

Editorial

Placebo use in Pfizer trial simply wrong

Issue: The use of a placebo in the clinical trial of SU11248

It's probably helpful to describe the decision-making process that led to our position regarding the use of a placebo. We are a diverse group of GIST patients, families and friends in about 30 countries. Some of us interact with one another solely through the Internet. Some of us belong to groups that meet face-to-face in such places as Chicago, the Netherlands, New York, Germany, Los Angeles, Switzerland, Detroit and Texas.

We created a 12-person clinical trials advisory group that has met for many hours of deliberation in person, by teleconference and through the Internet. This group of 10 GIST patients and two caregivers includes an accountant, lawyer, medical doctor, executive, scientist, newspaper editor, MIS director, Marine Corps colonel, public

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Battling gastrointestinal stromal tumor



LIFE RAFT GROUP

January 2004

In memory of Tuomas Hemminki

Vol. 5, No. 1

U.S., Germany launch 'Gleevec combo' trial

Phase II trial of PKC412 plus 600 mg Gleevec charts new territory

Combination treatments are very common in cancer therapy. It has long been speculated that adding a second drug to Gleevec might improve the results over Gleevec alone. The first of these "Gleevec combination" trials to reach phase II testing is Gleevec plus PKC412.

Phase II trials are starting in Berlin, Germany, and in Portland, Ore-



REICHARDT



BLANKE

gon, U.S.A. Lead researchers are Dr. Peter Reichardt at the Robert-Rössle-Klinik, Charité Campus Buch in Berlin, and Dr. Charles Blanke at Oregon Health & Sciences

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Novartis told of Gleevec tablet side effects

Life Raft, pharmaceutical giant share information in ongoing war on GIST

Novartis agrees further investigation is warranted into the side effects being experienced by patients as they switch from Gleevec capsules to the new tablets.

That was one of several points made during a Jan. 15 meeting between representatives of the Life Raft Group and Novartis.

Jerry Call, the Life Raft Group's science coordinator, and Norman Scherzer, executive director, visited Novartis Oncology headquarters in Florham Park, N.J. The meeting marked the continuation of a dialogue that has been going on for more than a

year and a half.

Novartis was represented in person and by teleconference from throughout the United States and Novartis corporate headquarters in Basel, Switzerland by Barbara Kennedy, executive director, Oncology Scientific Operations; Dr. Nicholas Shand, Oncology Clinical Research in Basel; Anna Tsyrova,

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PKC412

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University in Portland. Jerry Call, Life Raft Group science coordinator, recently had an e-mail exchange with both researchers.

PKC412 and Gleevec are both manufactured by Novartis. Reichardt, who conducted the Phase I trial for this combination, describes PKC412:

“PKC412 is an inhibitor of protein kinase C (PKC). The PKC family consists of at least 12 isoforms of serine/threonine kinases that play a major role in signal transduction. It has been shown that PKC inhibitors can also reduce tumor angiogenesis. PKC412 is a very active and more selective derivative of the PKC-inhibitor staurosporine.”

Reichardt describes the reason for using PKC412 in combination with Gleevec.

“The main reason for combination is that even in progressive GIST, many of the tumor cells are still under control of Gleevec. If Gleevec is stopped, a much faster progression can result. This has been seen in patients.”

Blanke was one of three U.S. doctors who conducted the phase II trials of Gleevec for GIST.

This phase II trial resulted in approval of Gleevec for GIST patients in the United States and other countries.

Blanke says PKC412 is “an inhibitor of protein kinase C, an enzyme important in cellular growth and division. It is less specific than Gleevec, inhibiting PKC, and kinases of KIT, VEGF, PDGF. Many of those kinases are important in GIST behavior.”

For patients to be eligible for the phase II Gleevec+PKC412 trial, Blanke said, they must have experienced disease progress while on 600 mg. Gleevec for at least two months.



At the Jan. 15 meeting with Novartis, the Life Raft Group's Jerry Call, center, is pictured with Dr. Bin Peng, Ph.D., senior clinical lead pharmacokineticist, and Barbara Kennedy, executive director, Oncology Scientific Operations

NOVARTIS

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Ph.D., senior clinical research scientist and global PKC412 clinical trial leader in Basel; Geoffrey Cook, director, U.S. Public Relations; Dr. Laurie Letvak, global brand medical director for Glivec; Dr. Pamela Cohen, executive director, PKC412; Alan Yap, Ph.D., senior clinical research scientist, PKC412; Dr. Bin Peng, Ph.D., senior clinical lead pharmacokineticist, and Ron Linnartz, clinical development, RAD.

The meeting began with a presentation by the Life Raft Group about side effects (nausea, vomiting) GIST patients have encountered when switching from Gleevec capsules to tablets. Novartis noted that they had received a few reports from both GIST and CML patients but have not yet determined any reason for this. Dissolution rates for the capsules and the tablets were checked and found to be the same. Novartis also clarified that there was only one production source for Gleevec, at their facility in Ireland.

Other than suggesting that patients

having problems with the 400 mg. tablets switch to four 100 mg. tablets, there were no other clear answers. Novartis volunteered that further investigation was needed. It was suggested that patients could try dissolving the tablets in either apple juice or water - approximately 50 mL (1/4 cup) for each 100 mg. tablet or 200 mL (3/4 cup) for a 400 mg. tablet.

The Life Raft Group then offered the following key points on clinical trials:

— GIST patients join clinical trials to survive: Although that may seem obvious, once stated, it is the principal prism through which patients view the clinical trial landscape.

— Patient enrollment in clinical trials can be facilitated by timely information, geographic accessibility, and financial accessibility.

— Trial coordination needs to be strengthened, particularly with regard to standardizing data designs between trials.

Strategic Suggestion:

The LRG suggested getting patients into Gleevec “combination” trials at an earlier stage. The rationale is that for

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Little progress with Pfizer over placebo issue

Efforts to lower risks of SU11248 trial fall short

The Life Raft Group held its fourth discussion with representatives of Pfizer on Jan. 14 at Pfizer's New York City headquarters.

Norman Scherzer and Jerry Call, Life Raft executive director and science coordinator, respectively, asked for a list of potential sites for the clinical trial of SU11248 for GIST patients who've had tumor growth while on Gleevec. The goal is to enable GIST patients and their physicians to plan whether they will be able to access trial sites.

Pfizer again refused to divulge potential trial sites, citing corporate policy not to make such information available until the individual trial site had internal institutional review board approval and had signed a contract with Pfizer.

We were told that this trial will have 357 patients enrolled — 119 on a placebo — but that there was no limit on the number of patients that could be enrolled at any one site.

The Life Raft also asked about expanded access for those patients unable to access the drug in a timely manner through a clinical trial. Pfizer

responded that they were working on this, but did not have anything to share at this point in time.

The third issue was a follow-up discussion about an alternative to a placebo group that could be filed with the FDA as a trial amendment. On Nov. 11, we were told by Dr. Blakely, the forward development team leader for SU11248, that Pfizer would work with the Life Raft Group to see if such an idea was feasible. At this meeting we learned that Pfizer considered our suggested substitute — the review of historical GIST progression data — to be a “waste of time,” to quote the senior official present, Dr. William Slichenmyer, vice president for Oncology Drug Development.

Further, Pfizer felt that data from the early trial did not demonstrate that the benefits of SU11248 outweigh the risk. They cited that although most patients seemed to demonstrate a period of stability, only 10 percent showed shrinkage equal to or greater than 30 percent, that 35 percent had drug toxicity, and that approximately half the patients who initially showed some benefit (shrinkage or stability) subsequently showed progression.

Pfizer believes documenting measurable clinical benefit requires a placebo group to control bias. Also, Pfizer be-

lieves that risk to the placebo group is justified by their view that there was no alternative “standard of care” for GIST patients.

The Life Raft Group argued that the risk for being in a placebo group has not been defined, and that disease progression data could be obtained without a placebo group.

We related information from a number of GIST specialists from around the world. These specialists agreed that stopping Gleevec may well accelerate progression and, most importantly, that the amount of progression required before the placebo patient was given the actual drug may be too high and was unlikely to reverse the progression that occurred (there seems to be general agreement with this latter point) and may place the patient's life at risk.

Using the SU11248 clinical trial rules, Jerry Call noted it's possible a placebo patient could experience 82 percent increase in tumor size before being allowed access to the drug.

One area on which both the Life Raft and Pfizer seemed to agree was that if enough patients in the placebo group realize they're on a placebo and drop out of the trial, this could jeopardize the design of their double blind placebo group.

Texas-area meeting planned Feb. 7 in Dallas

The first Texas-area meeting of the Life Raft Group has been scheduled Saturday, Feb. 7 at Gilda's Club North Texas in Dallas.

The meeting will be from 10 a.m. to 1 p.m. A light lunch will be served.

This first meeting will offer Life Rafter's a chance to meet one another and talk about how they can support each other. There also will be an opportunity for small group discussions.

Life Raft Group members in Texas,

Oklahoma, New Mexico, Arkansas and Louisiana are especially encouraged to attend, though anyone, regardless of membership in Gilda's Club or the Life Raft Group is welcome — especially GIST caregivers.

Gilda's Club North Texas is a new \$4.5 million facility that offers a variety of support services to cancer patients and their families, free of charge. It's located at One Works of Grace Plaza, 2710 Oak Lawn. Special thanks to Denise Edminston, director

of Gilda's Club, for her help in arranging this meeting.

For more information or to RSVP, contact Kerry Hammett via e-mail at yaloo@gvtc.com or by phone, (830) 237-1016.

Do you need transportation? Just ask, someone may be going your way! Need a ride from the airport? Need the name of great hotel or motel? Just ask!

There will be an audio tape of the meeting available free for those who are unable to attend.

Editorial: Pfizer placebo is wrong

From Page 1

health professional and others. This group unanimously opposes the use of a placebo.

We listened attentively to the explanations offered for a placebo. At our third meeting with Pfizer, we naively accepted in good faith their offer to work with us to construct a database that could be considered as an alternative to a placebo group. At our last meeting we discovered Pfizer considered this to be a “waste of time,” to quote the senior Pfizer representative present.

We have yet to see a scintilla of evidence supporting the need for a placebo, nor any assumption of the burden of proof incumbent upon anyone pursuing such a research protocol. We have yet to see any analysis of the risk a placebo poses to patients, nor any risk benefit determination for using such a placebo.

We have heard many carefully scripted statements to the effect that Pfizer must “document measurable clinical benefit,” and that “historical data lacks scientific validity and does not exist,” (although a Pfizer vice president acknowledged he had not looked at the historical data, deeming it “a waste of his time”).

We’ve been told the United States Food and Drug Administration sup-

ports the use of a placebo. Let’s see what the FDA actually has to say: Historical data “is particularly useful **when the disease being treated has high and predictable death or illness rates** ... Is it ethical to give patients a placebo when effective treatment is available? ... the generally accepted practice ... is that fully informed patients can consent to take part in a (placebo) ... trial, even when effective therapy exists, **so long as they are not denied therapy that could alter survival or prevent irreversible injury ...**” (from “Testing Drugs in People,” <http://www.fda.gov/cder/about/whatwedo/testtube-3a.pdf>, bold type added for emphasis.)

We submit that GIST has a high and predictable death rate. We submit that GIST patients on the placebo will experience irreversible progression of their tumors, causing injury, and possibly death.

It is also striking that the only consent form given study patients in this trial that we have seen fails to include a single statement addressing dangers to the placebo patient.

Since it seems abundantly clear Pfizer has no intention of reconsidering the use of a placebo in this trial, what is the point of going on record

as opposing it?

The Life Raft Group is a tiny patient organization that is less than two years old. Pfizer is the largest pharmaceutical company in the world, with huge financial and political resources. There is a disconnect between our patient group and those behind this study and, frankly, we are somewhat afraid and intimidated by the consequences of opposing them. It could discourage Pfizer from holding clinical trials needed to develop drugs for GIST and other cancers, and it will likely eliminate the Life Raft Group from any possible grant support from Pfizer for our educational and outreach activities. To quote our Pfizer colleagues, the train has “certainly left the station.”

The voice of our group is nonetheless focused and clear.

It is wrong to give a sugar pill to a cancer patient for whom there is no documented treatment other than the trial drug.

It is wrong to give a sugar pill to a cancer patient whose almost inevitable disease progression may not be reversed by a too-late switch to the actual drug.

It is wrong to trade irreversible, life-threatening damage to cancer patients for an undocumented rationale focused upon bringing a drug to market faster.

We oppose the use of a placebo in this trial simply because it is wrong.

NOVARTIS II

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at least one class of drugs, the results of adding the second drug may be enhanced if tumors still retain sensitivity to Gleevec.

Jerry Call submitted that Gleevec-resistance paradigms provide a possible window of opportunity. That the lower the resistance to Gleevec, the more likely the addition of a second

drug — to which Gleevec is sensitive — will yield synergistic activity.

Some Life Raft Group recommendations: Get patients into Gleevec combination trials early, allow “stable” patients to enter, and to not set the bar for progression too high. Further, to not require progression at higher doses (or to not require progression at all), to drop the use of RECIST criteria and to incorporate resistance testing (when this becomes feasible).

Novartis made a few points for the

current standard of requiring progression before allowing patients to enter combination trials, citing that it is easier to gauge the results of the second drug in a tumor that you know is resistant (growing) versus in a stable patient. Further discussions are planned.

Novartis then briefed us on two combination clinical trials for GIST.

PKC412 plus Gleevec:

Phase II trials are underway in Berlin,

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Tuomas Hemminki, 41, fought GIST three years



Tuomas Hemminki shows off his nice catch last July while at the family cottage at Lake Inari.

Kari Tuomas Hemminki of Vaasa, Finland, died peacefully Jan. 2, 2004, in Vaasa Central Hospital. He was 41. His battle with GIST lasted three years.

Tuomas was born Nov. 14, 1962, in Tervola, the son of Irma and Juho Hemminki.

He graduated from Tervola senior high school and Vaasa University, where he studied economics, and received a master's degree in administration and financial management.

He worked for VTT (Technical Research Centre of Finland), Norway, Navigation Administration and Vaasa Polytechnic school.

Tuomas enjoyed the outdoors, fishing and hunting. His most precious place was his parents' summer cottage at Lake Inari in

northern Finland. He didn't miss any summer there. He liked reading, and aikido was his hobby. He was an active member of Junior Chamber in Vaasa.

Tuomas married Leena Kettunen on June 20, 1986. He was a proud and loving father of Heidi, 16, and Ilkka, 11.

The Life Raft Group was a great support and comfort for Tuomas. He was not alone with his illness. The fact that he was able to communicate with fellow sufferers and get all possible information on GIST was very important for him.

Tuomas is survived by his wife, Leena; daughter, Heidi; son, Ilkka; parents, Irma and Juho; brothers, Antti, Juha and Matti and their wives; a sister, Tiina-Liisa and her husband, and many nephews and nieces.

In Memoriam

There have been 30 deaths in the Life Raft Group to date:

Debbie Nance, 38, Oct. 2, 2000, wife to Eddie, mother of Chris.

Jim Ackerman, 49, Jan. 16, 2001, husband to Betsy, father of Jill and Tom.

Jim Perham, 63, May 2001, husband to Karen, father of Craig, Kathy, Jennifer.

Amy Barney, 25, June 10, 2001, wife to Reed, mother of Joshua.

Jeff Prichard, 52, July 11, 2001, husband to Joyce, father of Gregory and Scott.

Ron Martinez, 60, July 25, 2001, husband to Jo Ann, father of Ron, Wendy, Natalie.

Ehud Nehemya, Aug. 7, 2001, father to Einat Zelinger, father-in-law of Ophir Zelinger, Hadar Nir.

Bruce Gunn, 43, Nov. 8, 2001, husband to Roisin, father of Seamus, Liam, Brendan and Aislinn.

Robert Carr, Dec. 30, 2001, father of Robert, Steven, Scott and Melissa.

Jonathan Montague, 23, Jan. 19, 2002, son of Ray and Sheila Montague, brother to Jamie, Adam, Meghan.

Robert Lecca, 49, Jan. 28, 2002, husband to Diane.

Jacob Winfield Waller III, 67, March 31, 2002, husband to Jerry, father to Rita, Richard.

Mary Golnik, 50, April 18, 2002, wife to Gary, mother to Timothy.

Ana Maria Baldor-Bunn, 30, April 19, 2002, wife to Stan, mother to William.

Stewart "George" Wolf, 51, April 19, 2002, husband to Maggy, father to Thomas.

Michael Cornwell, April 19, 2002, husband to Cathy.

Jerry Pat Rylant, 61, May 5, 2002, husband to Pamela, father of four, grandfather to 10.

Jill B. Meyer, 53, June 9, 2002, mother of Aliza.

Todd Hendrickson, 44, June 29, 2002, husband to Janet, father to Max, Tyler and T.J.

Chet Duszak, 79, Oct. 5, 2002, husband to Kay, father to Lori.

Nora Shaulis, 42, Nov. 4, 2002, wife to David, mother to Griffin.

Howard Delapenha, 41, Dec. 14, 2002, husband to Sandra, father to Joshua and Hannah.

Kathy Colwell, 45, Jan. 5, 2003, wife to Tom, mother of Katherine, Mary and Tom.

Cynthia G. Whitson, 64, Jan. 19, 2003, wife to Jerry, mother to Steve, Jill, Randy and Donna.

Abdul Hai, 76, Feb. 26, 2003.

William Lawson, 56, July 3, 2003, husband to Gwen, father of Cory, Jennifer and Rhonda.

Laura Blanchette, 47, Aug. 4, 2003; wife of Mitch, mother of Sarah and Curtis.

Maryann Klein, 56, Sept. 4, 2003; wife of Gary, mother of Michelle, grandmother to Brandon.

Pat Ford, 48, Sept. 6, 2003; wife to Brad, mother to David and Laura.

Frank Weigand, 66, Oct. 24, 2003; husband to Ruth, father to Susan and Drew.

Tuomas Hemminki, 41, Jan. 2, 2004; husband to Leena, father to Heidi and Ilkka

SU11248 clinical trials are beginning

Pfizer is launching a phase II trial of SU11248 for GIST patients who've experienced disease progression while on Gleevec. Pfizer will not release the locations of clinical trial sites unless the local institutional review board has given its approval and a contract has been signed between the institution and Pfizer.

However, because GIST patients who are resistant to Gleevec, and their physicians, need to plan their survival strategies in a timely way, the Life Raft Group has compiled an informal list of trial sites for SU11248. The information is compiled both from patients and clinical trial physicians. It is possible therefore that there may be errors and likely that we may have missed a few sites. Patients are encouraged to contact the individual site and verify the information for themselves.

The Life Raft Group will maintain this information at its Web site at www.liferaftgroup.org. We welcome corrections or additions to this list:

UNITED STATES CALIFORNIA

LOS ANGELES, Calif.
UCLA, Jonsson Comprehensive Cancer Center
Dr. Carolyn Britten

SANTA MONICA, Calif.
Cancer Institute Medical Group
Dr. Lee Rosen

PALO ALTO, Calif.
Stanford University, Clinical Cancer Center
Charro Jambalos, R.N., M.S., clinical research nurse; (650) 725-8233

DUARTE, Calif.
City of Hope
Dr. Warren Chow
(626) 256-4673, ext. 62307

ILLINOIS

CHICAGO, Ill
Evanston Northwestern Healthcare
University of Chicago

Dr. Hedy Kindler

MASSACHUSETTS

BOSTON, Mass.
Dana-Farber Cancer Institute
Dr. George Demetri

MICHIGAN

ANN ARBOR, Mich.
University of Michigan Cancer Center
Dr. Laurence Baker

NEW YORK

NEW YORK, N.Y.
Memorial Sloan-Kettering Cancer Center
Dr. Robert Maki

Columbia Presbyterian Medical Center
Dr. Mary-Louise Keohan

NORTH CAROLINA

DURHAM, N.C.
Duke University Medical Center
Dr. Herbert Hurwitz

OHIO

CLEVELAND, Ohio
Cleveland Clinic
Taussig Cancer Center
Ruth Fritskey, RN, MSN, clinical nurse specialist
1-800-862-7798
Expected start date April 2004

PENNSYLVANIA

PHILADELPHIA, Penn
Fox Chase Cancer Center
Dr. Margaret Von Mehren

TEXAS

HOUSTON, Texas
M.D. Anderson Cancer Center
Dr. Robert Benjamin

WASHINGTON

SEATTLE, Wash.
Fred Hutchinson/University of Washington Cancer Consortium.
Dr. Scott Schuetze, principal investigator
Contact Sarah Wallace, research coordinator, (206) 667-1906.

WASHINGTON, D.C.

Washington Hospital Cancer Center
Dr. Dennis Priebat

BELGIUM

LEUVEN
University Hospital Leuven

Dr. Allan vanOosterom
Expected start date February 2004

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CALGARY, Alberta
Tom Baker Cancer Centre
University of Calgary
Dr. Vivien Bramwell-Wesley

TORONTO, Ontario
Mount Sinai Hospital
Dr. Martin Blackstein

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Charité Campus Buch
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Department of Hematology, Oncology and Tumorimmunology
Dr. Peter Reichardt
Expected start date February/March 2004

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MILANO
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Dr. Paolo Casali

NETHERLANDS

ROTTERDAM
Academisch Ziekenhuis Rotterdam
Dan. Den Hoed Kliniek
Prof. Jaap Verweij
Expected start date April 2004

GRONINGEN
Academisch Ziekenhuis Groningen
Dr. Winette vd Graaf
Expected start date April 2004

SWITZERLAND

LAUSANNE, Switzerland
Centre Hospitalier Universitaire Vaudois (CHUV)
Prof. Leyvraz
Expected start date March 2004

UNITED KINGDOM

LEEDS, West Yorkshire
St. James' Hospital,
Dept. of Medical Oncology, Chancellor Wing
Dr. M. Leahy

Future sites:

Oregon Health & Sciences University
Tampa, Florida (site unknown)
Singapore, (site unknown)
Australia (site unknown)

Chicago's Evanston aims for excellence

This is the second article on "centers of excellence" for GIST treatment in the Chicago area, profiling Evanston Northwestern Healthcare. It comes from Dr. Bruce Brockstein via the Chicago chapter of the Life Raft Group. The October 2003 newsletter profiled the University of Chicago.

Evanston Northwestern Healthcare comprises Evanston, Glenbrook and Highland Park hospitals, the ENH medical group and the ENH Research Institute. The oncology program is a single unified program, offering excellent and extremely well integrated care amongst all disciplines.

Our seven surgical oncologists, five radiation oncologists, 12 medical oncologists, and cooperating disciplines (ranging from pathology to radiology, psychosocial oncology to clinical research coordination) meet daily for tumor-specific multidisciplinary case conferences, at which nearly all cases are discussed.

Our GIST cases are generally discussed at both our weekly gastrointestinal malignancy conference, and our semiweekly sarcoma conference. Cases are referred in from around the region, in general either to surgical or medical oncology. Over the past four years, we have seen 30 cases, with an increase over the past two years. Generally, the patients are followed either

by sarcoma oncologist Dr. Bruce Brockstein, or GI oncologist Dr. Gershon Locker.

Since October of 2000, ENH has been an active participant in nearly all GIST clinical trials. With the identification and publication to the medical community of the efficacy of Gleevec in GIST, we searched through our pathology and tumor registries in an attempt to assess GIST patients' eligibility for trials, and to reclassify intestinal leiomyosarcomas as GIST tumors. Based on this effort, we enrolled two patients in the initial phase II trial of Gleevec for GIST. One of these two patients benefited greatly from the drug, though ultimately succumbed to the disease. The other patient was, unfortunately, one of the few patients refractory to the drug effects. Both, however, provided tissue for early important studies about c-kit mutation and resistance.

Additionally, through our reclassification efforts and subsequent referrals, we accrued seven patients to the phase III trial, and early on, with the enrollment of five patients at the beginning of the trial, we were one of the leading institutions nationally in enrollment. Subsequently, we have had patients enrolled on both of the ACOSOG adjuvant gleevec trials, and have had one



BROCKSTEIN

patient participate in the SU11248 trial. Additionally, we have treated approximately 10 patients outside of the clinical trials.

The efficacy of the signal transduction inhibitors in GIST is one of the few major breakthroughs in oncology in the past few decades. ENH, as an oncology tertiary care center, is both prepared and excited to care for patients with GIST, and participate in the search for a cure for this disease.

ENH is a member of ECOG (the Eastern Cooperative Oncology Group), and an NCI-funded CCOP (Community Clinical Oncology Program). ENH is one of the primary teaching hospitals of Northwestern University, along with Northwestern Memorial Hospital and Children's Hospital. We are a part of the Lurie Comprehensive Cancer Center of Northwestern University Medical School.

Patients interested in coming to Evanston for a consult can call (847) 570-2110 and speak to Elaine Behrs, new patient coordinator, or collaborative sarcoma nurse Ellen Mosak, (847) 570-2000, ext. 3685.

Dr. Bruce Brockstein is with the Medical Oncology Department of Medicine, Evanston Northwestern Healthcare. He is also an assistant professor at the Feinberg School of Medicine at Northwestern University.

NOVARTIS III

From Page 4

Germany and at Oregon Health & Sciences University in Portland. Patients must be on 600 mg. (or more) Gleevec for at least two months prior to entry into the trial — although there may be exceptions for patients who demonstrate significant progression prior to two months.

RAD001 (RAD) plus Gleevec:

Phase I trials are ongoing but a change is being made in the dosing schedule from 20 mg. every eight days to a daily dose escalation (from 2.5 mg. to 10 mg.). A strong interaction was noted between Gleevec and RAD. Gleevec inhibits CYP3A4, which

causes metabolism of RAD to be inhibited. This typically caused a three- to five-fold increase in RAD concentrations. Thus 2.5 mg. per day would be equivalent to at least 7.5 mg.

There will be four clinical trial locations: Lyon, France; Berlin, Germany; Leuven, Belgium, and Boston, U.S.A.

THE LIFE RAFT GROUP

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Who are we and what do we do?

The Life Raft Group is an international, Internet-based, non-profit organization providing support through education and research to patients with a rare cancer called GIST (gastrointestinal stromal tumor). The Association of Cancer Online Resources provides the group with several listservs that permit members to communicate via secure e-mail. Many members are being successfully treated with an oral cancer drug Gleevec (Glivec outside the U.S.A.). This molecularly targeted therapy inhibits the growth of cancer cells in a majority of patients. It represents a new category of drugs known as signal transduction inhibitors and has been described by the scientific community as the medical model for the treatment of cancer. Several new drugs are now in clinical trials.

How to join

GIST patients and their caregivers may apply for membership free of charge at the Life Raft Group's Web site, www.liferaftgroup.org or by contacting our office directly.

Privacy

Privacy is of paramount concern, and we try to err on the side of privacy. We do not send information that might be considered private to anyone outside the group, including medical professionals. However, this newsletter serves as an outreach and is widely distributed. Hence, all articles are edited to maintain the anonymity of members unless they have granted publication of more information.

How to help

Donations to The Life Raft Group, incorporated in New Jersey, U.S.A.,

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