Drug Information Bulletin

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Regulatory Affairs Division (RAD), IPA

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Content

Editorial

Every alternate weekend I face challenge to choose the topic from several issues to write editorial for this bulletin. This time I have no hesitation in choosing the topic as Dr. M.R. Rajagopal has been awarded "Padmashree Award" for his exemplary work for last few decades to provide palliative care to the patients suffering from pain especially for terminally ill patients suffering from cancer and HIV/AIDS. Long term legal battle under his leadership forced the Govt. of India to redraft some clauses of Narcotic and Psychotropic Substances Act (NDPS) for making more accessible to Essential Narcotic drugs for treatment purpose only. Though India is the largest producer of medicinal Narcotics and exporting throughout the globe, per capita consumption of Morphine is quite less in comparison to other countries. This situation was developed due to inadequate training to the health care providers for judicious use of narcotics for medicinal purpose and fear of stringent penal provisions of the NDPS. In 2015 the NDPS Act has been amended making a provision for approving a medical Institution as "Recognized Medical Institution" with certain conditions by a single authority i.e. Drugs Controller of the state. This mechanism will improve access to the Essential Narcotic Drugs for palliative care.

I am fortunate to have contact with him during last three decades since I was a researcher on developing drug delivery system for terminally ill patients. He was so committed that he came to meet me all the way from Kerala along with Dr. S.S.Mitra of UK for helping them to initiate work in this state especially with the Govt. Kudos to Dr. Rajagopal for his leadership in this movement for the millions of terminally ill patients who need palliative care.

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New Drug: Ceritinib

INDICATIONS AND USAGE: It is a kinase inhibitor indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test.

DOSAGE AND ADMINISTRATION: 450 mg orally once daily with food.

DOSAGE FORMS AND STRENGTHS:

Capsules: 150 mg

WARNINGS AND PRECAUTIONS: Gastrointestinal Adverse Reactions: It can cause gastrointestinal• adverse reactions. If severe or intolerable, withhold if not responsive to antiemetics or antidiarrheals, then dose reduce ZYKADIA. Hepatotoxicity: It can cause hepatotoxicity. Monitor liver• laboratory tests at least monthly. Withhold then dose reduce, or permanently discontinue ZYKADIA. Interstitial Lung Disease (ILD)/Pneumonitis: Occurred in 2.4% of patients.• Permanently discontinue ZYKADIA in patients diagnosed with treatmentrelated ILD/pneumonitis. QT Interval Prolongation: ZYKADIA can cause QTc interval prolongation.• Monitor electrocardiograms and electrolytes in patients with congestive heart failure, bradyarrhythmias, electrolyte abnormalities, or those who are taking medications that are known to prolong the QTc interval. Withhold then dose reduce, or permanently discontinue ZYKADIA. Hyperglycemia: ZYKADIA can cause hyperglycemia. Monitor fasting• glucose prior to treatment and periodically thereafter as clinically indicated. Initiate or optimize antihyperglycemic medications as indicated. Withhold then dose reduce, or permanently discontinue ZYKADIA. Bradycardia: ZYKADIA can cause bradycardia. Monitor heart rate and• blood pressure regularly. Withhold then dose reduce, or permanently discontinue ZYKADIA. (2.3, 5.6) Pancreatitis: Elevations of lipase and/or amylase and pancreatitis can occur.• Monitor lipase and amylase prior to treatment and periodically thereafter as clinically indicated. Embryo-Fetal Toxicity: ZYKADIA can cause fetal harm. Advise females• of reproductive potential of the potential risk to a fetus and to use effective contraception.

ADVERSE REACTIONS: The most common adverse reactions (incidence of at least 25%) in patients treated with ZYKADIA 750 mg fasted are diarrhea, nausea, fatigue, vomiting, abdominal pain, decreased appetite, and weight loss. (6) To report SUSPECTED ADVERSE REACTIONS, contact Novartis Pharmaceuticals Corporation at 1-888-669-6682 or FDA at 1-800-FDA1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS: CYP3A Inhibitors and Inducers: Avoid concurrent use of ZYKADIA with• strong CYP3A inhibitors or inducers. If concurrent use of a strong CYP3A inhibitor is unavoidable, reduce the dose of ZYKADIA. CYP3A and CYP2C9 Substrates: Avoid concurrent use of ZYKADIA with• CYP3A or CYP2C9 substrates with narrow therapeutic indices.

USE IN SPECIFIC POPULATIONS: Lactation: Advise not to breastfeed.

Ref. US FDA

Status in India: Ceritinib Capsules 150 mg approved by CDSCO on 28-12-2017 as monotherapy is indicated for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK) – positive advanced non small cell lung cancer (NSCLC). With the condition: to be sold by retail on the prescription of Oncologist only.

Safety Issues:

Clozapine Potentially fatal risk of intestinal obstruction, faecal impaction, and paralytic ileus

The Medicines and Healthcare Products Regulatory Agency (MHRA) has reminded healthcare professionals that clozapine (Clozaril®, Denzapine®, Zaponex®) is contraindicated in patients with paralytic ileus and when prescribing clozapine, particular care should be taken in patients at risk of constipation. Clozapine is an atypical antipsychotic drug. In the United Kingdom, there have been 370 reports of gastrointestinal obstruction associated with clozapine between 3 August 1993 and 11 September 2017. In this time period, there have also been 135 reports of faecaloma and 86 of

paralytic ileus. The risk of gastrointestinal adverse effects is long established with clozapine. Warnings are provided in the Summary of Product Characteristics and Patient Information Leaflet and in the British National Formulary. However, in August 2017, a Coroner investigating a death raised concerns to the MHRA that health-care professionals might have a lack of awareness about the risk of pseudoobstruction or paralytic ileus and the fast onset. Patients are advised that if they develop constipation, they should tell their doctor immediately before taking the next dose of clozapine. The MHRA stated that it is vital that constipation is recognised early and actively treated.
Reference: Drug Safety Update, MHRA, Volume 11, issue 3: 4, October 2017 (www.gov.uk/mhra)

Isotretinoin Rare reports of erectile dysfunction and decreased libido

The MHRA has stated that cases of sexual dysfunction, predominantly involving erectile dysfunction and decreased libido, have been reported rarely in patients taking oral isotretinoin (Roaccutane®) for severe acne. In the United Kingdom, the MHRA have received 14 Yellow Card reports of sexual dysfunction associated with isotretinoin between the 1985 and 7 September 2017. In the same time period, there have been 49 reports of erectile or ejaculation dysfunction, and 23 reports of decreased or loss of libido associated with isotretinoin. The MHRA has advised healthcare professionals to be aware of reports of sexual adverse effects, including erectile dysfunction and decreased libido, in patients taking oral isotretinoin, indicated for severe acne. The exact incidence of these adverse reactions is unknown but is considered to be rare.
Reference: Drug Safety Update, MHRA, Volume 11, issue 3: 3, October 2017 (www.gov.uk/mhra) (See WHO Pharmaceuticals Newsletter No.1, 2017: Potential risk of impotence (erectile dysfunction) in Canada)

Hospitals are starting their own drug company

A collection of major hospital systems is banding together to create their own nonprofit generic drug company to combat shortages and price spikes. With about 300 hospitals on board and more likely to join, the group is staying quiet about which drugs it plans to make to prevent competitors from manipulating the market to shut them out.
The New York Times (free-article access for SmartBrief readers)

Brexit may hamper access, development of rare-disease drugs

Patient-advocate group Eurodis raised concerns that Brexit will affect access to drugs for rare diseases and inhibit their research and development. "If the UK leaves the single market, there will likely be an inflation in the costs of pharmaceutical products as, unless a special agreement is reached, industry will have to adopt costly measures to run regulatory affairs in the UK and also in the EU," said Virginie Hivert, speaking for the organization.
Ref. In-Pharma Technologist

European agency grants orphan status to leukemia candidate

The European Medicines Agency granted orphan drug designation to MEI Pharma's investigational drug candidate pracinostat as a treatment for adult patients with acute myeloid leukemia who are unsuited to undergo induction chemotherapy. MEI and its partner, the Helsinn Group, are conducting a late-stage combining pracinostat with azacitidine as an AML treatment regimen.
Ref. Seeking Alpha (free registration)

Maharashtra State Transfusion Council Slaps Notice on 25 Blood Banks For Overcharging

The State Blood Transfusion Council (SBTC) has issued notices to around 25 blood banks in city for overcharging . According to the notices sent, the blood banks from public, private and charitable hospitals were overcharging different amounts for blood bags, fresh frozen plasma (FFP), platelets, and cryoprecipitate.

The notice details were known after copies were received through Right To Information (RTI) application filed by RTI applicant Chetan Kothari. Earlier, the applicant had written to the state information commission (SIC) on lack of blood banks details displayed on the SBTC website.

As per the actual charges levied by the government, whole blood cost ₹ 1,450; FFP cost ₹ 400; platelet cost ₹ 400 and cryoprecipitate cost ₹ 250. The 25 blood banks in the different hospitals were overcharging whole blood by ₹ 1,500 to ₹ 3,300; FFP is overcharged by ₹ 480 to ₹ 850; platelets are overcharged by ₹ 450 to ₹ 1,050 and cryoprecipitate is overcharged by ₹ 390 to ₹ 700.

The SBTC officials refused to comment on the overcharging issues at blood banks in the city. One of the officials on condition of anonymity, said, "The blood banks are sending us to reply to the notices sent to them with an explanation of the issue. We are yet to get a reply from all the blood banks."

"Previously many blood banks were found overcharging, but they were let off, by warning but still they repeated the violation. When SBTC has got a rate card that the blood banks should be charging, they should put it up on the website for transparency," said RTI activist Chetan Kothari.

Ref. Drugs control.org

Forthcoming Event:

Indian Pharmaceutical Association

National Convention

2017-2018

10-11 February 2018

Chennai

Organized by :

IPA, Tamil Nadu Branch

Theme:

Pharma Vision 2030: Planning the Future

Venue:

B.S. Abdus Rahaman Crescent Institute of Science & Technology, Vandalur, Chennai, Convention Centre

For details: www.Ipanationalconvention.com

Refresher Course to Registered Pharmacists

As per sec 4.2 of the Pharmacy Practice Regulations, 2015 refresher course will be provided by IPA- Bengal Branch on 3rd February 2018 onwards.

REGISTRATION FORM

Name……
Registration No……
Gender: Male/Female……..
Date of Birth……
Renewal up to……..
Professional address
……
Mobile No……
Email……
Food Preference: Veg/Non-Veg……
Mode of Payment: Cash/DD/Cheque
No……Dated……
Drawn on
Bank……Branch……
……
Rupees (in words)……

Signature of the Pharmacist
Date: Place: