Octapharma AG will conduct its largest study of intravenous immune globulin (IVIG) to treat chronic inflammatory demyelinating polyradiculoneuropathy (CIDP). The double-blind, placebo-controlled, randomized, multicenter, adaptive, two-stage Phase II/III dose-finding study will investigate the efficacy and safety of Octapharma’s novel 10% IVIG in the treatment of CIDP and, together with results from additional ongoing and upcoming studies, will support its regulatory filing in Europe and the U.S. The study is one more study of a series to investigate Octapharma’s new 10% IVIG for a range of neurologic and hematological conditions, including immune thrombocytopenic purpura (ITP), Guillain-Barré syndrome (GBS), Kawasaki disease and CIDP.

The U.S. Food and Drug Administration has issued a warning about Advair Diskus inhalers stolen in 2009 from a GlaxoSmithKline warehouse that have been found in some pharmacies, and is advising consumers not to use them. Advair Diskus, generically known as fluticasone propionate and salmeterol inhalation powder, is used to treat those who suffer from asthma and chronic obstructive pulmonary disease. Stolen pharmaceutical products such as these have risks because they may have been stored at incorrect temperatures and humidity levels, which can cause them to lose potency, and they may have been tampered with and may be contaminated.

Two lots were stolen, totaling 25,600 inhalers. The lot numbers include 9ZP2255-NDC0173-0696-00 and 9ZP3325-NDC0173-0697-00. Patients who have products with these lot numbers should stop using them, contact GlaxoSmithKline’s customer response center at (888) 825-5249, and follow up with their physician or pharmacist to obtain a proper replacement.

The state of New York has passed a new law that prohibits commercial health insurance plans from creating specialty tiers within their prescription drug formularies. According to the law, the justification for the ban on specialty tiers is as follows:

As the cost of prescription drugs continues to climb, health insurance plans in California, Minnesota, Maryland and Alabama have created new specialty tiers to increase the copayments that consumers pay. Instead of a three-tiered drug formulary structure used by most plans (where Tier 1 is for generics, Tier 2 is for brand-name preferred drugs, and Tier 3 is for brand-name non-preferred drugs), some plans have begun to add fourth and fifth tiers for the most expensive medications. These additional tiers assign a percentage of the cost of the medication as coinsurance, as opposed to a set dollar amount used in the other three tiers. An example might be $10 for Tier 1 generics, $25 for Tier 2 brand-name preferred drugs, and $50 for Tier 3 brand-name non-preferred drugs.

In the states allowing specialty tiers, medications placed in Tiers 4 and 5 are typically assigned a coinsurance payment of between 20 percent and 35 percent. Therefore, a patient being treated for multiple sclerosis (MS), for example, could have a monthly copayment that could reach $775. People living with chronic illnesses, such as MS, rheumatoid arthritis and hemophilia, or people with a life-threatening condition, such as HIV, breast or colorectal cancers, leukemia and non-Hodgkin’s lymphoma, are the patients who are most affected.

According to the New York law, specialty tiering is contrary to the original purpose of insurance, which is to spread the cost. Instead, it creates a structure where those who are most sick pay more, which is an unlawful discriminatory practice.
**Medicine**

**Gamunex-C Approved for Subcutaneous Administration**

The U.S. Food and Drug Administration (FDA) has approved Talecris Biotherapeutics’ Gamunex-C (immune globulin injection [human] 10% caprylate/chromatography purified) for subcutaneous administration in the treatment of primary immunodeficiency (PIDD). Gamunex-C can be administered subcutaneously and intravenously, whereas Talecris’ previously FDA-approved Gamunex can be administered intravenously only.

Intravenous (IV) delivery for both products is FDA-approved to treat PIDD, chronic inflammatory demyelinating polynévropathy (CIDP) and idiopathic thrombocytopenic purpura (ITP). Gamunex-C has labeling and packaging information that describes both IV and subcutaneous routes of administration. Gamunex has labeling and packaging information that describes only IV administration.

“The FDA approval of Gamunex-C is important because it provides another option for patients with primary immunodeficiency and their healthcare professionals when they are considering the various treatment modalities,” says Fred Modell, cofounder of the Jeffrey Modell Foundation. “We consider it significant for patients to have multiple modes of delivery so they can select the option that best suits their individual needs.”

**Medicine**

**Cangene to Manufacture New IVIG Product**

Cangene Corp. has announced that it is developing an intravenous immune globulin (IVIG) product — a product that was included, but unidentified, in the company’s pipeline for the past two years. According to a Cangene press release, the company is currently scaling up its manufacturing processes for clinical trials, which are expected to begin in 2011. The process of manufacturing the IVIG product will incorporate a different platform technology for plasma fractionation than the one the company uses for its specialty hyperimmune products, such as WinRho SDF and HepaGam B. Cangene is also building an inventory of the source plasma needed for the manufacture of IVIG to be used in clinical trials. Source plasma differs from the specialty plasma the company uses to manufacture its hyperimmune products because it has not been selected for the presence of specific antibodies.

“The potential uses of [IVIG] continue to expand. We believe this product has great potential for us and that it would be a good addition to our hospital-based commercial product lineup,” says Dr. John Langstaff, Cangene’s president and CEO. “We are also working with some new technology for manufacturing this product, which may in turn be used for future products.”

**Medicine**

**Hizentra Shelf Life Extended to 24 Months**

The U.S. Food and Drug Administration has approved a supplemental biologics license application (sBLA) to extend the shelf life of Hizentra, immune globulin subcutaneous (human) 20% liquid, from 18 months to 24 months. Hizentra is indicated for the treatment of primary immunodeficiency.

The sBLA was based on a study that assessed the product’s physicochemical, biological and immunological parameters over 24 months’ storage under controlled conditions at 77 degrees Fahrenheit. Data generated from the study support that when Hizentra is stored at room temperature (up to 77 degrees Fahrenheit) and protected from lights, it is stable for up to 24 months.
Medicine

Octagam Withdrawal Issued for All Lots

Octapharma USA has initiated a voluntary withdrawal of all lots of Octagam (immune globulin intravenous [human] 5% liquid preparation) from the U.S. marketplace due to an unusually high number of thromboembolic events that have been associated with people being administered the drug. This follows an initial announcement in August of a voluntary withdrawal of selected lots of Octagam 5%, which reported at least nine events in which blood clots dislodged and traveled through the body, causing injury and pain to patients.

According to Octapharma USA, while the company has not received any reports of thromboembolic events since its initial voluntary market withdrawal, “the Food and Drug Administration and Octapharma agree that until a root cause analysis of the previously reported thromboembolic events can be determined, the most prudent course of action is to suspend further administration of Octagam 5%.”

The company requests that customers quarantine all lots of Octagam 5% and then contact the Octapharma customer service department at (201) 604-1141 to return the product. This withdrawal is for Octagam only. Octapharma’s Albumin (Human) and Wilate, Von Willebrand Factor/Coagulation Factor VIII Complex (Human), are unaffected and are readily available in all sizes for purchase.

Research

Scleroderma, Cancer Linked in Study

Researchers at Johns Hopkins University School of Medicine have found that patients with a certain type of scleroderma may get cancer and scleroderma simultaneously. The small study, which examined blood and tumor samples from 23 patients with both scleroderma and cancer, looked for specific immune markers in each patient to determine which type of antibodies the patients made. Those with antibodies called anti-RNA polymerase I/III had the most closely related onset of cancer and scleroderma; patients got both diseases within two years of one another. However, the reasons for the apparent link are not understood, and it is not known whether cancer could be causing scleroderma or if scleroderma could be causing cancer.

Scleroderma is a complex autoimmune disease, with visible symptoms affecting the skin, or invisible symptoms affecting internal organs. For some people living with scleroderma, it affects both. The study was published online in the journal *Arthritis and Rheumatism.*

Medicine

FDA Approves Grifols’ Flebogamma 10% DIF IVIG

Grifols has obtained U.S. Food and Drug Administration approval for its next generation of intravenous immunoglobulin (IVIG) 10% concentration, under the name Flebogamma 10% DIF. Flebogamma DIF (double inactivation and filtered) is a polyvalent IVIG that incorporates two specific viral inactivation methods and the additional safety step of nanofiltration at 20 nanometers. These processes produce higher yields of the product to maximize the amount of life-saving medicine that can be produced from each plasma donation.

With this approval, Grifols is the first company in the U.S. to offer patients and clinicians two concentrations of liquid IVIG (5% and 10%).