APhA DrugInfoLine®

March 2018

Infectious Diseases

Advising on this article: Allana Sucher

March 6, 2018

Surgical site infection risk increased in patients who reported a penicillin allergy

Key Point

Patients undergoing a variety of surgical procedures who reported a penicillin allergy were at a 50% increased odds of having a surgical site infection, according to results of a retrospective analysis published in Clinical Infectious Diseases.

Source URL:

http://www.aphadruginfoline.com/infectious-diseases/surgical-site-infection-risk-increased-patients-who-reported-penicillin-allergy

Infectious Diseases

Advising on this article: Allana Sucher

March 12, 2018

PPIs decrease the effectiveness of hepatitis C antivirals

Key Point

Sustained virologic responses (SVRs) were lower in patients with hepatitis C taking direct-acting antivirals with proton pump inhibitors (PPIs) compared with those not receiving PPIs, according to results of a comprehensive review published in the Journal of Clinical and Translational Hepatology.

Source URL:

http://www.aphadruginfoline.com/infectious-diseases/ppis-decrease-effectiveness-hepatitis-c-antivirals

Focus on Anticoagulation Care

Advising on this article: Sarah Ray

March 12, 2018

Mortality varies in patients with intracerebral hemorrhage using different anticoagulants

Key Point

In-hospital mortality after an intracerebral hemorrhage was lower in patients with prior use of non-vitamin K antagonist oral anticoagulants (NOACs) compared with those who used warfarin previously, according to an observational analysis published in JAMA.

Source URL:

http://www.aphadruginfoline.com/focus-anticoagulation-care/mortality-varies-patients-intracerebral-hemorrhage-using-different

Focus on Asthma Care

Advising on this article: Devra K. Dang

March 20, 2018

New recommendations on allergic rhinitis

Key Point

An updated guideline for pharmacological treatment of seasonal allergic rhinitis recommends monotherapy with an intranasal (I.N.) corticosteroid over combination therapy with an I.N. corticosteroid and oral antihistamine as the initial treatment for patients aged 12 years and older, and clearly states that I.N. corticosteroids should be used over a leukotriene receptor antagonist for patients aged 15 years and older.

Source URL:

http://www.aphadruginfoline.com/focus-asthma-care/new-recommendations-allergic-rhinitis

Alternative Medicines Corner

Advising on this article: Nicole M. Maisch

March 20, 2018

Omega-3 fatty acid supplementation and CV benefits

Key Point

Use of omega-3 fatty acids in high-risk patients did not result in any significant reductions in the risk of fatal or nonfatal coronary heart disease (CHD) or any major vascular events, according to results of a meta-analysis published in JAMA Cardiology.

Source URL:

http://www.aphadruginfoline.com/alternative-medicines-corner/omega-3-fatty-acid-supplementation-and-cv-benefits

Oncology

Advising on this article: Gary C. Yee

March 27, 2018

CAR T-cell therapy effective, but serious toxicities and high cost are considerations

Key Point

A single infusion of tisagenlecleucel (Kymriah—Novartis) administered to pediatric patients and young adults with B-cell acute lymphoblastic leukemia (ALL) resulted in a highly durable remission rate, according to results of a Phase II study published in the New England Journal of Medicine.

Source URL:

http://www.aphadruginfoline.com/oncology/car-t-cell-therapy-effective-serious-toxicities-and-high-cost-are-considerations

Respiratory

Advising on this article:

March 27, 2018

Combination therapy for pulmonary fibrosis may be an option

Key Point

Combination therapy with nintedanib (Ofev—Boehringer Ingelheim) and pirfenidone (Esbriet—Genentech) for patients with idiopathic pulmonary fibrosis (IPF) was found to be adequately tolerated, according to results of the INJOURNEY trial published in the American Journal of Respiratory and Critical Care Medicine.

Source URL:

http://www.aphadruginfoline.com/respiratory/combination-therapy-pulmonary-fibrosis-may-be-option

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 1, 2018	
Abiraterone acetate ***(Zytiga—Janssen Biotech)*** **Agent plus prednisone approved for treatment of earlier form of metastatic prostate cancer**	FDA approved a new indication for abiraterone acetate in combination with prednisone for the treatment of patients with metastatic, high-risk castration-sensitive prostate cancer (CSPC). Approval was based on Phase III data from the pivotal LATITUDE clinical trial, which found that in patients with metastatic, high-risk CSPC, abiraterone acetate in combination with prednisone reduced the risk of death by 38% compared with placebos. The most common adverse reactions (?10%) from pooled safety data were fatigue, arthralgia, hypertension, nausea, edema, hypokalemia, hot flush, diarrhea, vomiting, upper respiratory infection, cough, and headache. On November 20, 2017, the European Commission granted approval to broaden the marketing authorization for abiraterone acetate in combination with prednisone or prednisolone to include newly diagnosed, high-risk, metastatic hormone-sensitive prostate cancer (HSPC). Similar submissions have been made in Japan, Canada, Mexico, Switzerland, Singapore, and the Philippines, and approved in Brazil and Taiwan. If approved, these submissions will broaden use of abiraterone acetate in combination with prednisone or prednisolone to include an earlier stage of prostate cancer than its current indications.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/agent-plus-prednisone-approved-treatment-earlier-form-metastatic-prostate

Alerts and Recalls

Generic Name (Trade Name—Company)	**Uses**/Notes
March 1, 2018	
Compounded products ***(No trade names—Cantrell Drug Co.)*** **FDA warns not to use compounded drugs from Cantrell Drug Co.**	FDA is alerting health professionals and patients not to use drug products produced by Cantrell Drug Co. of Little Rock, AK, including opioid products and other drugs intended for sterile injection. The agency is concerned about serious deficiencies in Cantrell's compounding operations, including its processes to ensure quality and sterility that put patient safety at risk. Administration of contaminated or otherwise poor quality drug products can result in serious and life-threatening injury or death. FDA has also sought legal action to prevent the company from further producing and distributing drugs and to require the company to recall all nonexpired drug products on the market. Health professionals should immediately check their medical supplies, quarantine any drug products from Cantrell Drug Co., and not administer them to patients. Examples of some of the drugs Cantrell has compounded include opioids and common antibiotics.

Source URL:

http://www.aphadruginfoline.com/alerts-and-recalls/fda-warns-not-use-compounded-drugs-cantrell-drug-co

New Drug Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 6, 2018	
Ibalizumab-uiyk ***(Trogarzo—TaiMed Biologics)*** **New HIV treatment approved for patients with limited treatment options**	FDA approved ibalizumab-uiyk, a new type of antiretroviral medication for adult patients living with HIV who have tried multiple HIV medications in the past (heavily treatment-experienced) and whose HIV infections cannot be successfully treated with other currently available therapies (multidrug resistant HIV, or MDR HIV). Ibalizumab-uiyki is administered intravenously once every 14 days by a trained medical professional and used in combination with other antiretroviral medications. Safety and efficacy the agent were evaluated in a clinical trial of 40 heavily treatment-experienced patients with MDR HIV-1 who continued to have high levels of virus (HIV-RNA) in their blood despite being on antiretroviral drugs. Many of the participants had previously been treated with 10 or more antiretroviral drugs. The majority of participants experienced a significant decrease in their HIV-RNA levels one week after ibalizumab-uiyk was added to their failing antiretroviral regimens. After 24 weeks of ibalizumab-uiyk plus other antiretroviral drugs, 43% of the trial's participants achieved HIV RNA suppression. The clinical trial focused on the small patient population with limited treatment options and demonstrated the benefit of ibalizumab-uiyk in achieving reduction of HIV RNA. The seriousness of the disease, the need to individualize other drugs in the treatment regimen, and safety data from other trials were considered in evaluating the ibalizumab-uiyk development program. The most common adverse reactions were diarrhea, dizziness, nausea and rash. Severe adverse effects included rash and changes in the immune system.

Source URL:

http://www.aphadruginfoline.com/new-drug-approvals/new-hiv-treatment-approved-patients-limited-treatment-options

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 9, 2018	
Lurasidone HCl ***(Latuda—Sunovion)*** **Approval expanded to treat bipolar depression in children aged 10 to 17 years**	Sunovion announced FDA expanded approval of lurasidone HCl (Latuda—Sunovion) to include treatment of major depressive episode associated with bipolar I disorder (bipolar depression) in pediatric patients (aged 10–17 y). The agent is also approved for the treatment of adults with bipolar depression as monotherapy and adjunctive therapy with lithium or valproate, and for the treatment of adolescents (aged 13–17 y) and adults with schizophrenia. Lurasidone HCl is available in five tablet strengths: 20 mg, 40 mg, 60 mg, 80 mg and 120 mg.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/approval-expanded-treat-bipolar-depression-children-aged-10-17-years

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 9, 2018	
Ciprofloxacin otic suspension 6% ***(Otiprio—Otonomy)*** **First single-dose antibiotic approved for acute otitis externa**	FDA has approved ciprofloxacin otic suspension 6% for treatment of acute otitis externa (AOE) resulting from *Pseudomonas aeruginos*a and *Staphylococcus aureus* in patients aged 6 months and older. It is the first single-dose antibacterial approved by the FDA for treating AOE. This sterile, preservative-free agent is administered as a single-dose by a health professional. The thermosensitive suspension exists as a liquid at or below room temperature and gels when warmed. For AOE, the agent is a single 0.2 mL (12 mg) administered to the external ear canal of each affected ear. In a single Phase III trial, the agent demonstrated statistically significant clinical response, defined as the complete absence of signs and symptoms of AOE (i.e., tenderness, erythema, edema, and otorrhea) compared with sham. For bilateral otitis media with effusion, the agent is administered during ear tube surgery as a single 0.1 mL (6 mg) intratympanic administration into each affected ear, following suctioning of the middle ear effusion. In two Phase III trials, a single intraoperative administration of the agent demonstrated a statistically significant reduction in the cumulative proportion of study treatment failures compared with tubes alone.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/first-single-dose-antibiotic-approved-acute-otitis-externa

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 12, 2018	
Cinacalcet hydrochloride ***(Sensipar—[Amgen] Aurobindo, Cipla)*** **FDA approves two first generics of Sensipar**	FDA has approved the first generics of Amgen's Sensipar, marketed by Aurobindo and Cipla. The cinacalcet hydrochloride tablets are indicated for treatment of secondary hyperparathyroidism in adult patients with chronic kidney disease on dialysis, hypercalcemia in adult patients with parathyroid carcinoma (PC), and severe hypercalcemia in adult patients with primary HPT who are unable to undergo parathyroidectomy. Both generics will be available in 30-, 60- and 90-mg dosage strengths.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/fda-approves-two-first-generics-sensipar

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 26, 2018	
Brentuximab vedotin	FDA expanded the approval of brentuximab vedotin for treatment of adults with previously untreated Stage III or IV classical Hodgkin lymphoma (cHL) in combination with chemotherapy. The agent was previously approved to treat cHL after relapse, cHL after stem-cell transplant when a patient is at high risk of relapse or progression, systemic anaplastic large cell lymphoma (ALCL) after failure of other treatment, and primary cutaneous ALCL after failure of other treatment. Brentuximab vedotin combines an antibody and drug, allowing the antibody to direct the drug to a target on lymphoma cells known as CD30. Approval for this indication was based on a clinical trial comparing the agent plus chemotherapy (Doxorubicin [Adriamycin], vinblastine and dacarbazine, or AVD) to a chemotherapy-only regimen common for cHL treatment (AVD plus bleomycin, also known as ABVD). The trial measured modified progression-free survival (mPFS), which considers the length of time it took for the disease to progress, death to occur, or new therapy to be initiated in patients who did not achieve a complete response. In the trial of 1,334 patients, after patients received an average of six 28-day cycles of treatment, those treated with brentuximab vedotin plus AVD were 23% less likely to experience progression, death, or initiation of new therapy compared with those receiving ABVD. A total of 117 (18%) patients were in the brentuximab vedotin plus AVD arm who experienced disease progression, death, or began new therapy, compared with 146 (22%) of patients in the ABVD arm. Common adverse effects include neutropenia, anemia, peripheral neuropathy, nausea, fatigue, constipation, diarrhea, vomiting, and fever. In the above clinical trial, 67% of patients treated with brentuximab vedotin plus chemotherapy experienced peripheral neuropathy.

(Adcetris—Seattle Genetics)

Approval expanded for first-line treatment of Stage III or IV classical Hodgkin lymphoma in combination with chemotherapy

In addition, neutropenia occurred in 91% of patients treated with brentuximab vedotin plus chemotherapy, which was associated with a 19% rate of febrile neutropenia (neutropenia and fever). Preventive treatment with G-CSF, a growth factor for the bone marrow to produce white blood cells, is recommended with brentuximab vedotin plus chemotherapy for first-line treatment of Stage III or IV cHL.

Brentuximab vedotin has a boxed warning that highlights the risk of John Cunningham virus infection resulting in progressive multifocal leukoencephalopathy (PML), a rare but serious brain infection that can result in death.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/approval-expanded-first-line-treatment-stage-iii-or-iv-classical-hodgkin

Product Withdrawals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 26, 2018	
Daclizumab	Biogen and AbbVie are voluntarily withdrawing daclizumab, a multiple sclerosis (MS) drug, from the global market, noting concern about the drug's evolving benefit/risk profile. FDA announced it is working closely with the manufacturers to help ensure a well-organized withdrawal from the market in the United States and to ensure that health professionals have the information they need to carefully transition their patients using daclizumab to another treatment. No new patients will start taking daclizumab or participate in clinical studies. The company has begun notifying health professionals and patients, and the drug will be available for patients as needed until April 30, 2018. Patients using daclizumab should not stop their medication without talking with their doctor and should contact their doctor immediately if they have any new and unexplained symptoms. Any questions or concerns about the withdrawal can be directed to the manufacturers' service center at 800-456-2255 or the manufacturer's website at www.zinbryta.com. FDA stated that it understands that this may be a difficult situation for some patients and will continue to work closely with the manufacturers throughout the withdrawal process. The complex safety profile of daclizumab has been recognized since the time of FDA approval. The drug's safety profile led to an indication of use generally limited to patients who have had an inadequate response to two or more MS drugs, to a boxed warning about the risk of liver injury and of other immune-mediated disorders, and to a Risk Evaluation and Mitigation Strategy making the drug available only through a restricted distribution program. FDA has continuously monitored adverse events associated with use of daclizumab and has updated product labeling as new information became available. Recently, the European Medicines Agency announced a

(Zinbryta—Biogen, AbbVie)

Daclizumab withdrawn after reports of serious inflammatory brain disorders

recall of daclizumab following 12 reports of serious inflammatory brain disorders worldwide. FDA is aware of these reports and is conducting a review of similar events. As the manufacturers move forward the withdrawal plan, any additional important information will be made available to the public.

FDA asks health professionals and consumers to report any adverse reactions or quality problems to FDA's MedWatch program at www.fda.gov/medwatch/report.htm.

Source URL:

http://www.aphadruginfoline.com/product-withdrawals/daclizumab-withdrawn-after-reports-serious-inflammatory-brain-disorders

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 26, 2018	
Lidocaine 1.8% topical patch ***(ZTlido—Scilex Pharmaceuticals/Sorrento)*** **FDA approves lidocaine 1.8% topical patch for postherpetic neuralgia pain**	FDA has approved lidocaine 1.8% topical patch to relieve pain associated with postherpetic neuralgia. The product contains 36 mg of lidocaine versus 700 mg in the 5% lidocaine patch, including more efficient delivery of lidocaine, superior adhesion, and less residual left in the patch after normal use, according to the manufacturer. The patch can be worn for 12 hours with effective delivery of the medication, including during exercise. The agent will become available on the market in 2018.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/fda-approves-lidocaine-18-topical-patch-postherpetic-neuralgia-pain

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 26, 2018	
Tildrakizumab-asmn ***(Ilumya—Sun Pharma)*** **FDA approves tildrakizumab-asmn for plaque psoriasis**	Sun Pharmaceuticals announced FDA approval of tildrakizumab-asmn for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Tildrakizumab-asmn is an interleukin (IL) inhibitor that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor, leading to inhibition of the release of proinflammatory cytokines and chemokines. The agent is administered at a dose of 100 mg by S.C. injection every 12 weeks, after the completion of initial doses at weeks 0 and 4. It is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/fda-approves-tildrakizumab-asmn-plaque-psoriasis

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 26, 2018	
Nilotinib ***(Tasigna—Novartis)*** **New indication to treat children aged 1 year and older with rare form of leukemia**	Novartis announced FDA approval of nilotinib to include treatment of first- and second-line pediatric patients aged 1 year or older with Philadelphia chromosome-positive chronic myeloid leukemia in the chronic phase (Ph+ CML-CP). Nilotinib is also indicated for the treatment of pediatric patients aged 1 year of age or older with Ph+ CML-CP that is resistant or intolerant to prior tyrosine kinase inhibitor (TKI) therapy, as well as adult patients with Ph+ CML in chronic phase and accelerated phase that is resistant or intolerant to prior therapy that included imatinib. Adverse reactions observed in these pediatric studies were generally consistent with those observed in adults, except for laboratory abnormalities of hyperbilirubinemia and transaminase elevation, which were reported at a higher frequency than in adult patients. One patients with resistant or intolerant pediatric CML progressed to advance phase/blast crisis after about 10 months on treatment.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/new-indication-treat-children-aged-1-year-and-older-rare-form-leukemia

Alerts and Recalls

Generic Name (Trade Name—Company)	**Uses**/Notes
March 26, 2018	
Aspirin, chlorpheniramine, phenylephrine	FDA is alerting consumers of a voluntary recall of Bayer's Alka-Seltzer Plus products because of labeling errors.
(Alka-Seltzer Plus—Bayer)	
Bayer recalls Alka-Seltzer Plus products because of labeling errors	Bayer is voluntarily recalling Alka-Seltzer Plus packages that 1) were sold only in the United States at Walmart, CVS, Walgreens, and Kroger (including Dillons Food Stores, Fred Meyer, Fry's Food Stores, Ralphs, King Soopers, and Smith's Food and Drug) after February 9, 2018; and 2) can be identified by checking the Bayer logo located on the lower left corner of the front of the carton. If the logo has an orange or green background, the product is included in the recall. The affected packages are being recalled because the ingredients listed on the front sticker of the carton may be different from the ingredients listed on the back of the carton as well as the product in the carton. This may lead consumers to ingest an ingredient to which they are allergic, or should not be taking because of the potential for serious health consequences. Consumers who purchased packages of Alka-Seltzer Plus that are being recalled should stop using the product immediately and contact their physician or health care provider if they experience any problems that may be related to using this drug product. Consumers can contact Bayer at (800) 986-0369 with questions, to report any issues they experienced with the product, or for instructions about how to receive a refund. FDA has not received any adverse event reports related to these recalled products.

Source URL:

http://www.aphadruginfoline.com/alerts-and-recalls/bayer-recalls-alka-seltzer-plus-products-because-labeling-errors

Alerts and Recalls

Generic Name (Trade Name—Company)	**Uses**/Notes
March 26, 2018 **Sildenafil, tadalifil** ***(Viagra, Cialis—Acme Generics)*** **FDA warns not to use unapproved erectile dysfunction products advertised on radio**	FDA is warning consumers not to purchase or use drugs advertised nationwide as a “healthy man alternative to the little blue pill” or “healthy man,” or “the power pill” for erectile dysfunction on broadcast and internet radio platforms such as iHeart Radio, as these drugs have not been approved by FDA. These drugs, purchased without a prescription, contain 100 mg of sildenafil, the active ingredient in Viagra. This is a dangerous dosage strength for certain patients, including older adults and those with impaired liver and kidney function. When sildenafil interacts with nitrates in some prescription drugs, such as nitroglycerin, a person’s blood pressure can reach dangerously low levels. People with diabetes, high blood pressure, high cholesterol, or heart disease often take nitrates. The label on the blister packs for these unapproved drugs states that the products are manufactured in India by Acme Generics. The label also bears the name Sun Pharma. FDA is concerned the seller may also be distributing to U.S. consumers unapproved tadalafil as a generic for the prescription drug Cialis. To date, FDA is not aware of any adverse events associated with these particular unapproved versions of sildenafil or tadalifil.

Source URL:

http://www.aphadruginfoline.com/alerts-and-recalls/fda-warns-not-use-unapproved-erectile-dysfunction-products-advertised-radio

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 29, 2018	
Efavirenz/lamivudine/tenofovir disoproxil fumarate 600 mg/300 mg/300 mg ***(Symfi—Mylan)*** **Triple-combination, once-daily HIV treatment approved in the U.S.**	Mylan announced FDA approval of efavirenz, lamivudine, and tenofovir disoproxil fumarate 600 mg/300 mg/300 mg tablets, a once-daily, single-tablet regimen (STR), indicated as a complete regimen for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 40 kg. The combination is the most widely taken antiretroviral (ARV) regimen outside of the United States, with more than 7 million users worldwide in 2016. The introduction of the new combo comes after FDA's recent approval of two Mylan ARVs: lamivudine and tenofovir disoproxil fumarate 300 mg/300 mg tablets (Cimduo), a once-daily combination of two nucleo(t)side reverse transcriptase inhibitors, which is indicated in combination with other ARVs to treat HIV-1 infection in adults and pediatric patients weighing at least 35 kg; and efavirenz, lamivudine, and tenofovir disoproxil fumarate 400 mg/300 mg/300 mg tablets (Symfi Lo), also approved for patients with HIV-1 in adults and pediatric patients weighing at least 35 kg. Following FDA approval, Mylan launched Symfi Lo earlier in March and expects Cimduo and Symfi to launch in the second quarter of 2018.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/triple-combination-once-daily-hiv-treatment-approved-us

Supplemental Approvals

Generic Name (Trade Name—Company)	**Uses**/Notes
March 29, 2018	
Blinatumomab	FDA granted accelerated approval to blinatumomab to treat adults and children with B-cell precursor acute lymphoblastic leukemia (ALL) who are in remission but still have minimal residual disease (MRD) and therefore an increased risk of relapse. Blinatumomab works by attaching to CD19 protein on the leukemia cells and CD3 protein found on certain immune system cells. Bringing the immune cell close to the leukemia cell allows the immune cells to attack the leukemia cells better. FDA first approved blinatumomab under accelerated approval in December 2014 for treatment of Philadelphia chromosome–negative relapsed or refractory positive B-cell precursor ALL. Full approval for this indication was granted in July 2017, and at that time, the indication was also expanded to include patients with Philadelphia chromosome–positive ALL. Approval was based on results of single-arm clinical trial that included 86 patients in first or second complete remission who had detectable MRD in at least 1 out of 1,000 cells in their bone marrow. Efficacy was based on achievement of undetectable MRD in an assay that could detect at least 1 cancer cell in 10,000 cells after one cycle of treatment with blinatumomab, in addition to the length of time patients remained alive and in remission (hematological relapse-free survival). Overall, undetectable MRD was achieved by 70 patients. More than one-half of the patients remained alive and in remission for at least 22.3 months. Adverse effects for this indication are consistent with those seen in other uses of the drug: infections (bacterial and pathogen unspecified), fever, headache, infusion-related reactions, neutropenia, anemia, febrile neutropenia, and thrombocytopenia. The agent carries a boxed warning alerting patients and health professionals that some clinical trial participants had problems with low blood pressure and difficulty breathing (cytokine release syndrome) at the start of the

(Blincyto—Amgen)

Approval expanded to treat patients with B-cell precursor ALL at risk for relapse

first treatment, and experienced a short period of difficulty with thinking (encephalopathy) or other adverse nervous effects.

Serious risks include infections, effects on the ability to drive and use machines, pancreatitis, and preparation and administration errors—instructions for preparation and administration should closely be followed. There is a risk of serious adverse reactions in pediatric patients due to benzyl alcohol preservative; therefore, the drug prepared with preservative-free saline should be used for patients weighing less than 22 kg.

Source URL:

http://www.aphadruginfoline.com/supplemental-approvals/approval-expanded-treat-patients-b-cell-precursor-all-risk-relapse