MYELOMA NEWS

The Leukemia & Lymphoma Society®
Fighting Blood Cancers

THE LATEST NEWS ON TREATING AND LIVING WITH MYELOMA

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Clinical Trials Lead to New Choices in Myeloma Treatment

DR. ASHER A. CHANAN-KHAN: MYELOMA EXPERT

People with myeloma have more treatment choices than ever. "This is a very exciting and hopeful time for patients with myeloma," said Dr. Asher A. Chanan-Khan, Assistant Professor of Medicine at the Roswell Park Cancer Institute, a Comprehensive Cancer Center in Buffalo, New York.

> "This is a very exciting and hopeful time for patients with myeloma."

Recent clinical trials are showing impressive results when myeloma medications are combined in different ways. In addition, several new medications have already entered clinical testing for myeloma, bringing hope to patients in the very near future. Dr. Chanan-Khan, an active researcher, added, "It is imperative that myeloma patients know about these novel drugs, and participation in clinical studies is the only way that we can quickly make these drugs available to all patients."

Physicians like Dr. Chanan-Khan, trial sponsors and — most importantly — patients are working together in clinical trials to find the most effective treatments. "Patients who participate in clinical trials are investing in their own future," said Dr. Chanan-Khan.

"The best hope for finding a cure is for patients to participate in clinical trials. They may be the first to benefit from new combinations of medications." Dr. Chanan-Khan added, "Many myeloma patients are alive today because they participated in clinical trials."

Dr. Chanan-Khan suggests that myeloma patients learn as much as possible about their disease from experts, other patients, health organizations and the National Cancer Institute. Because myeloma is a rare disease, patients should seek out a medical center with expertise in treating myeloma. "Do not be shy about going to a myeloma center to seek a second opinion, even if you can't stay there for your therapy," said Dr. Chanan-Khan.

Individuals living with myeloma and their family members can learn more about their disease and share their experiences by participating in educational programs and support groups. "People are often more comfortable asking questions outside of a clinic or hospital," said Dr. Chanan-Khan. You will have the opportunity to listen to and ask questions of Dr. Chanan-Khan on April 4, 2007, during The Leukemia & Lymphoma Society's free telephone education program on myeloma. ■

To register for upcoming programs or to access transcripts or audio files of past programs, visit www.LLS.org/myelomaeducation.

FREE TELEPHONE EDUCATION PROGRAMS UPDATE YOU ON MYELOMA

OUTLOOK *on* MYELOMA

Learn about the latest updates on myeloma through the *Outlook on Myeloma* teleconference series. Each program features a leading myeloma expert, who presents cutting-edge information and answers participants' questions during the hour-long question-and-answer session.

Patients, caregivers and healthcare professionals can call in from any phone. Before the teleconference, The Leukemia & Lymphoma Society will provide you with the toll-free phone number and a packet of information about myeloma, the featured speaker and the Society's services.

Two easy ways to register: Call our toll-free number (866) 992-9950 (x302) or visit www.LLS.org/myelomaeducation.

UPCOMING PROGRAM

APRIL 4, 2007
1:00 – 2:30 PM ET

"Myeloma Treatment: Exploring Your Options"

Asher A. Chanan-Khan, MD

Q&A: Over one hour dedicated to answering your questions

PAST PROGRAMS YOU CAN ACCESS

Read, listen to, or view past programs at www.LLS.org/myelomaeducation, including:

- *Latest Advances in Myeloma Therapies: Update from the American Society of Hematology (ASH) Annual Meeting*, with Seema Singhal, MD (January 24, 2007)
- *Understanding Myeloma: Current Issues and a Look Ahead*, with Robert Z. Orlowski, MD, PhD (October 25, 2006)

Finding Hope Through Clinical Trials

JERRA BARIT: MYELOMA SURVIVOR OF NEARLY 10 YEARS

When Jerra Barit was diagnosed with Stage III myeloma in 1998 at the age of 52, she decided to fight the disease aggressively. "Clinical trials were the way I wanted to go. I was more than willing to try anything available," said Jerra. Because she did, today Jerra is enjoying every minute of every day.

Clinical trials are research studies that test new ways to screen for, diagnose or treat cancer. Jerra participated in two clinical trials, both at Roswell Park Cancer Institute in Buffalo, New York. The first study, in 2002, was of bortezomib (Velcade®), which is now widely used in people who have had at least one prior treatment for myeloma. The second study, in 2004, combined bortezomib, liposomal doxorubicin (Doxil®), and thalidomide (Thalomid®). Clinical trials offer patients access to new therapies being tested to see if they can increase survival or improve quality of life.

Doctors conduct myeloma clinical trials at major cancer centers, university hospitals, local medical centers or their offices. Some clinical trials are available at a few specialized centers, while others are offered at many locations nationwide.

As a participant in a clinical trial, you will receive high-quality care from the research team, including doctors, nurses, social workers and study coordinators. The team will closely monitor both your health and your response to treatment. Researchers also follow strict scientific guidelines and ethical principles to protect you.

Members of your healthcare team can help you decide if a clinical trial is right for you, and will tell you about the benefits and risks of participation. Before making her decision, Jerra learned about clinical trials in general and specifically about two studies from her oncologist. She made sure that she understood the facts and that her questions were answered. According to Jerra, "The only dumb question is the one you don't ask."

> "People with myeloma have to be like mini–super heroes. We need to keep trying until there is a cure."

Talk to members of your healthcare team about how your treatment may affect your day-to-day life. For example, Jerra has experienced treatment-related neuropathy, which causes nerve pain and tingling, as a side effect. "I would say that neuropathy is a small price to pay for extending my life," she said.

Jerra knows she may need treatment in the future, and says she would participate in another clinical trial. "People with myeloma have to be like mini–super heroes," she said. "We need to keep trying until there is a cure." ■

Talking about Clinical Trials

Patients: Use the "Can We Talk about Clinical Trials?" stickers in the envelope with this newsletter to start conversations about participating in clinical trials. Wear one to your next doctor's appointment. Give some to members of your healthcare team. Let other patients see you wearing the sticker, and encourage them to ask about clinical trials, too.

Understanding the Informed Consent Process

DAWN DEPAOLO, RN, BSN: RESEARCH COORDINATOR

If you decide to participate in a clinical trial, your healthcare team will share vital information with you during a process called *informed consent*. "This process provides you with the important facts about a clinical trial," said Dawn DePaolo, RN, BSN, a research coordinator at Roswell Park Cancer Institute in Buffalo, New York. Dawn oversees the informed consent process with patients who are thinking about participating in a study and with patients who have already enrolled. Once they decide to participate, Dawn checks on patients regularly to see how they are doing, to answer their questions and to provide support.

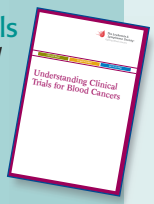
During the informed consent process, a doctor or nurse from the research team will describe what you should expect during the study and what is expected from you. Informed consent is an ongoing, interactive process between you and the research team. "You can — and should — ask questions and discuss your concerns at any time," said Dawn.

(Continued on page 4)

Finding the Right Clinical Trial for You: LLS Can Help

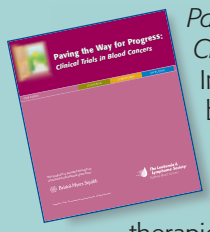
Clinical trials are ongoing, testing new drugs and combinations for myeloma at all stages. Many of these studies will accept older patients. To find a clinical trial that is right for you, start by talking with your healthcare team. You also can call The Leukemia & Lymphoma Society's Clinical Trial Service and talk with an information specialist (social workers and health educators) who will search for clinical trials for you, help you find out if you are eligible to participate, and where trials are available. Call toll-free (800) 955-4572 Monday through Friday, 9 AM to 6 PM ET, or visit www.LLS.org from 10 AM to 5 PM ET to access LIVE Help online. You can also search online at www.LLS.org/clinicaltrials.

Other LLS Resources on Clinical Trials



Understanding Clinical Trials for Blood Cancers: This free booklet includes information on how to decide if a clinical trial is right for you.

LLS Chapter Programs: Local Society chapters offer free education programs for patients, caregivers and healthcare professionals periodically throughout the year.



Paving the Way for Progress: Clinical Trials in Blood Cancers. In this program led by a local blood cancer expert you will learn about the role of clinical research in the development of new medications and therapies for blood cancers, and explore clinical trials as a treatment option.

Breaking Through the Age Barrier: Getting the Best Cancer Treatment. A local blood cancer expert will present the program, which contains valuable information that older adults can use when researching treatment options. For example, patients should know that age alone is no longer a key factor in determining a treatment option.

For information on these programs, call (800) 955-4572 or visit www.LLS.org. ■

Frequently Asked Questions About Myeloma

What are some initial treatments for myeloma?

First-line treatment (called front-line, first-line or induction therapy) of myeloma often includes high-dose chemotherapy or radiation therapy followed by stem cell transplant. Another treatment, melphalan combined with prednisone, has been used for 40 years and has a high response rate. However, melphalan is not typically used in patients who are candidates for a stem cell transplant. Dexamethasone is an initial treatment for myeloma that can be used either alone or in combination with other agents. The combination of thalidomide (Thalomid®) and dexamethasone was approved by the Food and Drug Administration for myeloma front-line therapy because of better clinical trial response rates when compared with dexamethasone alone.

Clinical trials are currently underway to study other combinations of medications that might be useful as initial therapy. For example, in newly diagnosed myeloma patients, combinations of lenalidomide (Revlimid®) and dexamethasone or bortezomib (Velcade®) and pegylated doxorubicin (Doxil®) are resulting in good overall response rates.

The improved response rates of initial combination therapies raise the question of whether to delay or eliminate stem cell transplant as initial therapy for myeloma. New clinical trials are being designed to answer this question.

What's new in clinical trials for relapsed myeloma?

Many combination therapies being tested in patients with relapsed myeloma were discussed at the American Society of Hematology (ASH) Annual Meeting. Researchers presented early results of clinical trials using treatment combinations such as bortezomib and lenalidomide with dexamethasone added for progressive disease. Many novel therapies being developed for patients with relapsed myeloma also look promising.

Which treatments provide the best quality of life?

All myeloma treatments have side effects, and these side effects often differ in individuals. Most clinical trials assess the effect of the study treatment on participants' quality of life, as well as their overall disease response. It is important to discuss with your doctor the side effects of your treatment and ways in which they can be controlled to help you maintain a good quality of life. ■

For more information on clinical trial results, go to Dr. Seema Singhal's presentation, "Latest Advances in Myeloma Therapies: Update from the American Society of Hematology (ASH) Annual Meeting," at www.LLS.org/myelomaeducation. You can also register on the Society's Web site for the Myeloma Links *e-newsletter, contact the Society's Information Resource Center at (800) 955-4572 or visit www.LLS.org/clinicaltrials.*

Resources for Financial Assistance

The Leukemia & Lymphoma Society:

- *Co-Pay Assistance Program:* This new program helps patients meet their private prescription drug insurance or Medicare Part D premiums or co-payments. Household income must be at or within 300% above the US Federal Poverty guidelines. For more information, call (877) LLS-COPAY [(877) 557-2672] or visit www.LLS.org/copay.
- *Patient Financial Aid:* This program provides up to $500 per year for specific approved drugs and other services for patients in significant financial need. For more information about this program, call (800) 955-4572 or visit www.LLS.org.

Medicare Part D: Everyone with Medicare, regardless of income or health status, can get prescription drug coverage from Medicare Part D. For more information, go to www.medicare.gov or call (800) MEDICARE [(800) 633-4227].

Patient Assistance and Prescription Savings Programs: Your social worker is a valuable resource and may have expertise in finding these programs. You can also call the Pharmaceutical Research and Manufacturers of America at (800) 762-4636 or visit www.phrma.org. ■

Supporting the Myeloma Patient in a Clinical Trial

As a caregiver, you play a very important role in helping the myeloma patient find out about the best treatment options and appropriate clinical trials.

You can aid the myeloma patient in making informed choices with confidence by:

- **Going to medical appointments.** Bring a list of prepared questions. Listen closely to the answers, then try to help the myeloma patient understand the information provided.
- **Doing some research.** Read about clinical trials and search for studies that may be right for the myeloma patient. The Leukemia & Lymphoma Society's Clinical Trial Service can help.
- **Participating in the informed consent process.** Participate in discussions about the clinical trial, and review the Informed Consent Form. Use the research team as your resource. Learn more in the article *Understanding the Informed Consent Process* in this edition of *Myeloma News*.

If the choice is to participate in a clinical trial, as a caregiver you can provide practical and emotional support. You can help the myeloma patient follow the study's requirements (called the *protocol*) by:

- Knowing the study's medication schedule
- Learning about potential side effects, how to look for them and what to do if they occur
- Keeping track of and going to appointments
- Helping with healthcare insurance questions and paperwork ■

Recursos Disponsibles en Español

La Socieded de Leucemia y Linfoma ofrece información y asistencia en español, incluyendo especialistas bilingües en información en nuestro Centro de Recursos Informativos (IRC): consigue información exacta, actual, enfermedad relacionada, da ayuda y apoyo.

Si usted siente que sería útil recibir este boletín de noticias en español, por favor llame el Centro de Recursos Informativos (IRC).

Para hablar con un especialista en información o para pedir publicaciones, llame a (800) 955-4572 o nuestro sitio Web de la Sociedad a www.LLS.org. ■

Understanding the Informed Consent Process (Continued from page 2)

LEARNING ABOUT THE *INFORMED CONSENT FORM*

Before you enroll in a study, a member of the research team will give you an Informed Consent Form, which is part of the informed consent process. The form includes the purpose and length of the study, explanations of the tests and other procedures used, and possible benefits and risks. A member of the research team will discuss the information in the Informed Consent Form with you. You may request to take the Informed Consent Form home to review the details of the study.

Remember that the Informed Consent Form is not a contract. "Patients sometimes believe that as soon as they sign their name on the Informed Consent Form, they will lose control. But that is not true," said Dawn. "I always remind patients that they can stop participating in a study at any time."

MAKING AN INFORMED DECISION

It is important to get all of the information you need before making a decision about participating in a clinical trial. "You don't have to sign the Informed Consent Form right away," said Dawn. "Take it home, and share it with your family and your doctor. Don't sign the form unless all of your questions have been answered."

LEARNING ABOUT STUDY DEVELOPMENTS

If you decide to participate in the study, remember that the informed consent process is designed to keep you informed throughout the study. You'll receive contact information for someone who can answer your questions. If researchers discover new benefits, risks or side effects, they'll tell you about them. Make sure to discuss new information and any concerns about your participation with members of your healthcare team. ■

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The Leukemia & Lymphoma Society®
Fighting Blood Cancers

The Leukemia & Lymphoma Society's mission is to cure leukemia, lymphoma, Hodgkin's disease and myeloma, and improve the quality of life of patients and their families.

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QUESTIONS TO ASK YOUR HEALTHCARE TEAM

[Clip this portion and bring it to your next healthcare appointment.]

Asking good questions will help you get the most appropriate care. Here are some key questions. Be persistent until you fully understand the answers.

1. What are my treatment options right now? What are the goals of these treatments?

2. Are there any clinical trials for which I might be eligible?

3. How would the study treatment be different from the standard treatment options?

4. What is the purpose of the study? Why do researchers think the approach may be effective?

5. How will I know if the study treatment is working for me?

6. If clinical trials are not an option for me now, will they be in the future?

7. How can I find out more about clinical trials that might help me?

8. Add other questions you may have prior to your healthcare appointment.

For additional questions to ask your healthcare team, call the Society's Information Resource Center at (800) 955-4572 or visit www.LLS.org.

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Fighting Blood Cancers

CLINICAL TRIAL TERMS YOU SHOULD KNOW

Clinical trial
A type of research study that tests how well new medicines or medical approaches work in people. A clinical trial tests new methods of screening, prevention, diagnosis or treatment of a disease. (Also called a clinical study.)

Eligibility criteria
The requirements that must be met for a person to be included in a clinical trial. These requirements help ensure that participants are similar to each other in terms of factors such as age, type and stage of cancer, general health and previous treatment. When all participants meet the same eligibility criteria, researchers have greater confidence that the study outcomes are a result of the study treatment and not other factors.

Informed consent process
A process in which a person is given important facts about a clinical trial before deciding whether to participate. It includes information about the possible benefits, risks and limitations of the medications or other testing that patients will receive. Informed consent also includes telling participants about new information that may affect their decision to continue in the study.

Institutional Review Board (IRB)
A committee, usually made up of doctors, nurses, researchers and patient advocates at a hospital or cancer center, that reviews study protocols (see below) to help ensure the studies are conducted fairly and that risks to participants are minimized. The IRB must approve a study before it can be conducted.

National Cancer Institute (NCI)
Part of the National Institutes of Health, the NCI is the federal government's main agency for cancer research and training.

Protocol
An action plan for a clinical trial that includes the purpose of the study, how many people will be in the study, who is eligible to participate, what study medications or other treatment will be given, safety measures, what tests will be performed and how often, and what information will be gathered about each participant during the study period.