**NEW MOLECULAR ENTITIES OF JANUARY TO JUNE 2011**

New molecular entities, biologic agents, drug formulations/combinations, and drug indications approved during 2011 (including indication, approval date, and comments) are presented in this issue of Pharmacy Précis. An explanation of the FDA classification of the new drugs also is included. If you need any additional information regarding these agents, please call the Samford University Global Drug Information Service at (205) 726-2659.

FDA classification for newly approved drugs is based on chemical classification and is outlined below.

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Ioflupane I 123 (DaTSCAN, GE Healthcare)
Pharmacology: A radiopharmaceutical with selectivity for the pre-synaptic dopamine transporter.
Indication: Diagnostic aid that helps in the evaluation of adult patients with suspected Parkinsonian syndromes.
Adverse Drug Reactions: Nausea, xerostomia, dizziness, headache, vertigo.
Dose: 111 to 185 megabecquerels (3 to 5 millicuries) IV over at least 15 to 20 seconds.
Formulation: 0.07 to 0.13 mcg ioflupane, 74 MBq (2mCi) per mL at calibration: packaged in 2.5mL.
Warnings/Contraindications: Known hypersensitivity to the active substance, any of the excipients, or iodine.
Notes: Pre-medicate with a thyroid blocking agent at least one hour prior to administration. Hydrate frequently prior to and following administration.

Spinosad (Natroba, ParaPRO Pharms)
Pharmacology: Topical antiparasitic agent; causes neuronal excitation, paralysis and eventual death of lice.
Indication: Topical treatment of pediculosis capitis (head lice) infestation in patients > 4 years of age.
Adverse Drug Reactions: Alopecia, erythema, skin irritation.
Dose: Shake bottle well. Apply enough topical suspension to cover dry scalp, then apply to dry hair. Leave on for 10 minutes, then rinse off with warm water. If live lice remain after 7 days, then a second treatment is warranted.
Formulation: 0.9% topical suspension: 4 oz. (120mL) bottle.
Warnings/Contraindications: Contains benzyl alcohol which has been associated with adverse effects and death in neonates and low birth weight infants.
Notes: For topical use only. Avoid contact with eyes, mouth, or any mucus membrane. Keep out of reach of children.

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**Vilazodone Hydrochloride (Viibryd, Trovis Pharma LLC)**

**Pharmacology:** Selective serotonin reuptake inhibitor and 5-hydroxytryptamine (5-HT1A) receptor partial agonist.

**Indication:** Major depressive disorder in adults.

**Adverse Drug Reactions:** Diarrhea, nausea, drowsiness, libido decrease, abnormal dreams, dyspepsia.

**Dose:** Initiate with 10 mg once daily for 7 days, then 20 mg once daily for the next 7 days. The maximum dosage limit is 40 mg per day.

**Formulation:** Oral tablets: 10 mg, 20 mg, 40 mg.

**Warnings/Contraindications:** Contraindicated in patients receiving MAOI therapy or within 14 days of taking an MAOI.

**Notes:** Take with food. In the fasted state, blood levels may decrease by 50% resulting in decreased efficacy.

**Sodium Nitrite; Sodium Thiosulfate (Nithiodote, Hope Pharma)**

**Pharmacology:** Sodium nitrite: reacts with hemoglobin to form methemoglobin with a high affinity for cyanide. Sodium thiosulfate: enzymatic transsulfuration to thiocyanate (SCN) which is excreted in the urine.

**Indication:** Sequential use for treatment of acute cyanide poisoning that is life-threatening.

**Adverse Drug Reactions:** Arrhythmias, hypotension, confusion, dizziness, nausea, acidosis, blurred vision, salty taste, prolonged bleeding time.

**Dose:** IV administration; Adults: Sodium nitrite – 10 mL at a rate of 2.5 to 5 mL/minute. Sodium thiosulfate – 50 mL immediately following sodium nitrite administration. Children: Sodium nitrite – 0.2 mL/kg (6 mg/kg or 6-8 mL/m² BSA) at a rate of 2.5 mL/minute not to exceed 10 mL. Sodium thiosulfate – 1 mL/kg of body weight (250 mg/kg or approximately 30-40 mL/m² of BSA) not to exceed 50 mL total dose immediately following administration of sodium nitrite.

**Formulation:** Sodium nitrite injection, 300 mg/10mL; sodium thiosulfate injection, 12.5 grams/50mL.

**Warnings/Contraindications:** Hypotension, Methemoglobinemia.

**Notes:** Use with caution if the diagnosis of cyanide poisoning is uncertain.

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**Azilsartan medoxomil (Edarbi, Takeda Pharmaceutical North America)**

**Pharmacology:** Angiotensin II receptor antagonist.

**Indication:** Used alone, or in combination with other therapies for hypertension.

**Adverse Drug Reactions:** Diarrhea, hypotension.

**Dose:** 80 mg once daily. Consider 40 mg by mouth once daily in patients receiving high-dose diuretic therapy.

**Formulation:** 40- and 80-mg oral tablets.

**Warnings/Contraindications:** Do not use in pregnant women to avoid fetal harm. Avoid in neonates. Use in caution in patients with severe congestive heart failure, renal artery stenosis and volume depletion.

**Notes:** May take with or without food.

**Roflumilast (Daliresp, Forest Research Institute, Inc.)**

**Pharmacology:** Phosphodiesterase 4 (PDE4) inhibitor.

**Indication:** Reduce COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

**Adverse Drug Reactions:** Diarrhea, weight loss, nausea, headache, back pain, influenza, insomnia, dizziness, and decreased appetite.

**Dose:** 500 mcg once daily.

**Formulation:** 500 mcg oral tablet.

**Warnings/Contraindications:** Acute bronchospasm, psychiatric events, weight loss, moderate to severe liver impairment.

**Notes:** May take with or without food.
Gadobutrol Injection (Gadavist, Bayer Healthcare)
Pharmacology: Gadolinium-based contrast agent (GBCA).
Indication: Intravenous contrast agent used in adults and children over 2 years of age for diagnostic MRI procedures. The agent identifies areas with disrupted blood brain barrier and/or abnormal vascularity of the CNS.
Adverse Drug Reactions: Most frequent adverse reactions were headache, nausea, injection site reaction, dysgeusia and feeling hot.
Dose: 0.1 mmol/Kg bolus at a 2ml/sec flow rate.
Formulation: Available in vials or pre-filled syringes.
Warnings/Contraindications: Anaphylactic reactions ranging from mild to severe have uncommonly occurred. Higher than recommended dosing can increase risk of Nephrogenic Systemic Fibrosis.
Notes: Screen patients for acute kidney injury and other disease states which impair renal function as this may lead to Nephrogenic Systemic Fibrosis. GBCAs should be avoided in this population.

Gabapentin Enacarbil (Horizant, GlaxoSmithKline)
Pharmacology: Anticonvulsant.
Indication: Treatment of moderate-to-severe primary Restless Legs Syndrome in adults.
Adverse Drug Reactions: Somnolence/sedation and dizziness.
Dose: Recommended dose is 600 mg once daily taken with food at about 5 PM.
Formulation: 600-mg extended release tablets.
Warnings/Contraindications: Dizziness and sedation/somnolence can occur with use of gabapentin enacarbil. Patients should be advised not to drive until they have seen how the medication will affect their ability to perform tasks. Gabapentin enacarbil is a prodrug of gabapentin, an antiepileptic drug. Antiepileptic drugs have shown an increased risk of suicidal thoughts or behaviors.
Notes: A daily dose of 1,200 mg provides no additional benefit compared to 600 mg once daily, but causes an increase in adverse reactions. For patients with compromised renal function gabapentin enacarbil should be administered on Day 1, Day 3, and every day thereafter.

Vandetanib (Vandetanib, AstraZeneca)
Pharmacology: Kinase inhibitor.
Indication: Treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advance or metastatic disease.
Adverse Drug Reactions: Diarrhea, rash, acne, nausea, hypertension, headache, fatigue, decreased appetite, abdominal pain, decreased calcium, increased ALT, and decreased glucose.
Dose: Recommended daily dose is 300 mg orally.
Formulation: 100-mg and 300-mg tablets
Warnings/Contraindications: Boxed warning for prolonged QT interval, torsades de pointes, and sudden death. Stevens-Johnson syndrome and interstitial lung disease resulting in death has been reported. Fetal harm can occur when administered to pregnant women.
Notes: Due to risks of QT prolongation, torsades de pointes and sudden death, vandetanib is available only through restricted use with the Vandetanib REMS Program.

Abiraterone acetate (Zytiga, Centocor Ortho)
Pharmacology: CYP17 inhibitor.
Indication: Treatment of patients with metastatic castration-resistant prostate cancer who have received prior treatment containing docetaxel.
Adverse Drug Reactions: The most commonly reported adverse drug reactions include: joint swelling or discomfort, hypokalemia, edema, muscle discomfort, hot flush, diarrhea, urinary tract infection, cough, hypertension, arrhythmia, urinary frequency, nocturia, dyspepsia and upper respiratory tract infection.
Dose: 1,000 mg orally once a day, along with 5 mg prednisone twice a day.
Formulation: 250-mg tablet.
**Abiraterone acetate (Zytiga, Centocor Ortho) continued**

**Warnings/Contraindications:** Contraindicated in women who are pregnant or may become pregnant.
- Monitor blood pressure, serum potassium and symptoms of fluid retention as this agent has not been studied in patients with heart failure. Increased doses of corticosteroid may be needed before, during and after stressful events, as this agent is taken with prednisone. Liver enzyme elevation has lead to discontinuation of therapy; monitor patient’s liver function and discontinue abiraterone acetate as recommended, if needed. Take on an empty stomach, as abiraterone acetate AUC increases 10-fold if taken with a meal.

**Notes:** Do not use in women who are pregnant or may become pregnant. Do not use in patients with severe hepatic impairment. Do not eat two hours before, and for at least one hour after abiraterone acetate dose.

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**Linagliptin (Tradjenta, Boehringer Ingelheim)**

**Pharmacology:** DPP-4 inhibitor.

**Indication:** Treatment for type 2 diabetes mellitus, in addition to diet and exercise

**Adverse Drug Reactions:** nasopharyngitis (> 5%), increased risk of hypoglycemia when used in combination with sulfonylurea.

**Dose:** Recommended dose is 5 mg once daily taken with or without food.

**Formulation:** 5-mg tablet.

**Warnings/Contraindications:** Contraindicated in patients who have a history hypersensitivity reaction to linagliptin, such as urticaria, angioedema or bronchial hyperreactivity.

**Notes:** Consider lowering the dose of secretagogue (e.g., sulfonylurea) to reduce the risk of hypoglycemia. Can be used during pregnancy if need is clearly indicated. Caution should be exercised in breast-feeding mothers.

**Boceprevir (Victrelis, Schering)**

**Pharmacology:** Protease inhibitor.

**Indication:** Treatment for chronic hepatitis C, in combination with peginterferon alfa and ribavirin, in adult patients (> 18 years of age) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy.

**Adverse Drug Reactions:** Fatigue, anemia, nausea, headache and dysgeusia (distorted sense of taste) when taken in conjunction with PegIntron and Rebetol (> 35%).

**Dose:** Recommended dose is 800 mg three times a day with a meal or light snack.

**Formulation:** 200-mg capsules.

**Warnings/Contraindications:** Contraindicated in patients who also have contraindications to peginterferon alfa and ribavirin as this agent must be used in conjunction with these agents. Contraindications for peginterferon alfa and ribavirin include pregnant women and men whose partners are pregnant, patients who are concomitantly taking potent CYP3A4 inhibitors or other agents which are highly dependent on CYP3A4 inhibitors. Anemia and neutropenia risk is increased when boceprevir is added to peginterferon alpha ribavirin.

**Notes:** Female patients should have a negative pregnancy test and must use two or more forms of contraception in addition to monthly pregnancy tests.

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**Rilpirivine (Edurant, manufacturer)**

**Pharmacology:** Non-nucleoside reverse transcriptase inhibitor.

**Indication:** Treatment in combination with other antiretroviral agents for the treatment of HIV-1 infection in treatment-naïve adult patients.

**Adverse Drug Reactions:** Depression, insomnia, headache and rash (>2%).

**Dose:** Recommended dose is 25 mg once a day with a meal.

**Formulation:** 25-mg tablet.

**Warnings/Contraindications:** Contraindicated in co-administration with other agents which may decrease
**Rilpirivine (Edurant, manufacturer) continued**

rilpirivine plasma concentration, which may result in loss of virologic response and subsequent resistance. Use caution when prescribing rilpirivine with drugs known to cause *Torsade de Pointes*, when prescribing with drugs known to reduce exposure of rilpirivine and depressive disorders.

**Notes:** Co-administration of rilpirivine with drugs that increase gastric pH (i.e., proton pump inhibitors) may decrease plasma concentrations of rilpirivine. Use in pregnancy only if potential benefit outweighs potential risk. Mothers should not breastfeed due to the potential for HIV transmission.

**Telaprevir (Incivek, Vertex Pharms)**

**Pharmacology:** Protease inhibitor.

**Indication:** Treatment of hepatitis C virus (HCV), in combination with peginterferon alfa and ribavirin, in adults with compensated liver disease, including cirrhosis, who are treatment naïve or who have been previously treated with interferon-based treatment, including prior null responders, partial responders and relapsers.

**Adverse Drug Reactions:** Rash, pruritus, anemia, nausea, hemorrhoids, diarrhea, anorectal discomfort, dysgeusia (distorted sense of taste), fatigue, vomiting and anal pruritis.

**Dose:** 750 mg taken 3 times a day (7-9 hours apart) with food (not low fat).

**Formulation:** 375-mg tablets.

**Warnings/Contraindications:** All contraindications to peginterferon alfa and ribavirin also apply since telaprevir must be administered with peginterferon alfa and ribavirin. Telaprevir is also contraindicated in pregnant patients and in males whose female partners are pregnant and in patients who are concurrently being treated with any strong CYP3A4 inducer which may lead to lower exposure and loss of efficacy. Warnings included the development of a mild to moderate rash which should be monitored for progression. Patients should also be warned about serious skin reactions including Stevens-Johnson’s Syndrome.

**Notes:** Patients must have a negative pregnancy test prior to initiating therapy, use two forms of contraception and undergo monthly pregnancy tests. Safety and efficacy have not been established in pediatric patients.

**Fidaxomicin (Dificid, Optimer Pharma)**

**Pharmacology:** Macrolide antibiotic.

**Indication:** Indicated in adults (≥18 years old) for the treatment of *Clostridium difficile*-associated diarrhea.

**Adverse Drug Reactions:** Nausea (11%), vomiting (7%), abdominal pain (6%), gastrointestinal hemorrhage (4%), anemia (2%) and neutropenia (2%).

**Dose:** 200 mg by mouth twice a day for 10 days with or without food.

**Formulation:** 200 mg film-coated tablet.

**Warnings/Contraindications:** No contraindications. Warnings: Do not use fidaxomicin for systemic infections, and only use fidaxomicin for infections strongly suspected to be caused by *C. difficile*.

**Notes:** Safety and efficacy has not been established in patients <18.

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Belimumab (Benlysta, Human Genome Sciences, Inc.) Continued

Dose: Recommended regimen is 10 mg/kg at 2-week intervals for the first 3 doses and at 4-week intervals thereafter. Administer as an IV infusion only, over a period of 1 hour.

Formulation: Available in single-use vials of lyophilized powder for reconstitution, dilution, and IV infusion. Available as: 120 mg in a 5 mL single-use vial; 400 mg in a 20 mL single-use vial.

Warnings/Contraindications: There were more deaths reported with belimumab than with placebo during the clinical trials. Serious infections have been reported in patients receiving immunosuppressive agents. Use caution in patients with chronic infections. Hypersensitivity reactions, depression, and suicidality have been reported. Live vaccines should not be given concurrently with belimumab. Contraindications include previous anaphylaxis to belimumab.

Notes: The efficacy of belimumab has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. It has also not been studied in combination with other biologics or IV-cyclophosphamide. Store vials refrigerated between 2° and 8°C.

Ipilimumab (Yervoy, Bristol-Myers Squibb Co.)

Pharmacology: Human cytotoxic T-lymphocyte antigen 4 (CTLA-4) blocking antibody.

Indication: Treatment of unresectable or metastatic melanoma.

Adverse Drug Reactions: Fatigue, diarrhea, pruritus, rash, and colitis.

Dose: 3 mg/kg administered IV over 90 minutes every three weeks for a total of four doses.

Formulation: Available in single-use vials of 50 mg/10mL and 200 mg/40mL.

Warnings/Contraindications: Immune-mediated adverse reactions involving any organ system can occur and warrant discontinuation of therapy. There are no listed contraindications at this time.

Notes: Monitor immune-mediated adverse events, evaluate liver function tests, thyroid function tests, and clinical chemistry panels prior to each dose.

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### NEW DRUG FORMULATIONS / COMBINATIONS OF 2011

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Lamivudine; Tenofovir Disoproxil Fumarate (Lamivudine; Tenofovir Disoproxil Fumarate, Aurobindo Pharma LTD)

Pharmacology: Tenofovir is a nucleotide diester analog of adenosine monophosphate. Lamivudine is a potent reverse-transcriptase inhibitor.

Indication: Indicated with at least one other antiretroviral product for the treatment of HIV-1 infection in adults and pediatric patients 12 years old and older.

Dosage form: 300mg/300mg combination oral tablet.

Dose: One tablet once daily.
Fentanyl (Abstral, ProStrakan, Inc.)
Pharmacology: μ- and kappa-opiate receptor agonist.
Indication: Management of breakthrough pain in cancer patients 18 years of age and older who are already receiving and are tolerant to opioid therapy.
Dosage form: Sublingual tablets: 100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg.
Dose: First episode: one 100 mcg tablet. An additional 100 mcg tablet may be taken 30 minutes after the previous dose was given. Do not use more than 2 doses per episode. Two hours must elapse before treating another episode. The dose may be increased by 100 mcg/episode up to 400 mcg, over consecutive breakthrough episodes until adequate analgesia is attained.

Gabapentin (Gralise, Abbott Prods)
Pharmacology: Exact mechanism of action is unknown; appears to be related to development as a GABA analog.
New Indication: Postherpetic neuralgia pain in adults 18 years old and older.
Dose: Titrate to an 1800 mg dose taken once daily with the evening meal as follows: Day 1: 300 mg, Day 2: 600 mg, Days 3-6: 900 mg, Days 7-10: 1200 mg, Days 11-14: 1500 mg, Day 15: 1800 mg.

Omeprazole; Clarithromycin; Amoxicillin (DAVA Pharmaceuticals, Inc.)
Pharmacology: Combination of proton pump inhibitor, protein synthesis inhibitor antibiotic (clarithromycin), and cell wall inhibitor antibiotic (amoxicillin).
Indication: Eradication of Helicobacter pylori in patients with active duodenal ulcer or history of duodenal ulcer.
Dose: Omeprazole 20 mg, clarithromycin 500 mg, & amoxicillin 1000 mg twice daily for 10 days.
Formulation: Omeprazole delayed-release 20 mg capsule; Clarithromycin 500 mg tablet; Amoxicillin 500 mg capsule.

Rufinamide (Banzel, Eisai Co.)
Pharmacology: Precise antiepileptic mechanism is unknown. Studies suggest principal mechanism is modulation of sodium channels and prolongation of the inactive state of the channel.
Indication: Adjunctive treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in children 4 years and older and adults.
Dosage form: 200 mg, 400 mg film-coated tablets; 40 mg/mL oral suspension.
Dose: Children 4 years and older: Treatment should be initiated at a daily dose of approximately 10 mg/kg/day administered in two equally divided doses. The dose should be increased by approximately 10 mg/kg increments every other day to a target dose of 45 mg/kg/day or 3200 mg/day, whichever is less, administered in two equally divided doses. Adults: Initiate treatment at a daily dose of 400-800 mg/day administered in two equally divided doses. The dose should be increased by 400-800 mg every other day until a maximum dose of 3200 mg/day, administered in two equally divided doses is reached.

Nevirapine (Viramune XR, Boehringer Ingelheim)
Pharmacology: Non-nucleoside reverse transcriptase inhibitor (NNRTI).
Indication: Combination antiretroviral treatment of HIV-1 infection in adults.
Dosage form: 400-mg tablet.
Dose: Adult patients must initiate therapy with one 200 mg tablet of immediate-release nevirapine once daily for the first 14 days, followed by one 400 mg tablet of nevirapine extended-release once daily. Adult patients already receiving immediate-release nevirapine twice daily can be switched to nevirapine extended-release 400 mg once daily without the 14 day lead-in phase.

Loteprednol etabonate (Lotemax, Bausch and Lomb)
Pharmacology: Corticosteroid.
Indication: Treatment of post-operative inflammation and pain following ocular surgery.
Dosage form: Ophthalmic ointment 0.5%.
**Loteprednol etabonate (Lotemax, Bausch and Lomb) continued**

*Dose:* Apply a small amount into the conjunctival sac four times daily starting 24 hours after surgery. Continue throughout the first 2 weeks of the post-operative period.

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**Calcium acetate (Phoslyra, Fresenius)**

*Pharmacology:* Phosphate binder.

*Indication:* Reduction of serum phosphorus in patients with end stage renal disease.

*Dosage form:* Oral solution 667 mg calcium acetate per 5 mL.

*Dose:* Recommended starting dose is 10 mL with each meal then titrate dose every 2 to 3 weeks until acceptable serum phosphorus level is reached.

**Famotidine; Ibuprofen (Duexis, Horizon Pharma)**

*Pharmacology:* NSAID (ibuprofen) and H-2 receptor antagonist (famotidine).

*Indication:* Relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers.

*Dosage form:* Oral tablet 800 mg ibuprofen/26.6 mg famotidine.

*Dose:* One tablet by mouth three times a day.

**Testosterone (Androgel, Abbott Prods)**

*Pharmacology:* Androgen replacement in the absence of endogenous testosterone.

*Indication:* In the absence of endogenous testosterone for the treatment of primary hypogonadism and hypogonadotropic hypogonadism (both congenital or acquired).

*Dosage form:* Gel for topical administration.

*Dose:* Starting dose-2 pump actuations (40.5 mg testosterone total dose) applied once daily in the morning. Dose adjustment is 1 pump actuation (20.25 mg testosterone). Maximum daily dose should not exceed 4 pump actuations (81 mg).

**Hydrocodone, chlorpheniramine, pseudoephedrine (Zutripro, Cypress Pharm)**

*Pharmacology:* Hydrocodone-mu opioid receptor antagonist having antitussive effects and respiratory drying effects, chlorpheniramine-H-1 receptor antagonist which suppresses the formation edema, flare and pruritis, pseudoephedrine-alpha and beta agonist leading to nasal vasoconstriction.

*Indication:* Relief of cough and nasal congestion associated with the common cold and upper respiratory allergies.

*Dosage Form:* Oral solution contains 5 mg hydrocodone, 4 mg chlorpheniramine and 60 mg pseudoephedrine per every 5 mL.

*Dose:* 5 mL every 4 to 6 hours as needed. Maximum daily dose not to exceed 20 mL in 24 hours.

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