoms, make an individual assessment regarding the risks and benefits of continuing the labour, versus emergency caesarean birth if this is likely to assist efforts to resuscitate the mother.

Management of Patients with COVID-19 Admitted to Critical Care Particular considerations for pregnant women are:

- Radiographic investigations should be performed as for the non-pregnant adult, especially CT chest, is essential for the evaluation of the patient with COVID-19 and should be performed when indicated, and not delayed due to foetal concerns. Abdominal shielding can be used to protect the foetus as per normal protocols.

- The frequency and suitability of foetal heart rate monitoring should be considered on an individual basis, If urgent delivery is indicated for foetal reasons, birth should be expedited as normal, as long as the maternal condition is stable.

Breastfeeding - During temporary separation, mothers who intend to breastfeed should be encouraged to express their breast milk to establish and maintain milk supply.

COMPLICATIONS OF COVID-19 DISEASE

Some life threatening complications of covid-19 have been seen in 1 in 6 patients. Many of these complications may be caused by a condition known as cytokine release syndrome or cytokine storm. This is when an infection triggers our immune system to flood your blood stream with inflammatory proteins called cytokines. They can kill tissue and damage the organs, including lungs, heart and kidneys.

Complications of COVID-19 include:

Pneumonia, Acute respiratory distress syndrome, Acute liver injury, Acute cardiac injury, Acute kidney injury, Septic shock , Disseminated intravascular coagulation, Blood clots, Multisystem inflammatory syndrome in children, Chronic fatigue, Rhabdomyolysis, Neurological disorders

Treatment update of COVID-19 include:

1. Convalescent plasma
2. Monoclonal antibodies
3. Dexamethasone
4. Bamlanivimab and Etesevimab
5. Casirivimab and Imdevimab(REGN-COV2)
6. Remdesivir

Treatment that NIH recommends against the use of COVID-19:

1. Hydroxychloroquine and chloroquine
2. Azithromycin
3. Tocilizumab and other IL-6 inhibitors

Various diagnostic tests recommended for patients recovered after COVID-19

- Ig G antibodies tests
- Complete blood picture
- Glucose, cholesterol tests
- Vitamin D test Chest scans
- Cardiac screening.

POST COVID FOLLOW UP CARE

- Nutritious diet
- Keep yourself hydrated
- Rest, exercise and meditation Avoid indulging in deleterious habits