

Informed Consent Form (Adults)
CSL830_2001 / CSP Amendment 2 v1.0, 30 March 2012

INFORMED CONSENT FORM FOR ENROLLMENT FOR ADULTS

Study Title: An open-label, cross-over, dose-ranging study to evaluate the pharmacokinetics, pharmacodynamics and safety of the subcutaneous administration of a human plasma-derived C1-esterase inhibitor in subjects with hereditary angioedema

Study Number: CSL830_2001

Center: H. Henry Li, M.D.
Institute for Asthma & Allergy PC
5454 Wisconsin Avenue, Suite 700
Chevy Chase, MD 20815

301-986-9292 (24 Hour Number)

Sponsor: CSL Behring GmbH

Clinical Research and Development

Emil-von-Behring-Strasse 76

D 35041 Marburg

Germany

Research Study Information

We are asking you to be in a research study initiated and funded by CSL Behring. Before you agree to be in this study, it is important that you read (or have read to you) and understand the information in this document.

An Independent Review Board (IRB) approved this clinical study. This is an independent group of experts who make sure that the rights, safety, and well-being of human subjects in a study are protected.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Being in this study is your choice. You should discuss any questions you have with the study doctor. You must sign this document if you want to be in this study. By signing this document, you will not give up any of your legal rights that you may have

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MLIRB Version 2

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Approved by MidLands IRB on 04/17/12

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(as a research subject) under federal or state laws and regulations. No study-specific procedures will be started before you sign this document.

Introduction and Purpose of the Study

Hereditary angioedema (HAE) is an inherited disease that can cause episodes of swelling of the skin and tissues of the abdomen and neck. In most cases, the disease is due to the lack of a working protein called C1-esterase inhibitor (C1-INH). Therapy for HAE includes giving C1-INH to treat an episode of swelling, or to give it regularly to prevent these episodes from occurring. However, C1-INH currently has to be given directly into a vein (intravenously), and this can be impractical for some patients. A more convenient way of giving C1-INH by an injection under the surface of the skin is being developed. We are asking you to be in a research study that will investigate how the body handles C1-INH that is injected under the surface of the skin.

Study Treatment and Procedures

This is a global clinical research study that will be done at approximately 13 centers in the United States and Germany. Approximately 18 subjects with HAE will be in the study.

You will be in the study for up to about 17 weeks. This may include an interval between treatments (up to four weeks); this may be granted in agreement with your study doctor and CSL Behring prior to starting the study.

Study Treatment

While you are in this study, you will get two forms of C1-INH:

- Berinert is an approved product for treatment of swelling episodes due to HAE in the United States and Germany. Berinert will be given to you once, intravenously, at the standard dose. The Berinert injection will last about 10 minutes.
- CSL830 is a new formulation of Berinert that can be dissolved in a tenth the volume of liquid. CSL830 is an investigational medicine, which means that it has not been approved by the drug approval agency in your country. You will receive CSL830 by needle injection under the skin in your abdomen at two of the following three doses:
 - 1500 international units (IU) in 3 mL, given two times a week for four weeks
 - 3000 IU in 6 mL, given two times a week for four weeks
 - 6000 IU in 12 mL, given two times a week for four weeks
- The doses you receive and the sequence in which you receive them, will be determined by the order you enter the study. Allocation is not random (by chance) and sequences will be assigned so that experience with the lower doses can be gained before the higher doses are given. Depending on the dose given, the injection will last from a few seconds to a few minutes (less than five).

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If you are joining the study as a replacement for a discontinued subject, your treatment sequence will be assigned by CSL Behring to match that missing from the subject you are replacing. In certain situations, this may mean that you will be allocated to a single CSL830 dose and will only need to have a single four-week CSL830 dosing period. Except for this difference, all other study procedures and visits will be as described below.

This is an open-label study, which means that both you and the study doctor will know which treatment you are getting.

Study Procedures

The study procedures and study visits will be:

- An initial screening visit to determine if you are suitable for the study;
- A single, intravenous dose of Berinert followed by two visits to assess how your body handles Berinert;
- Two four-week CSL830 dosing periods to assess the safety of the dose and how your body handles CSL830;
 - For each four-week dosing period, visits are two times a week for the first three weeks, and daily on the fourth week;
 - Over each four-week dosing period, you will receive two injections of CSL830 under the skin every week, which will be an overall total of 16 injections of CSL830;
 - Between the two dosing periods, an interval of up to one month may be granted in agreement with your study doctor and CSL Behring prior to starting the study;
- An exit visit one week after the last CSL830 dosing period.

When you start the study, you will be asked to visit the study center approximately 30 times during this study. These visits will take place over a period of up to about 17 weeks and are described in more detail below.

Screening visit

Before you can start the study, your study doctor will need to make sure that you meet the entry criteria for this study. Your study doctor will check your medical records to do this. If the study doctor is not your regular doctor, he or she may contact your regular doctor.

In addition, your study doctor will have to do some tests to make sure you should be in the study. This means that the study doctor will do the following:

- Ask you about your medical history and your use of any medicines;
- Perform a physical examination that includes measuring your height, weight, temperature, pulse rate, blood pressure and breathing rate;
- Collect blood and urine samples (including urine pregnancy test for females of childbearing potential);

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- Assess risk of deep vein thrombosis (which may include arranging an ultrasound scan of your legs if your study doctor deems necessary).

As your health status can affect the safety of your participation in this study, you must tell the study doctor:

- Any illness or medical conditions that you have;
- All medications that you are currently taking or have taken recently;
- If you are participating in any other clinical studies;
- If you are a woman, whether you are trying to become pregnant during the course of the study or are breastfeeding;
- Any other information that can affect your suitability for this clinical study.

After your study doctor has made sure you meet all the entry criteria, you can start the study. It can take up to a few days for the blood and urine results to be available. If necessary, you may need to have some of the blood tests repeated if the first results were unclear.

At your first visit (the screening visit), you will be provided with a diary/memory aid to record any changes to your health and medications taken during the study. If you experience any swelling episodes due to HAE during the study, you will need to record details of the episode and any medications used to treat it.

Study visits associated with Berinert injection

Before the start of your first CSL830 dosing period, you will have three visits over three days to see how your body handles a standard dose of Berinert that is given to you intravenously.

These three visits will be scheduled between two to seven days before the start of the first CSL830 dosing period. (However, the three visits will be postponed if you have recently experienced swelling that was caused by HAE and that required treatment. Please let your study doctor know if you experience any swelling episodes prior to this visit.)

On the first day, which will be the day of the Berinert injection, you will have a review of your health status and any medications taken. Your doctor will also review the inclusion/exclusion criteria for the study and your lab results from the screening visit. You and your doctor will then discuss the study drug treatment schedule. You will then be given Berinert intravenously. The injection takes about 10 minutes. You will be monitored at the study center for at least 30 minutes afterwards in case of any immediate reactions. Two blood samples will be taken: before Berinert is given to you and also at the end of this visit.

On each of the two days following the Berinert injection, you will have a review of your health status and any medications taken. A blood sample will also be taken each day.

If the visit for the second day following Berinert injection coincides with the visit at the

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start of the CSL830 dosing period detailed below, then the study procedures will not be duplicated.

CSL830 dosing periods

There are two, four-week CSL830 dosing periods. During each of the two, four-week dosing periods, you will receive two injections per week of CSL830 under the skin, which will be an total of 16 injections of CSL830. Depending on the dose given, the injections will last from a few seconds to a few minutes (less than five).

Two different doses of CSL830 will be given to you during each four-week period. The first dosing period will be scheduled to start within 30 days of the screening visit.

During each of the four-week dosing periods, visits will be twice a week for the first three weeks and daily on the fourth week.

At each of the twice-weekly visits during the first three weeks of each dosing period, you will have

- A review of your health status and any medications taken,
- A blood sample drawn
- An injection of CSL830 under the skin in your abdomen by a study center staff member.

After receiving CSL830 on the first day of each dosing period, you will be monitored by the study staff for at least 30 minutes in case of any immediate reactions.

At the daily visits during the fourth week of each dosing period, you will have:

- A review of your health status and any medications taken.
- A blood sample will be drawn.
- An injection of CSL830 under your skin by a study center staff member (on two of these visits only).

Urine samples will be collected once on Day 1 and once during Week 3 (Day 15) of each dosing period. Your temperature, pulse rate, blood pressure and respiratory rate will be measured before and after CSL830 injection on Day 1 and Day 4 in the first week, and during two visits (Day 22 and Day 25) in the fourth week. A physical examination will also be conducted on Day 25. During each dosing period, there will be a weekly assessment (Day 8, Day 15, and Day 22) for the risk of deep vein thrombosis, which may include arranging an ultrasound scan of your legs if your study doctor deems necessary.

If an interval of up to four weeks between both dosing periods has been agreed to with the study doctor and CSL Behring, you will need to continue to record your health status and medications taken during this interval. If the interval is longer than seven days, then the study staff will contact you approximately seven days into this interval to see how you are doing.

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Exit visit

Approximately one week after the end of the last CSL830 dosing period, you will have a review of your health status and any medications taken, a physical examination (including measurement of your temperature, pulse rate, blood pressure and respiratory rate). Blood and urine samples (including a urine pregnancy test for women of childbearing potential) will be taken.

Possible Benefits and Risks

This study will help us learn more about how the medicine CSL830 is handled by your body and how safe it is when given to patients with HAE by injection under the skin. This information will help in the development of a convenient and effective therapy in preventing swelling episodes caused by HAE.

You may or may not benefit from this study. Your condition is not expected to get better or worse because of your participation in this study.

Beriner is approved for use in the treatment of HAE in a number of countries worldwide. The most common adverse reactions reported with Beriner use were those related to the HAE illness, and have included HAE attacks, headache, abdominal pain, nausea, muscle spasm, pain, diarrhea and vomiting. In addition, other events such as injection-site pain, injection-site redness, chills and fever have also been reported.

CSL830 has not been previously studied in humans. Because CSL830 contains the same active ingredient as Beriner (i.e., C1-INH), adverse reactions observed with Beriner can also be expected with CSL830.

Both Beriner and CSL830 are made from human blood. All blood products may contain infectious agents, such as viruses (for example, hepatitis or human immunodeficiency virus), that can cause disease. The risk that you will become infected by treatment with Beriner or CSL830 has been significantly reduced by

- Screening blood donors for viral infections;
- Testing all their blood samples for viruses;
- Inactivating and removing viruses from the blood samples.

Despite this, such products may still potentially contain infectious agents, including some not yet known or identified. Thus, the risk of transmission of infectious agents cannot be totally eliminated. You will be monitored for the development of certain viral infections during the study.

Beriner and CSL830 contain proteins from human plasma. Like any other protein molecules, they can cause development of antibodies. Antibodies are substances that your immune system produces to help your body fight diseases. Such antibodies can theoretically reduce the effectiveness of Beriner or CSL830 that is given to you. Although development of these antibodies has not been observed with the clinical use

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of Berinert, we will monitor you for development of antibodies to C1-INH during this study.

Berinert and CSL830 can cause severe allergic reactions including skin rashes, anaphylactic shock, difficulty breathing or a drop in your blood pressure which may be life-threatening. As such, you are required to be monitored for at least 30 minutes

- 1) after your Berinert injection and
- 2) after you receive your first dose of CSL830 at the start of each of the two dosing periods.

Formation of blood clots is a potential risk with all C1-INH products (both Berinert and CSL830). Although this risk is low, your risk of having a blood clot will be reviewed regularly by your study doctor. If there is a chance that you may have developed a blood clot, additional tests such as an ultrasound of your legs will be arranged to confirm if a blood clot has occurred and to help determine if any other appropriate therapy is required.

As CSL830 will be administered under the surface of the skin, this injection is expected to be associated with local reactions such as irritation, swelling and bruising. Such reactions were reported in a previous study with Berinert injections under the skin and were reported to be mild, with the patients recovering completely. Any such reactions developing during this study will be closely monitored by the study doctor.

Berinert has been used during pregnancy with no evidence of harm; however there is no information about the risks of pregnancy during treatment with CSL830. In addition, pregnancy can affect the way your body handles CSL830. Therefore, you are not allowed to get pregnant while being in this study. If you are sexually active, you must use contraception while in this study. Your study doctor will tell you about appropriate contraceptive methods.

If you become pregnant, you must tell your study doctor and we will take you out of the study. Your study doctor will tell you about the possible risks and inconveniences to you during the pregnancy and, if applicable, to an embryo, fetus or nursing infant. Your study doctor may need to contact your obstetrician.

If you are a male who is sexually active, you must inform your partner(s), if they are able to have children, that the effects of the investigational product on sperm are unknown. You or your partner(s) must use methods of birth control, so your partner(s) does/do not become pregnant.

Blood samples will be taken from a vein in your arm during the study. This may lead to pain at the needle site, bruising, bleeding, swelling or fainting, and (rarely) infection. The maximum amount of blood that will be taken on any day of the study is about 47.5 mL (3.2 tablespoons). The total amount of blood that will be taken over the entire study is about 297 mL (approximately 1 ¼ cups). This compares to a standard blood donation of 2 cups (500 mL).

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When assessing your vital signs, your blood pressure and heart rate will be measured. An inflatable cuff will be placed on your arm, and a machine will measure your blood pressure and heart rate after you have been sitting down for at least five minutes. You may experience mild discomfort in your arm while the cuff is inflated.

There may be other risks and discomforts associated with administration of Berinert or CSL830 that are not yet known.

New Findings

Your study doctor will tell you right away if there is new information that could be important to your decision to be in the study.

Expenses and Compensation

Costs to you

You will not have to pay for the study medicine (Berinert or CSL830), hospital stays, and any tests or procedures which are required only as a result of being in the study (for example any additional blood tests or ultrasound scans). CSL Behring will pay for these. You or your health insurance company will be responsible for paying all other medical costs that are not related to this study. This includes any routine or standard treatment for HAE that you would have received if you had not been in the study.

Compensation

There is no charge to you for participating in this research study. The study sponsor pays all the study costs. Institute for Asthma & Allergy PC will receive payment from the sponsor for the time spent on this study.

For your participation in this study, you may be compensated up to a total of \$1,870.00. Your compensation will be broken down as follows:

Dosing Period 1

Visit 1	Screening	\$120.00
Visit 2	IV Berinert Infusion	\$90.00
Visit 3		\$50.00
Visit 4		\$50.00
Visit 5	Day 1	\$95.00
Visit 6	Day 4	\$55.00
Visit 7	Day 8	\$55.00
Visit 8	Day 11	\$55.00
Visit 9	Day 15	\$70.00
Visit 10	Day 18	\$45.00
Visit 11	Day 22	\$55.00
Visit 12	Day 25	\$55.00
Visit 13	Day 23	\$45.00

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Visit 14	Day 24	\$45.00
Visit 15	Day 26	\$45.00
Visit 16	Day 27	\$45.00
Visit 17	Day 28	\$45.00
Visit 18		\$90.00

Total for Period 1 \$1,110.00

Dosing Period 2

Visit 3		\$50.00
Visit 4		\$50.00
Visit 5	Day 1	\$95.00
Visit 6	Day 4	\$45.00
Visit 7	Day 8	\$40.00
Visit 8	Day 11	\$40.00
Visit 9	Day 15	\$70.00
Visit 10	Day 18	\$45.00
Visit 11	Day 22	\$55.00
Visit 12	Day 25	\$55.00
Visit 13	Day 23	\$45.00
Visit 14	Day 24	\$45.00
Visit 15	Day 26	\$45.00
Visit 16	Day 27	\$45.00
Visit 17	Day 28	\$45.00
Visit 18		\$90.00

Total for Period 1 \$860.00

If you do not complete the study, you will be compensated for the Visits you have completed.

Research-related Injury - Information about Insurance

If you get hurt or sick as a result of being in the study, you should immediately contact your study doctor and seek medical treatment.

Dr. H. Henry Li

Telephone Number: 301-986-9292 (24 Hour Number)

If you experience a study-related injury, necessary and available medical care (including hospitalization) will be provided. A study-related injury is a physical injury or illness that is directly caused by any procedure or treatment used in this study and that is different from the treatment you would receive if you were not in this study. If you are physically injured because of any substance or procedure properly given under the plan of this study, we will pay for the reasonable costs of the treatment of that injury that are not covered by any other responsible third party. If your health

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insurance plan has a cost-sharing system (for example co-payments or deductibles), you may still have to pay these.

You will not get any money for medical treatment of an injury or illness that is not the result of getting Berinert or CSL830 as part of this study. You will not get any money for wages lost. You will not get any money for the costs of receiving physical therapy or other recovery services. You will not get any money for pain and/or suffering that may occur during the study or for injuries or problems related to your underlying medical condition(s).

Alternative Treatments

You do not have to be in this study to get treatment for your condition.

Your study doctor will tell you about benefits and risks of alternative procedures and treatments for the prevention of swelling episodes due to HAE. Alternative treatment options may include oral steroids or intravenous C1-INH injection.

Treatment after the End of the Study

Berinert and CSL830 will not be provided to you after the study is completed. More information will need to be collected before it is decided if CSL830 injection under the skin can be used to prevent swelling episodes in HAE.

After this study is completed, you may return to your prior treatment as prescribed by your doctor.

Voluntary Participation and Right to Withdraw

Your participation in this study is completely voluntary. You may refuse to be in the study. You may also stop the study at any time. In either case, there will not be a penalty or loss of benefits to which you have a right. If you choose to stop the study, you will be asked to see your study doctor for a final study visit/examination. This is important to make an orderly end to your study treatment and to tell you about other treatment options.

You may be taken out of the study without your agreement. This decision can be made by your study doctor, by CSL Behring or by the IEC/IRB for the following reasons:

- If your study doctor feels that it is in your best medical interest.
- If you do not follow the study instructions.
- If CSL Behring decides to stop the study.
- In the case of safety concerns.

If you stop the study (or if you are taken out of the study) you will not get any additional study treatment. You will be asked to return for a final visit so that the study doctor can assess your safety.

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If you withdraw your consent or if you are taken out of the study, the Sponsor or their representatives may still use study data collected before you withdrew your consent or were taken out of the study.

Confidentiality

During this clinical study, we will collect personal data about you. This data may be sensitive, such as your date of birth, race, gender, and medical findings. We will keep your identity and your personal records confidential during and after the study.

To be in this study, you must allow your regular doctor and your other health care providers to give your health information to the study doctor and other study personnel. You must also allow CSL Behring representatives, the IRB, and the regulatory authority(ies) access to your health information to monitor the clinical study and as required by law. Your identity will remain confidential, as allowed by the applicable laws and regulations.

Results from this study may be published in medical journals and presented at scientific meetings. Study results may also be posted in a public database on the internet. However, your identity will not be disclosed.

This section of the Informed Consent describes what sponsor and its representatives may do with the study data, which include all of your health information obtained during the course of the study. The Sponsor and its representatives may use and disclose this data:

- To conduct, monitor, and/or audit the research and to confirm the research results.
- To evaluate the performance of CSL830.
- To assure the safety, effectiveness, and quality of research and of medical products and therapies, which may include, but is not limited to, the collection and reporting of adverse event information as permitted by law.
- To conduct new medical research and develop proposals for new medical products or therapies.
- As required by law.

Individuals from the Institute for Asthma & Allergy PC, MidLands Independent Review Board, Clinical Trials Office, the US Food and Drug Administration and other US and foreign government agencies, data safety monitoring boards, and representatives of the sponsor including those from PAREXEL International and contracted laboratories may look at and copy the health information created or collected about you as part of this study, to assure quality control, to analyze the information and as otherwise permitted by law.

You understand that once your health information has been disclosed to a third party, federal laws may no longer protect the information from further disclosure.

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The results of this study conducted by the study investigator(s) and sponsor may be published or presented at meetings but will not include your name or reveal your identity.

Use of Blood Samples for Future HAE Research

After we complete our tests, CSL Behring would like to save any left-over blood for future research on HAE. Your blood sample will be frozen and will be stored with a number assigned to it instead of your name. The number will be linked to your name, which means you can withdraw permission for use of your blood sample at any time. Your consent to have your samples saved for future HAE research is independent of your participation in the current study, and your decision on the future use of your blood sample for HAE research does not affect whether you can participate in the current study.

The future use of your blood in HAE research may result in new products, tests or discoveries that may have potential commercial value. Donors of tissue (such as blood) do not retain property rights to the materials. As such, you would not share in any financial benefits from these products, tests or discoveries.

The results of the study of your samples will be used for research purposes only, and you will not be told the results of the tests.

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

This Authorization governs how your health information will be used and disclosed (released) by your health care providers and study investigator(s) as part of the study. Your health information that may be used and disclosed includes all information collected during the study, as well as any health information in your medical records that is relevant to the study, including certain personal data, which may be sensitive, such as you date of birth, race, and gender.

This authorization does not have an expiration date. If you do not cancel this authorization in writing, then it will remain in effect indefinitely. To cancel this authorization you must notify your study doctor in writing at the address listed on page 1 of this document.

YOU AGREE TO PERMIT INSTITUTE FOR ASTHMA & ALLERGY PC, AND YOUR HEALTH CARE PROVIDERS TO DISCLOSE HEALTH INFORMATION IN YOUR MEDICAL RECORDS TO THE STUDY INVESTIGATOR(S) AND ITS STAFF, AND OTHER PERSONS WHO EXAMINE OR PROCESS INFORMATION AS PART OF THE STUDY (TOGETHER "RESEARCHERS"), AS WELL AS TO THE SPONSOR. YOU ALSO AGREE TO PERMIT YOUR PROVIDERS TO DISCLOSE YOUR HEALTH INFORMATION AS REQUIRED BY LAW AND TO REPRESENTATIVES OF FOREIGN AND DOMESTIC GOVERNMENT AND REGULATORY ORGANIZATIONS, REVIEW BOARDS, AND OTHER PERSONS WHO WATCH OVER THE SAFETY AND EFFECTIVENESS OF MEDICAL DRUGS AND

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*THERAPIES AND THE CONDUCT OF RESEARCH TO MONITOR THE STUDY
AND AS REQUIRED BY LAW.*

*YOU ALSO AGREE TO PERMIT THE RESEARCHERS TO DISCLOSE YOUR
HEALTH INFORMATION TO THE SPONSOR AND ITS REPRESENTATIVES TO
CONFIRM THE RESEARCH RESULTS; TO ASSURE THE SAFETY,
EFFECTIVENESS, AND QUALITY OF RESEARCH AND OF MEDICAL PRODUCTS
AND THERAPIES, INCLUDING DEVELOPING PROPOSALS FOR NEW MEDICAL
PRODUCTS OR THERAPIES; TO COMPLY WITH APPLICABLE LAWS; AND AS
OTHERWISE PROVIDED FOR IN THE INFORMED CONSENT.*

PERSONS TO CONTACT FOR QUESTIONS, CONCERNS, OR COMPLAINTS

If you have any questions, concerns or complaints about this study, call Dr. H. Henry Li at 301-986-9292 (24 Hour Number).

If you have questions about your rights, general questions, complaints or concerns about this research, or questions about your rights as a person taking part in this study, call the MidLands Independent Review Board (IRB) at (913) 385-1414 or (800) 636-4445. If, at any time during or after your participation in this research, you would like information or offer input about your research experience, you can call the MidLands IRB at the number above or you can go to the MidLands IRB website at www.mlirb.com and give us your comments. Either way you do not have to give us your name, if you do not want to.

You have the right to ask any questions concerning the potential and/or unknown hazards of this study, at any time. If you have any questions concerning your participation in this study, or if at any time you feel you have experienced a research-related injury or a reaction to the study drug, contact Dr. H. Henry Li at 301-986-9292 (24 Hour Number).

LEGAL RIGHTS

You will not lose any of your legal rights to which you are otherwise entitled by signing this consent form.

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Consent to Participate

Confirmation:

I have answered all questions of the study doctor to the best of my knowledge. I will continue to do so. I will follow all instructions related to this clinical study. I understand that incomplete or wrong information could result in a risk to my health.

Written Consent:

I have been informed in detail about the purpose and the procedures of this clinical study with CSL830. I have read (or it has been read to me), and I understand the informed consent form. I have had enough time for my decision, and all my questions have been answered satisfactorily. I formally give my consent to participate in this clinical study. I will get a copy of the signed and dated version of this consent document.

My participation is voluntary. I know that I may withdraw this consent at any time. I do not need to give a reason. If I withdraw consent, I will not be penalized or lose benefits to which I have a right. By signing this consent document, I do not give up any of my legal rights.

I agree that my medical data are documented and given to CSL Behring and to the relevant authorities in a confidential way. I agree that CSL Behring representatives, the IRB and the relevant regulatory authorities will get direct access to my original medical records.

The following statement regarding the use of your blood samples for future research should also be reviewed. Note that your decision here does not affect your consent to participate.

I consent to my left-over blood samples being saved for future ☒ YES ☐ NO
HAE research.

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Adult subject:

Signature

Print name

04/30/12 9:05am

Date and time of
signature must be
personally entered
by the subject

Person who
conducted the
informed consent
discussion:

Signature

Print name

4/30/12 9:07

Date and time of
signature must be

personally entered
by the person who
conducted the
informed consent
discussion

I have witnessed the accurate reading of the consent document to the potential participant. The individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Impartial witness:

A witness
independent of the
study, who could not
be unfairly
influenced by people
involved with the
study.

Signature

Print name

Date and time of
signature must be
personally entered by
the witness

APPROVED BY

APR 17 2012

MLIRB
Midlands Independent Review Board