Spring 2016

KHF Hemosphere

Best Vegasville Ever!

KHF's annual gala was a smashing success. The best ever, we were told repeatedly. Credit to a large extent goes to this year's phenomenal local band, the Remedy. Guests danced until the clock struck midnight, and the event concluded. We greatly appreciate the Remedy's generous donation of providing the after-dinner entertainment at our event.

Also contributing to the overall success of Vegasville, were Steve Fazzini's renditions of classic Vegas tunes, the popular casino-style gaming activities expertly facilitated by John Silletto and friends, the array of ever so alluring silent auction items, the stunning grand prize aquamarine pendant and chain (won by Myra Loeser), the insightful testimonial by our camper, Tyler Marcum, and the lovely little cheerleaders who entertained our dinner guests.

Many thanks are due to all sponsors, donors, contributors, and volunteers. The Royal Flush table sponsor was Forcht Bank. Baxalta was the Straight Flush table sponsor, and Bayer HealthCare and CSL Behring were Four of a Kind table sponsors. Biogen, CVS Caremark, Kosair Charities, Novo Nordisk, and Pfizer were Full House table sponsors. Group seating tables were sponsored by Mr. & Mrs. Henry W. Boyd, III, HEMA Biologics, Louisville Oral Surgery & Dental Implants, and Republic Bank & Trust Company. The primary Special Ask contributor was Kosair Charities, and major in-kind donors were Business First, Deborah & Glen Hitt, Sr., and Publishers Printing.

A special thank you to Master of Ceremonies, Jared Heil, from WHAS 11, our planning committee led by Melissa Hitt, and all of our wonderful event volunteers and staff who put on a super event. In all, everyone had a great time and essential funds were raised to support KHF's programs and services for Kentucky's bleeding disorders community. The event raised $57,000.

Researchers Make Gene Therapy Breakthrough in Dogs with Factor VII Deficiency

In a recently published paper in the journal Blood, a team of researchers from the University of North Carolina (UNC) and The Children's Hospital of Philadelphia (CHOP) reported the successful application of gene therapy in dogs with factor VII (FVII) deficiency. This represents a significant advance, demonstrating the safety and efficacy of a novel therapy in large animal studies is a standard precursor to eventual clinical trials in humans.

FVII deficiency is a rare bleeding disorder with an incidence of 1 in 300,000 to 500,000, as both parents need to carry the gene in order to pass it on to their children. The condition, which affects men and women equally, is characterized by inadequate production of the FVII clotting protein. Babies are often diagnosed within the first six months of life after sustaining an intracranial hemorrhage or bleeding in the gastrointestinal tract. People with the more severe form of FVII deficiency often experience joint and muscle bleeds, easy bruising and bleeds after surgery. Bleeding can also occur in the skin, mouth, nose and genitourinary tract, while women often experience severe menorrhagia (prolonged, heavy periods). The primary treatment for FVII deficiency is recombinant factor VIIa.

The study, "Sustained Correction of FVII Deficiency in Dogs Using AAV-Mediated Expression of Zymogen FVII," was published in the February 4, 2016 issue of Blood. The senior investigator was Paris Margaritis, D.Phil., head researcher at CHOP and Penn's Perelman School of Medicine. Leading the UNC team was Tim Nichols, MD, professor of medicine and pathology at the UNC School of Medicine.

For the study, Margaritis cloned the canine factor VII gene and enclosed that genetic material inside adeno-associated viruses (AAVs). These viruses act as delivery vehicles, or vectors, to carry the genetic material into living cells to sustain therapeutic effect without causing disease or triggering significant immune responses. In this case, the AAVs are designed to elicit the production of the FVII. Nichols and his colleagues then treated four FVII deficient dogs with a single injection of the therapy, administering different amounts of AAVs in each of the animals.

They found that the amount of factor VII generated was directly proportional to the amount of AAVs given to the individual dogs. Nichols's team also monitored the dogs' progress over a period of three years and found that they all produced FVII levels that were sufficiently therapeutic – this is particularly encouraging for investigators as the amount of FVII necessary to achieve a sustained therapeutic effect in dogs correlates closely to that for humans. "This work is very exciting and promising," said Nichols. "The FVII-deficient dogs tolerated the initial gene therapy infusions very well and have had no adverse side effects over several years of follow up. In other related studies in dogs with hemophilia B (FIX), similar positive findings have translated to people with hemophilia B."

In addition, blood, kidney and liver function tests all showed that therapy was safe and did not trigger an unwanted immune response. The next step will be to conduct clinical trials in humans. "The table is now set to propose clinical trials that would treat people who suffer from FVII deficiency," concluded Nichols.

Source: *UNC Health Care news release dated January 20, 2016*

Study of 50 Years of Hemophilia Healthcare Outcomes Yields Surprises

Results from a new study indicate that despite 50 years' worth of advances in the area of comprehensive care for patients with bleeding disorders, males with hemophilia still grapple with significant health-related issues affecting their quality of life. The study, "Men with Severe Hemophilia in the United States: Birth Cohort Analysis of a Large National Database," was published online on March 16, 2016, in the journal Blood. The lead author of the article was Paul E. Monahan, MD, of the Gene Therapy Center at the University of North Carolina at Chapel Hill. Co-investigators included professionals from the hemophilia treatment center (HTC) network and the Centers for Disease Control and Prevention (CDC).

To better understand the connections between the many changes in hemophilia healthcare and the dynamics affecting overall health, Monahan and his team reviewed data collected from 4,899 men with severe hemophilia and 2,587 men with mild hemophilia. All of these men had received care at HTCs from 1998-2011. Data were organized into four time periods, or "eras," representing major healthcare developments and therapeutic breakthroughs relevant to people with hemophilia: Era A included the oldest group, men born prior to 1958; Era B grouped men born between 1958 and1975; Era C included men born from 1976-1982; and Era D represented the youngest group, men born between 1982 and1993.

The main findings of the study included:

- In Era D more than one in three men with severe hemophilia reported frequent bleeds (more than five bleeds in six months), despite being treated with the most modern therapies. One in four of these men also reported a recurrent bleed in a "target joint."
- Across all eras, compared to men with mild disease, those with severe hemophilia were about three times more likely to report activity limitations. Further, they were twice as likely to report some use of assistive devices to help them move around, such as a cane or wheelchair.
- In every era, the proportion of men with severe hemophilia that missed at least 10 days of work or school in the last year due to upper or lower joint problems was two or three times that of men with mild hemophilia.
- Nearly half of the men in Era A were disabled and unable to work. Moreover, men with severe hemophilia were about three times more likely to be disabled as their mild hemophilia counterparts in every era.
- Infection-related health problems due to hepatitis B, hepatitis C and HIV are common among men with severe hemophilia, particularly in the older eras.
- Of the 551 deaths reported during the study period, liver failure was the most commonly reported cause of death, regardless of hemophilia severity or era. Bleed-related deaths accounted for 14.6% of deaths in men with severe hemophilia and 10.7% of deaths in men with mild hemophilia across all eras.

The study also yielded some unexpected findings. The overall rates of joint bleeding remain relatively high, even with the availability of more effective treatments. Also, despite the proven effectiveness of prophylactic factor therapy in preventing joint damage, men in all eras continue to underuse this option.

"Clear disparities remain in terms of frequent bleeding and disability between men with severe hemophilia and mild hemophilia across every decade of adult life. We thought the difference in functional outcomes would have narrowed over the years; that is, men with severe hemophilia should look more like those with mild disorder given improved therapeutics and access to care, but this wasn't the case," said Monahan. "What needs examination is why—despite widespread availability of preventive and on-demand therapies for home use—we still see disparities. It speaks to the need for continued disease surveillance to monitor and inform hemophilia interventions and outcomes."

Source: PRNewswire, March 16, 2016

Event News

Spring Scholarship Awards

Congratulations to our KHF scholarship recipients Andrew Harmon of Bedford and Kevin Loeser of Louisville. Andrew was awarded the Betty Meadors Mattingly Memorial Scholarship and Kevin the Herb Schlaughenhoupt, Jr. Memorial Scholarship. Each recipient received $500 for post-secondary education studies. Andrew is a student at Jefferson Community and Technical College, and Kevin is a student at the University of Louisville.

KHF Advocacy Day in Frankfort

KHF and the Tri-State Bleeding Disorder Foundation joined forces to organize this impactful annual event. A group of nearly thirty advocates gathered at the Capital Plaza Hotel in Frankfort for an early morning training breakfast on February 11 in preparation for meetings with Kentucky legislators. The training session facilitated by Kelly Fitzgerald, Melissa Bowie, and Marvin Poole inspired and reassured all participants. Talking points discussed during meetings with legislators focused on the importance of access to healthcare for the bleeding disorders community, continued funding for premium assistance programs, and capping excessive co-pay payments. Participants reported a friendly reception by legislators along with a listening ear and statements of support. A wrap-up lunch for our enthusiastic advocates at the Capitol Annex concluded this important activity. Many thanks to all who participated on behalf of Kentucky's bleeding disorders community and to our sponsors who underwrote associated costs. They were Baxalta, Biogen, CSL Behring, and Pfizer.

Washington Days

In February, the National Hemophilia Foundation (NHF), also held its annual advocacy activity on behalf of individuals with hemophilia and similar bleeding disorders in Washington, DC. Advocates from all across the U. S. participated including Eric and Tyler Marcum from Louisville who represented KHF. We thank NHF for this opportunity, and we thank Eric and his son, Tyler, for meeting with Kentucky members of Congress to discuss the needs and concerns of the bleeding disorders community. This year, advocates asked Congress to: 1. Support maintaining funding for the federal hemophilia programs at the Maternal and Child Health Bureau (MCHB) and Centers for Disease Control and Prevention (CDC) in their appropriations requests; 2. Co-sponsor Representative Aaron Schock's (IL-18) legislation to improve access to skilled nursing facilities (SNFs) for hemophilia patients in the House or introduce companion legislation in the Senate; and 3. Co-sponsor the Patients' Access to Treatment Act (House) or introduce companion legislation (Senate) to increase access to life-saving drugs on specialty tiers by prohibiting insurers from imposing exorbitant co-insurance requirements on patients.

Event News

Steps for Living Training

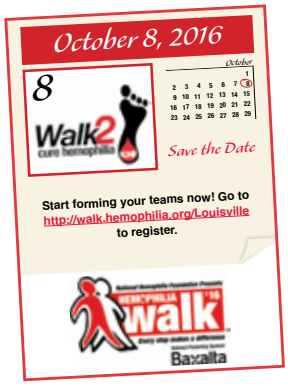
In March, we were delighted to welcome representatives from NHF to Louisville to conduct its semi-annual Steps for Living Training. Approximately twenty participants from all over the U.S. along with NHF staff convened at the Hyatt Regency for three days of training. Julia Kluesner, Senior Social Worker at the Lexington Hemophilia Treatment Center, and Ursela Kamala, KHF Executive Director, participated in the intensive, interactive training, which they deemed invigorating and inspiring and enjoyed thoroughly. The consensus among participants consisted of praise for the training and its application and the Steps for Living Program as a whole. Steps for Living is a marvelous and comprehensive educational program for all ages developed by NHF. For Steps for Living educational and every day living resource tools, go to **https://stepsforliving.hemophilia.org/**

Easter Lilies

The end of March brought with it KHF's Easter Lily and Spring Flowers Sale. This annual fundraiser involves the sale of Easter lilies, tulips, hyacinths, and mums to area churches, businesses, and individuals. This fundraiser would not be possible without our dedicated volunteers who take orders from family, friends, co-workers, and fellow church members.

We appreciate them greatly and hope others will want to follow suit in their communities. Many thanks to Janet Goff and Sharon Clary in Owensboro with most flowers sold, Pat Cooper at Kentucky Blood Center in Lexington, Tina Pelly in Campbellsville, Karen Lucky in Cynthiana, Deborah Hitt in Shelbyville, and Sadalia Sturgill in Lebanon Junction. In Louisville, we thank Jenifer Schultz, Diane Burnett, James and Doris Ray, and Nita Wayne Zehnder.

2016 Kentucky Hemophilia Walk



You may have received the Save the Date postcard for this year's Walk, but it is not too early to get started. Go ahead, form your teams, and start asking for pledges. The Walk date is Saturday, October 8 at the same location as before, lovely Wetherby Park in Middletown. Walkers should register on line and donations should also be made on line when possible.

The Walk website is up and running and more user friendly this year. Simply go to: **http://walk.hemophilia.org/Louisville** to register and to make a donation.

The earlier you start to recruit walkers for your team, the more money you can raise via family, friends, co-workers, and others in your circle of personal and business contacts, the better the prizes are that you can win, and the more Kentucky's bleeding disorders community will benefit from your efforts. Everyone is invited to participate in the Walk. Remember as you sign up that the Hemophilia Walk is a powerful community forum from which we together grow a network to help us create change now and for the generations who will come after!

More News

Kentucky Hemophilia Foundation Donors

Thank You To All Donors For Their Generous Contributions

January 1, 2016 – March 31, 2016

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KHF Membership 2015 – 2016

We appreciate your involvement and support!

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Charles & Ruth Hall

Champion/Corporate Members, $500
Dr. Joseph H. Cieslak
Louisville Oral Surgery & Dental Implants
Mark Osborne
First Choice Home Infusion

Join us in the Red Tie Challenge

How do you tie your red tie in support of the bleeding disorders community?

Family Day & Walk Call to Action
Saturday, June 11 ~ The Louisville Zoo

Play A Round For a Cure Golf Scramble
Monday, June 27
Oxmoor Country Club, Louisville, KY

Post-Secondary Education Scholarship
Submission Deadline for Fall 2016 Semester
July 15, 2016

Summer Camp
Sunday, July 10 - Thursday, July 14
Cedar Ridge Camp - Louisville, KY

Summer Family Event
Saturday, August 6
Hyatt Regency - Louisville, KY

Hemophilia Walk Fundraiser
Saturday, October 8
Wetherby Park ~ Louisville, KY

Do The Five

Follow these steps to prevent or reduce complications of bleeding disorders

1. Get an annual comprehensive checkup at a hemophilia treatment center.
2. Get vaccinated – Hepatitis A and B are preventable.
3. Treat bleeds early and adequately.
4. Exercise to protect your joints.
5. Get tested regularly for blood-borne infections.

To find out more about the National Prevention Program developed by the National Hemophilia Foundation in collaboration with the Centers for Disease Control and Prevention (CDC), click on www.hemophilia.org or call toll-free 800-42-HANDI.

KHF neither recommends nor endorses the products in this publication and does not make recommendations concerning treatment regimen for individuals. KHF suggests that you consult your physician or treatment center before pursuing any course of treatment. This publication is for general information only.

In Memory

January 1 – March 31, 2016

Gone from our sight but never our memories; gone from our touch but never our hearts…

William L. Farmer, Sr.
Mrs. William L. Farmer, Sr.

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E: tricia.oppelt@biogen.com T: 585-737-9060

Indications

ELOCTATE [Antihemophilic Factor (Recombinant), Fc Fusion Protein] is a recombinant DNA derived, antihemophilic factor indicated in adults and children with Hemophilia A (congenital Factor VIII deficiency) for: control and prevention of bleeding episodes, perioperative management (surgical prophylaxis), and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. ELOCTATE is not indicated for the treatment of von Willebrand disease.

Important Safety Information

Do not use ELOCTATE if you have had an allergic reaction to it in the past.

Tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines, have any allergies, are breastfeeding, are pregnant or planning to become pregnant, or have been told you have inhibitors (antibodies) to Factor VIII.

Allergic reactions may occur with ELOCTATE. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.

Your body can also make antibodies called, "inhibitors," against ELOCTATE, which may stop ELOCTATE from working properly.

Common side effects of ELOCTATE are joint pain and general discomfort. These are not all the possible side effects of ELOCTATE. Talk to your healthcare provider right away about any side effect that bothers you or that does not go away, and if bleeding is not controlled after using ELOCTATE.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see Brief Summary of full Prescribing Information on the next page.

This information is not intended to replace discussions with your healthcare provider.

Biogen

FDA-Approved Patient Labeling

Patient Information

ELOCTATE™ /el' ok' tate/
[Antihemophilic Factor (Recombinant), Fc Fusion Protein]

Please read this Patient Information carefully before using ELOCTATE and each time you get a refill, as there may be new information. This Patient Information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is ELOCTATE?
ELOCTATE is an injectable medicine that is used to help control and prevent bleeding in people with Hemophilia A (congenital Factor VIII deficiency).

Your healthcare provider may give you ELOCTATE when you have surgery.

Who should not use ELOCTATE?
You should not use ELOCTATE if you had an allergic reaction to it in the past.

What should I tell my healthcare provider before using ELOCTATE?
Talk to your healthcare provider about:

- Any medical problems that you have or had.
- All prescription and non-prescription medicines that you take, including over-the-counter medicines, supplements or herbal medicines.
- Pregnancy or if you are planning to become pregnant. It is not known if ELOCTATE may harm your unborn baby.
- Breastfeeding. It is not known if ELOCTATE passes into the milk and if it can harm your baby.

How should I use ELOCTATE?
You get ELOCTATE as an infusion into your vein. Your healthcare provider will instruct you on how to do infusions on your own, and may watch you give yourself the first dose of ELOCTATE.

Contact your healthcare provider right away if bleeding is not controlled after using ELOCTATE.

What are the possible side effects of ELOCTATE?
Common side effects of ELOCTATE are joint pain and general discomfort.

Allergic reactions may occur. Call your healthcare provider or emergency department right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash or hives.

Your body can also make antibodies called, "inhibitors," against ELOCTATE, which may stop ELOCTATE from working properly. Your healthcare provider may give you blood tests to check for inhibitors.

How should I store ELOCTATE?

- Keep ELOCTATE in its original package.
- Protect it from light.
- Do not freeze.
- Store refrigerated (2°C to 8°C or 36°F to 46°F) or at room temperature [not to exceed 30°C (86°F)], for up to six months.
- When storing at room temperature:
  - Note on the carton the date on which the product is removed from refrigeration.
  - Use the product before the end of this 6 month period or discard it.
  - Do not return the product to the refrigerator.

Do not use ELOCTATE after the expiration date printed on the vial or, if you removed it from the refrigerator, after the date that was noted on the carton, whichever is earlier.

After reconstitution (mixing with the diluent):

- Do not use ELOCTATE if the reconstituted solution is not clear to slightly opalescent and colorless.
- Use reconstituted product as soon as possible
- You may store reconstituted solution at room temperature, not to exceed 30°C (86°F), for up to three hours. Protect the reconstituted product from direct sunlight. Discard any product not used within three hours.

What else should I know about ELOCTATE?
Medicines are sometimes prescribed for purposes other than those listed here. Do not use ELOCTATE for a condition for which it was not prescribed. Do not share ELOCTATE with other people, even if they have the same symptoms that you have.

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Issued June 2014

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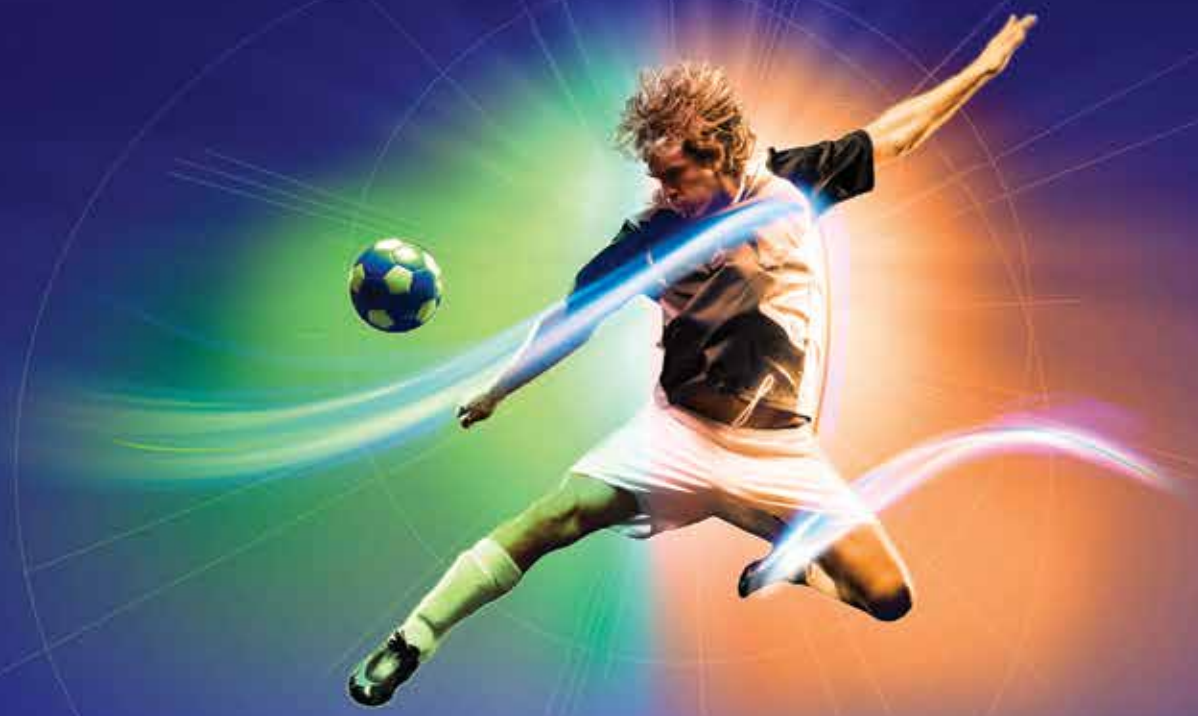

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*Results are statistically significant with a 95% confidence interval with a 6.5% margin of error and are based on a blinded national survey of 75 HTC-based Hematologists from a list of federally and non-federally funded HTCs within the US, conducted and validated by a reputable, independent third party, Adivo Associates LLC, on behalf of Grifols USA from October 2014 - January 2015. In order to qualify to complete the survey, Hematologists were rigorously screened according to market research standards having the necessary experience in the relevant treatment segment. Respondents were asked to assume no difference in terms of availability, cost, and reimbursement when indicating their most preferred plasma-derived FVIII brand.

HTC=Hemophilia Treatment Center; pdFVIII=plasma-derived factor VIII

Indications

ALPHANATE® (antihemophilic factor/von Willebrand factor complex [human]) is indicated for:

- Control and prevention of bleeding episodes and perioperative management in adult and pediatric patients with factor VIII (FVIII) deficiency due to hemophilia A
- Surgical and/or invasive procedures in adult and pediatric patients with von Willebrand disease (VWD) in whom desmopressin (DDAVP) is either ineffective or contraindicated. It is not indicated for patients with severe VWD (type 3) undergoing major surgery

Important Safety Information

ALPHANATE is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components.

Anaphylaxis and severe hypersensitivity reactions are possible with ALPHANATE. Discontinue use of ALPHANATE if hypersensitivity symptoms occur, and initiate appropriate treatment.

Development of procoagulant activity-neutralizing antibodies (inhibitors) has been detected in patients receiving FVIII-containing products. Carefully monitor patients treated with AHF products for the development of FVIII inhibitors by appropriate clinical observations and laboratory tests.

Thromboembolic events have been reported with AHF/VWF complex (human) in VWD patients, especially in the setting of known risk factors.

Intravascular hemolysis may occur with infusion of large doses of AHF/VWF complex (human).

Rapid administration of a FVIII concentrate may result in vasomotor reactions.

Because ALPHANATE is made from human plasma, it may carry a risk of transmitting infectious agents, eg, viruses, the variant Creutzfeldt-Jakob disease (vCJD) agent, and, theoretically, the Creutzfeldt-Jakob disease (CJD) agent, despite steps designed to reduce this risk.

Monitor for development of FVIII and VWF inhibitors. Perform appropriate assays to determine if FVIII and/or VWF inhibitor(s) are present if bleeding is not controlled with expected dose of ALPHANATE.

The most frequent adverse drug reactions reported with ALPHANATE in >1% of infusions were pruritus, headache, back pain, paresthesia, respiratory distress, facial edema, pain, rash, and chills.

Please see accompanying full Prescribing Information for ALPHANATE in pocket for complete prescribing details.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

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For more information: **Grifols Biologicals Inc.**
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