OUR LADY OF THE LAKE RMC

In*Pharm*ation

The official publication of the Pharmacy Department

Volume 1, Issue 2

Inside this issue:

Staff Spotlight

Danielle Sidney, PharmD

Position: pharmacist

Favorite Scripture: Proverbs 3: 5-6 "Trust in the Lord with all of your heart and lean not on your on understanding; in all your ways submit to Him, and He will make your paths straight."

Danielle, born and raised in New Orleans, loves traveling and experiencing new places and cultures. If given the opportunity, she would travel to Italy. When Danielle is not at work, you can find her taking weekend trips with friends or family, heading to a music based event or chowing down on her favorite meal, lasagna! Danielle also loves watching Broadway shows. She sees every touring that comes through New Orleans. Besides traveling, Danielle loves providing the best possible care to patients.

Danielle really loves traveling, but what makes her adventures so special is that she is a "live in the moment" person. She would rather have the memories of an experience that she has fully immersed herself in than capture the moment from afar.

The Buzz on Biosimilars

By Carli Nesheiwat, Pharm.D., BCOP

The healthcare community is buzzing over the arrival of biosimilars in the US drug market: how are they different from generic drug products and what impact will this have in the pharmaceutical marketplace?

Biosimilars are different than generic medications because biologic agents are developed differently from traditional drugs. Conventional medications are synthesized following a chemical recipe which leads to a pure chemical substance and known structure, which lends to the traditional generic drug development process. Biologic medications can be difficult to replicate as they are complex molecules often derived from living organisms and involve sensitive manufacturing processes. The FDA's Associate Director for Therapeutic Biologics stated:

"Because of the differences in complexity of the structure of the biologic and the process used to make a biologic, biosimilars are not as easy to produce as generics, which are copies of brand name drugs. A biosimilar is not an exact duplicate of another biologic; rather, a biosimilar is highly similar to the reference product."

The FDA, which regulates approval of biosimilars under the Public Health Service Act, considers a biological product to be biosimilar if it is "highly similar" to an approved product for use in the US. A biosimilar drug must have the same mechanism of action, dosing, and administration as the reference drug but will be allowed to have minor variations in inactive portions of the product. Reference and respective biosimilar drugs will have the same indications. The manufacturer must submit analytical and animal studies, as well as at least one clinical study to demonstrate safety, purity, and potency for which the original product has already obtained approval for use. The clinical study could include immunogenicity profiling or a pharmacokinetic trial.

A list of reference biologic agents and any biosimilarity or interchangeability data will be contained in the Purple Book. A biosimilar product may also be deemed interchangeable if it meets additional standards. Biosimilar interchangeability will be defined as one of the following: not similar, similar, highly similar, and highly similar with fingerprint-like similarity. An interchangeable biologic product may be substituted by the pharmacist without physician authorization. Like any new medication, each FDA-approved biosimilar will require individual evaluation for hospital formulary consideration through the P&T Committee.

Filgrastim-sndz, or Zarxio™, was the first biosimilar to receive FDA approval in March 2015. It has the same indications as Neupogen® but is not an interchangeable product. This product became an approved biosimilar in Europe in 2009 under a similar brand name.

Zarxio™ and future biosimilars are projected to cost 10-30% less than the reference products and are predicted to avoid more than $40 billion over 10 years. Reference drugs retain exclusivity for at least 12 years before a biosimilar may be approved. While Zarxio™ is the only approved biosimilar to date, biosimilar development and submission is underway for key products including Humira®, Enbrel®, Remicade®, and Neulasta®.

The era of biosimilars in pharmacy has arrived. The biosimilar approval process has been established, but the impact of biosimilars on healthcare delivery remains unclear.

Formulary Changes

- **Opdivo (nivolumab):** formulary; **restricted** to outpatient use for patients with melanoma (unresectable or metastatic) or metastatic non-small cell lung cancer. Dose is 3 mg/kg once every two weeks
- **Lemtrada (alemtuzumab**): formulary, **restricted** outpatient use for patients with relapsing forms of multiple sclerosis (failed ≥ 2 therapies). Dose is 12mg/day x 5 days, then 12 months later, 12mg/day x 3 days.
- Covera HS, Isoptin SR, and Verelan PM therapeutically **interchange to Verelan**. (See Formweb). Verelan can be opened and sprinkled over applesauce or administered via enteral tube if needed.

Deletions

- Bumetanide 0.25mg/mL, 2mL vl
- Topical starch, 51% supp
- Atropine 1%, 2mL vial
- Etoposide 50mg caps
- Sunitinib 12.5mg cap
- Theophylline ER 300mg cap
- Mebendazole 100mg tab
- Becamplermin 0.01%
- Captopril 50mg tab
- Ery/sulfisoxazole oral susp (200-600/5mL)
- Magnebind 200mg, 300mg, 400mg
- Phisohex 3% , 148mL,

Pharmacy Practice Changes

Staff meeting changes: Three-month pilot of bi-weekly (every other week) staff meetings underway. Also, huddle now begins promptly at 7am.

Meds-to-beds: expansion to STU go-live May 5, 2015

Medications requiring special monitoring (MRSM): updated document on LakeLink under Lake MD Documents and Calendars and Formweb under Med Use Guidelines

Physician Refusal to Sign: A new SOP has been created to address physician orders that are routed to the wrong physician. Refer to SOP folder on pharmacy homepage.

Fentanyl continuous infusions: A premixed fentanyl 2500mcg/250mL continuous drip has been added to formulary and may be used in the following units: MICU, SICU, HV3, and TNCC. It must be hung inside of a locked box. Keys are located in the CII room as well as the unit Pyxis machines.

Procrit: medication use evaluation discovered $6000/month in wasted patient-specific doses of Procrit. Waste elimination process: 2,000, 3,000, 4,000, and 10,000 unit vials added to formulary. Enter as MED and use nearest vials size to dispense vials for doses ≤ 12,000 units (Max: 2 vials/dose). Doses >12,000 should be entered as INTERMITTENT and routed to the IV room to draw up. (Exceptions: exact doses of 20,000 & 40,000 units on 5-WEST; loaded in the Pyxis machine). Please see Tommy with questions.

Patient Safety Corner

ISMP Best Practices (2014-2015)

- **ISMP Best Practice 2:**

  Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.

  Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

KCentra

- Remember if you receive an order for KCentra, it should always be treated as a STAT order. This medication is used for life threatening bleeds and if administration is delayed, it can result in severe patient harm or death.

Clinical Practice

Rasburicase MUE

Rasburicase is indicated for the initial management of plasma uric acid levels in patients receiving chemotherapy who are high risk for tumor lysis syndrome (TLS) based on malignancy type, tumor burden, and baseline laboratory parameters such as elevated uric acid. Tumor burden is typically greatest with the first cycle of chemotherapy in a newly diagnosed or relapsed patient. Rasburicase works by converting uric acid to the soluble metabolite allantoin.

During a 17-month period 26 inpatients received 36 doses of rasburicase. The majority were indicated to receive rasburicase and classified as high risk for TLS due to cancer diagnosis (advanced stage Burkitt's lymphoma, acute leukemia with high WBC, t-cell and/or mantle cell lymphoma) or intermediate risk malignancy with presence of abnormal labs. Most patients received weight-based dosing of rasburicase; the physician rounded the dose to the nearest 1.5 or 7.5 mg vial size in two-thirds of patients. Six patients were prescribed more than one dose. Baseline uric acid levels ranged from 1.3 – 22 mg/dL. Uric acid levels were elevated to >7.5 mg/dL after the first dose of rasburicase in only 3 patients; however, two of those patients didn't receive chemotherapy and one received a flat dose of 2 mg. Patients received allopurinol or hydration for 16/26 and 23/26 admissions, respectively.

Uric acid levels require special collection and handling procedures for up to 4 days after a dose of rasburicase to prevent falsely low uric acid levels. Methods of uric acid collection during the study are unknown.

After presentation of current literature, a cap of a one-time flat dose of rasburicase 6 mg was approved as well as criteria for use. Rasburicase and post-rasburicase uric acid levels will be ordered as part of a power-plan, which is currently in development. If orders for rasburicase are received prior to power-plan completion, please contact prescriber to inform him/her of the P&T approved dose cap of 6 mg.

Regulatory

Recent FDA Drug Approvals

- **Opdivo** (nivolumab) **–** a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, BRAF inhibitor
- **Zarxio** (filgrastim-SNDZ) – a leukocyte growth factor indication for use in febrile neutropenia in patients with nonmyeloid malignancies, neutropenia following chemotherapy treatment in AML patients, neutropenia following bone marrow transplant, and stem cell mobilization
- **Cresemba** (isavuconazonium sulfate) – an azole antifungal approved for use in treatment of invasive aspergillosis and mucormycosis
- **Unituxin** (dinutuximab) – a GD2-binding monoclonal antibody indicated, in combination with granulocyte-macrophage colony-stimulating factor, interleukin-2, and 13 -cis-retinoic acid, for the treatment of pediatric patients with high-risk neuroblastoma who achieve at least a partial response to prior first-line multiagent, multimodality therapy
- **Cholbam** (cholic acid) – a bile acid indicated for use in the treatment of bile acid synthesis disorders due to single enzyme defects and adjunctive treatment of peroxisomal disorders
- **Kalydeco** (ivacaftor) – a cystic fibrosis transmembrane conductance regulator potentiator indicated for treatment of cystic fibrosis in patients ≥ 6 years of age who have one of the following mutations in the CFTR gene: G551D, G1244E, G1349D, G178R, R117H, S1251N, S1255P, S549N, or S549R

FDA Drug Recalls for March:

None affecting OLOL

Joint Commission Quick Safety Tip:

Delays in treatment, such as not receiving a critical medication in a timely manner, can result in significant patient harm or death. Some recommendations for avoiding delays in treatment include improved communication between pharmacists and other healthcare personnel, ensuring adequate staffing, and optimizing use of health information technology (such as Medboard and Pyxis Connect).

Are You Ready for the Joint Commission Survey

Question: What is a Sentinel Event and what needs to occur afterwards?

Answer: A Sentinel Event is an unexpected occurrence that results in serious injury or death of a patient (or a risk thereof). Hospitals must conduct an analysis of the event and develop a plan of action to prevent it from happening again in the future, usually including changing current policies or procedures.

Louisiana Board of Pharmacy:

On March 15, 2015, the Louisiana Board published an up-to-date edition of the *Louisiana Pharmacy Law Book* to replace the previous January 2014 edition.

Emergency Ruling: Department of Health and Hospitals Office of Public Safety:

5f-AB, also known as "Blue Nugs" is yet another synthetic designer drug that has recently been banned in Louisiana. It has reportedly been linked to serious adverse events, including severe agitation, paranoia, seizures, intense hallucinations, suicidal thoughts, and psychotic episodes.

QUESTIONS, COMMENTS OR SUGGESTIONS?

Please contact:

Monica Morgan, PharmD

225-374-5760

Monica.morgan@ololrmc.com

IN*PHARM*ATION EDITORIAL STAFF

Editor-in-Chief
Monica Morgan, PharmD

Content Editor
Carli Nesheiwat, PharmD, BCOP

Page Editor
Jennifer Jones, PharmD, BCPS

Writing Staff
Sara Dejong, PharmD
Cortney Dodson, PharmD
Ashley Joseph, PharmD
Brandi LaFrance, PharmD, BCPS

Dates to Remember

April 21st: Tommy Mannino's Birthday

April 22nd: Brittany Robertson's Birthday and Earth Day

April 24th: Leann Fontenot's Birthday

April 27th: Kristy White's Birthday

April 30th: Monica Morgan's Birthday

May 1st: Wendy Gaudet's Birthday and Newsletter Content Due

May 10th: Darla Fontenot's Birthday and Mother's Day

May 12th: Tommy Greene's Birthday