Shaukat Khanum Memorial Cancer Hospital and Research Center

Pharmacy Newsletter

Volume XI, Issue # 2, 2021

Issued By:

Drug Information Centre, SKMCH & RC

P&TC Updates:

Following drugs are approved by Pharmacy & Therapeutics Committee (P&TC) during 2021 SKMCH&RC:

1. **Tapentadol Tab (IR)** – As regular formulary item.
2. **Morphine Sulfate Inj (Preservative Free) for IT** - As regular formulary item.
3. **Palbociclib Tab** – Restricted by Cost (In Stage IV metastatic breast cancer only)
4. **Brentuximab Inj** – Restricted by Cost (3 Indigent slots / year)
5. **Venetoclax Inj** – Restricted by Cost (6 Indigent cycles / year)
6. **Azacitidine Inj** – Restricted by Cost (6 Indigent cycles / year)

New Approvals:

Trilaciclib: First Drug to Reduce Bone Marrow Suppression Caused by Chemotherapy

The US food and drug administration recently approved, a first drug of its class to reduce the frequency of chemotherapy induced bone marrow suppression in adult cancer patients. By inhibiting cyclin-dependent kinase 4/6 enzyme, Cosela (trilaciclib) help protect bone marrow cells from damage caused by platinum/etoposide- or topotecan-based regimen for extensive-stage small cell lung cancer. Three randomized, double-blind, placebo-controlled studies involving total of 245 patients evaluated the effectiveness of trilaciclib in patients suffering with extensive-stage small cell lung cancer. Either a placebo or trilaciclib infusion was administered through vein before chemotherapy. Both groups were compared for proportion of patients with severe neutropenia and duration of severe neutropenia in the first cycle of chemotherapy. It was identified that as compared to placebo, patients in trilaciclib group not only had shorter episode of severe neutropenia but also had a lower chance of getting it.

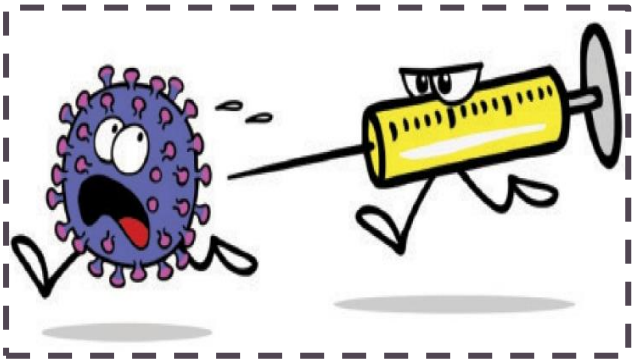
Fatigue; low levels of calcium, potassium and phosphate; increased levels of aspartate aminotransferase; headache; and infection in the lungs (pneumonia) are the most common side effects of trilaciclib. In addition to them patients must be educated about injection site reactions, acute drug hypersensitivity, interstitial lung disease/pneumonitis (lung tissue inflammation) and embryo-fetal toxicity. Recommended dose of trilaciclib is approved as 240 mg/m^2/dose; administered prior to chemotherapy on each day chemotherapy is administered.

Ref: https://www.fda.gov/news-events/press-announcements/fda-approves-drug-reduce-bone-marrow-suppression-caused-chemotherapy

News & Updates:

Newer COVID 19 Vaccines Registered in Pakistan – Vaccine Tracker

The Drug Regulatory Authority of Pakistan (DRAP) granted permission to use the vaccine under section VII of the Drug Act 1976. The DRAP Registration board has approved the vaccine's use for children older than 12. It can also be administered to those with low immunity — including pregnant women — and those above 40 who wish to perform Haj. Pakistan received its first shipment of the Pfizer-BioNTech vaccine from Covax on May 28, 2021. It is the sixth Covid vaccine to be approved for use in the country.



ZF2001, trade-named RBD-Dimer, is a COVID-19 vaccine candidate developed by Anhui Zhifei Longcom in collaboration with the Institute of Microbiology at the Chinese Academy of Sciences. As of December 2020, the vaccine candidate was in Phase III trials with 29,000 participants in China, Ecuador, Indonesia, Malaysia, and Uzbekistan. If the trials are successful, the company plans to make 300 million doses of the vaccine each year. The vaccine has been approved by the DRAP and trials have begun from April 5, 2021 in five different territories of Pakistan.

Ref: https://covid19.trackvaccines.org/vaccines/6/, https://covid19.trackvaccines.org/vaccines/27/

Dose Reductions Trigger Type-A ADRs: Need to Report

Retrospective review of cytotoxic dose reductions has revealed that most of the time the reason behind the dose reduction in subsequent cycles is tolerance and adverse drug reaction (ADR). Therefore, we reviewed dose reductions and identified potential ADRs responsible for them. ADR reporting improved, considering dose reduction a trigger tool to identify type-A ADRs. Thus, it is recommend, that dose reductions resulting from type-A ADRs must be reported and should not be ignored.

John Cunningham (JC) Virus Infection: A Clinical Conundrum

Progressive multifocal leukoencephalopathy (PML) is a weakening and frequently lethal central nervous system (CNS) demyelinating illness brought about by JC virus (JCV). It is a progressive disease and can leads to death within months if the patients remain immunocompromised. Prior to the mid-1980s, PML was a generally uncommon illness, answered to happen fundamentally in those with basic neoplastic conditions and in allograft beneficiaries getting immunosuppressive medications. Notwithstanding, with the beginning of the AIDS pandemic, the occurrence of PML has expanded drastically. Around 3 to 5% of HIV-contaminated people will foster PML, which is named as AIDS-characterizing illness. Furthermore, the new approach of refined monoclonal immunizer treatment immune system provocative illnesses like Crohn's sickness has additionally prompted an expanded danger of PML as a symptom of immunotherapy including Lenalidomide and thalidomide. In this manner, the investigation of JCV and the explanation of the basic reasons for PML are significant and dynamic spaces of examination that may prompt new experiences into safe capacity and host antiviral guard, just as to possible new treatments.

Ref:https://hpr-rps.hres.ca/reg-content/summary-safety-review-detail.php?lang=en&linkID=SSR00268, https://jcpsp.pk/archive/2019/SS_Jun2019/08.pdf

Use of NSAIDs Beyond 20 Weeks of Pregnancy and Risk of Kidney Damage to Unborn Babies: An Update

After 20 weeks of pregnancy, the use of non-steroidal anti-inflammatory drugs (NSAIDs) may cause rare but serious kidney problems in an unborn baby. This can lead to low levels of amniotic fluid surrounding the baby, since, after around 20 weeks of pregnancy; the unborn babies' kidneys produce most of the amniotic fluid. Health Canada suggested that pregnant women should not use NSAIDs from approximately 20 to 28 weeks of pregnancy. If necessary, then consider ultrasound monitoring of amniotic fluid and discontinue treatment if oligohydramnios is found.

35 cases were reported to FDA of low amniotic fluid levels or kidney problems in 2017. Out of which two died with kidney failure and had confirmed low amniotic fluid because mothers took NSAIDs during pregnancy. Three of them who died had kidney failure without confirmed low amniotic fluid. Low amniotic fluid levels were detected in 11 patients during pregnancy. According to reports, the condition was reversed when NSAID was stopped, and it reappeared when the same NSAID was started again.

Ref:https://www.fda.gov/drugs/drug-safety-and-availability/fda-recommends-avoiding-use-nsaids-pregnancy-20-weeks-or-later-because-they-can-result-low-amniotic, https://www.biospace.com/article/releases/labelling-update-regarding-the-use-of-non-steroidal-anti-inflammatory-drugs-nsaids-beyond-20-weeks-of-pregnancy-and-risk-of-kidney-damage-to-unborn-babies/, https://www.newswire.ca/news-releases/labelling-update-regarding-the-use-of-non-steroidal-anti-inflammatory-drugs-nsaids-beyond-20-weeks-of-pregnancy-and-risk-of-kidney-damage-to-unborn-babies-866

FDA Alerts Health Care Professionals & Patients to a Voluntary Recall of Varenicline (Chantix) to the Warehouse Level

FDA is alerting patients and health care professionals to Pfizer's voluntary recall of nine lots of the smoking cessation drug, varenicline (brand name Chantix), to the warehouse level. This is because it may contain nitrosamine impurity, called N-nitroso-varenicline, above FDA's acceptable intake limit. N-nitroso-varenicline may be associated with a potential increased cancer risk in humans with long-term use, and the health benefits of stopping smoking outweigh the cancer risk from the nitrosamine impurity in varenicline. Although there are no data available to directly evaluate the carcinogenic potential of N-nitroso-

varenicline, information available on closely related nitrosamine compounds was used to calculate lifetime exposure limits for N-nitroso-varenicline. The affected lot nos. are 00020231, 00020232, 00020357, 00020358, 00020716, 00019213, ET1607, ET1609 and EC6994.

Ref:https://www.fda.gov/drugs/drug-safety-and-availability/fda-alerts-health-care-professionals-and-patients-voluntary-recall-varenicline-chantix-warehouse

Sinopharm COVID 19 Vaccine Results Published in JAMA

The published results were about a pre-specified interim analysis of an ongoing randomized, double-blind, phase 3 trial in the United Arab Emirates and Bahrain among adults 18 years and older without known history of COVID-19. Study enrolment began on July 16, 2020. Data sets used for the interim analysis of efficacy and adverse events were locked on December 20, 2020, and December 31, 2020, respectively. Participants were randomized to receive 1 of 2 inactivated vaccines developed from SARS-CoV-2 WIV04 (5 µg/dose; n = 13 459) and HB02 (4 µg/dose; n = 13 465) strains or an aluminium hydroxide (alum)–only control (n = 13 458); they received 2 intramuscular injections 21 days apart. The primary outcome was efficacy against laboratory-confirmed symptomatic COVID-19 14 days following a second vaccine dose among participants who had no virologic evidence of SARS-CoV-2 infection at randomization. The secondary outcome was efficacy against severe COVID-19. Incidence of adverse events and reactions was collected among participants who received at least 1 dose.

Among 40 382 participants randomized to receive at least 1 dose of the 2 vaccines or alum-only control (mean age, 36.1 years; 32 261 [84.4%] men), 38 206 (94.6%) who received 2 doses, contributed at least 1 follow-up measure after day 14 following the second dose, and had negative reverse transcriptase–polymerase chain reaction test results at enrolment were included in the primary efficacy analysis. During a median follow-up duration of 77 (1-121) days, symptomatic COVID-19 was identified in 26 participants in the WIV04 group (12.1 [95% CI, 8.3-17.8] per 1000 person-years), 21 in the HB02 group (9.8 [95% CI, 6.4-15.0] per 1000 person-years), and 95 in the alum-only group (44.7 [95% CI, 36.6-54.6] per 1000 person-years), resulting in a vaccine efficacy, compared with alum-only, of 72.8% (95% CI, 58.1%-82.4%) for WIV04 and 78.1% (95% CI, 64.8%-86.3%) for HB02 ($P < .001$ for both). Two severe cases of COVID-19 occurred in the alum-only group and none occurred in the vaccine groups. Adverse reactions 7 days after each injection occurred in 41.7% to 46.5% of participants in the 3 groups; serious adverse events were rare and similar in the 3 groups (WIV04: 64 [0.5%]; HB02: 59 [0.4%]; alum-only: 78 [0.6%]).

In this pre-specified interim analysis of a randomized clinical trial, treatment of adults with either of 2 inactivated SARS-CoV-2 vaccines significantly reduced the risk of symptomatic COVID-19, and serious adverse events were rare. Data collection for final analysis is pending.

Ref: Al Kaabi N, Zhang Y, Xia S, et al. Effect of 2 Inactivated SARS-CoV-2 Vaccines on Symptomatic COVID-19 Infection in Adults: A Randomized Clinical Trial. JAMA. 2021;326(1):35–45. doi:10.1001/jama.2021.8565

GELCLAIR: An Oral Protective Gel for Mucositis Relief

To combat mucositis in cancer patients post chemotherapy, a combination of Polyvinylpyrollidone (PVP) & Sodium hyaluronate as oral protective gel for mucositis relief (brand name Gelclair®) has been introduced at SKMCH & RC.

For use, pour 15ml of Gelclair® into a glass and add approximately 40ml of water. Stir mixture well and use at once. Rinse around the mouth for at least one minute or as long as possible to coat tongue, palate, throat, inside of cheeks and all oral tissue thoroughly. Gargle and spit out. Discard any unused mouthwash.

In patients who are unable to rinse and gargles, it is suggested to apply the product directly into the mouth by using sponge or swab. The gel can be used 3 times a day or as needed. In addition, eating and drinking should be avoided for at least 30-60 minutes following treatment.

Sharing is Caring:

A Visit to Pharmacy SKMCH & RC by Shifa International Hospital Pharmacists

A delegate from Shifa International Hospital visited pharmacy SKMCH & RC Lahore for observing expert practices and procedures required for American Society of Health-System Pharmacists, International Pharmacy Practice Residency program (IPPR) accreditation. In addition to visit to all areas of pharmacy and introduction to different services provided, the delegate had sessions with director, associate director pharmacy, residency program director, preceptors and residents. At the end of the visit, the delegate shared their thoughts that this visit will definitely help them to improve their practices in compliance with the standards provided by ASHP for accreditation of IPPR program. We wish them best of luck for accreditation.

Kudos to Resident Upon Successful Completion of Residency

Congratulations! The pharmacy team SKMCH & RC is delighted to announce that one more resident of American Society of Health-System Pharmacists, International Pharmacy Practice Residency program, Ms. Erum Mumtaz has successfully completed her residency. We wish her best of luck for her future.

Presentations, Webinars & Conferences

Department of pharmaceutical services proudly announces the highlights of different presentations and sessions presented virtually. The sessions were conducted at different dates and in collaboration with different forums. The details are as following,

- **Leadership is Mentorship**
  Presented by Mr. Omar Akhlaq Bhutta, SKMCH & RC, on 12/6/2021 in Giving Back to Pharmacy in Pakistan
- **COVID-19 Vaccination: Debunking the Myths**
  Presented by MR. Muhammad Rehan Khan, SKMCH & RC, on 23/4/2021 in UCP Health Club
- **Advancements and Opportunities in Pharmacy Profession**
  Presented by Ms. Saba Mazhar, SKMCH & RC, on 1/5/2021 in Lahore Pharmacy College
- **Self-Medication of Antibiotics**
  Presented by Mr. Muhammad Rehan Khan, SKMCH & RC, on 20/5/2021 in Giving Back to Pharmacy in Pakistan
- **Health Risks of Self-Medication and its Role in COVID 19**
  Presented by Mr. Nasir Mehmood, SKMCH & RC, on 30/5/2021 in Giving Back to Pharmacy in Pakistan
- **The Status of Antibiotic Stewardship in Pakistan**
  Presented by Mr. Ghulam Mujtaba, SKMCH & RC, on 5/6/2021 in Giving Back to Pharmacy in Pakistan
- **COVID19 vaccination: Role of Pharmacists and Tackling Misinformation**
  Presented by Mr. Shoaib Shammas, SKMCH & RC, on 27/6/2021 in Giving Back to Pharmacy in Pakistan

Publications:

1. **The crux of Pakistan's prolonged rabies vaccine shortage: A rising mortal threat in the COVID-19 pandemic**

   ***Contributors: Adeel Siddiqui**, Ali Ahmed, Maria Tanveer, and Asma Arshad*

   ***Journal:** Journal of Medical Virology (IF-2.327)*

2. **The mystery of plummeting cases of measles during COVID-19 pandemic in Pakistan: Hidden impact of collateral damage**

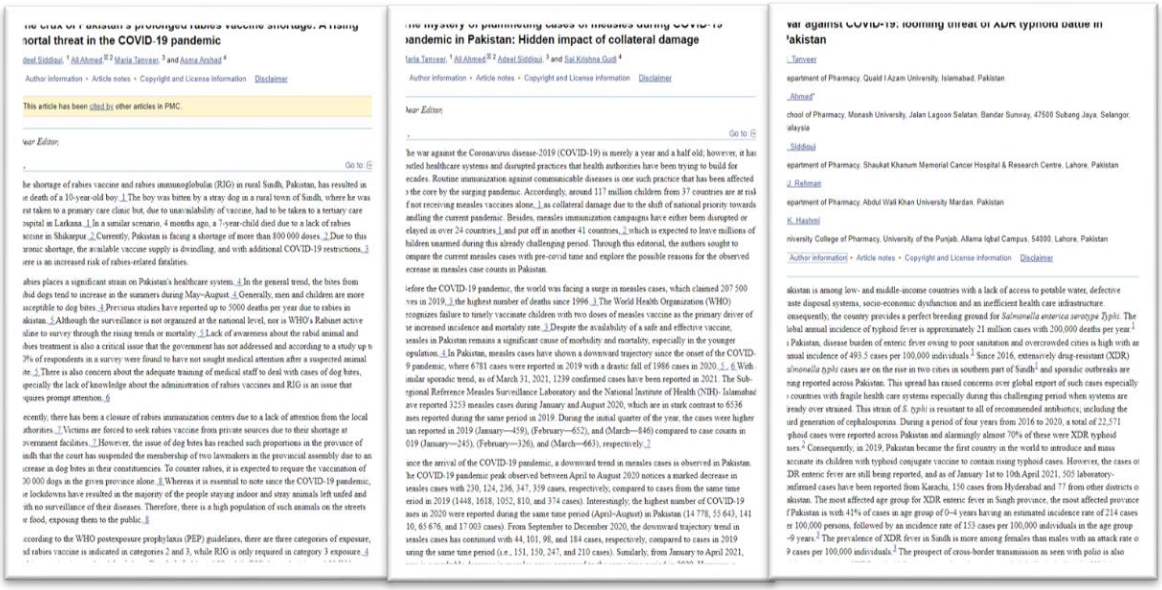
   ***Contributors:** Maria Tanveer, Ali Ahmed, **Adeel Siddiqui**, and Sai Krishna Gudi*

   ***Journal:** Journal of Medical Virology (IF-2.327)*

3. **War against COVID-19: looming threat of XDR typhoid battle in Pakistan**

   ***Contributors:** Maria Tanveer, Ali Ahmed, **Adeel Siddiqui**, Inayat Ullah Rehman, and Furqan Khurshid Hashmi*

   ***Journal:** Public Health (IF-2.427)*



COVID-19 Cases Surge in Pakistan Again

Nowadays, people of Pakistan are facing the fourth wave of COVID-19. Reports of delta variant prevalence in Pakistan have been published. Thus, the number of affected patients is again on the rise, but on the other side vaccinated population is also increasing. It is recommended by Government of Pakistan that everyone above 18 years of age, should be vaccinated. We must follow safe practices to make our society, free of COVID-19.

Feedback

To keep the Pharmacy Newsletter updated,
Please contact at druginfo@skm.org.pk