

Glivec wins OK for GIST in Europe

Approval for second use comes just 7 months after CML treatment OK

BASEL, Switzerland — Novartis announced May 31 that the European Commission (EC) has issued approval, in record time, for the breakthrough drug Glivec (imatinib, or Gleevec in the U.S.) for the treatment of patients with Kit-positive inoperable and/or metastatic malignant gastrointestinal stromal tumours (GISTs).

The approval follows a positive recommendation by the EU's Committee for Proprietary Medicine in February. It is the second EC approval for Glivec in seven months: the first, last November, was as an oral therapy for the treatment of adults with chronic myeloid leukemia (CML) in chronic phase after failure of interferon-alpha therapy, or in accelerated phase or blast crisis.

"Patients with GISTs have traditionally had very limited treatment options, so we are especially pleased that authorities are recognizing the value of Glivec in treating this life-threatening cancer," said Dr. Daniel Vasella,

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Novartis wins international Galien Prize for Glivec

After obtaining the national Galien Prize for 2002 in six countries, Glivec has now received a supreme award on an international level

For the first time, Novartis has been awarded the prestigious international Galien Prize for therapeutic innovation. It was awarded to the innovative drug, Glivec (imatinib, or Gleevec in

the U.S.), a molecularly-targeted treatment for chronic myeloid leukemia and gastrointestinal stromal tumor.

A signal transduction inhibitor, Glivec is one of the first cancer drugs to be developed using rational drug design, based on an understanding of how some cancer cells work.

In the past two years, Novartis research was honored nine times with

Battling GIST with Gleevec (STI571)



LIFE RAFT GROUP

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In memory of Jerry Rylant, Jill Meyer

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UK cost-cutting agency stalls the use of Glivec

Patients may be denied life-saving cancer drug

By Nigel Hawkes, Health Editor
The Times of London, May 28
(Reprinted with permission)

A cancer drug that is bringing patients back from the verge of death will be denied to National Health Service patients.

The remarkable results reported with Glivec make it the most promising new cancer drug for years. Yet the National Institute for Clinical Excellence (NICE) is poised to reject it for many NHS patients, to the disbelief of the drug industry and those whose lives it has transformed.

One of them is Dr. David Cook, director of studies at the Chemistry De-

partment at Sheffield University, who has gastrointestinal stromal tumor, an uncommon cancer.

Since he started taking Glivec last September, his tumors have disappeared. By coincidence, he has a neighbor who is also being treated with the drug, for a different cancer, chronic myeloid leukemia. His life, too, has been hugely improved by the drug.

Glivec was developed to treat chronic myeloid leukemia, and data presented at the American Society for Clinical Oncology meeting in Orlando, Florida, showed that it was three times more effective than existing treatments as a first-line therapy for that cancer.

But a preliminary assessment published on the NICE Web site in May

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Galien Prizes for therapeutic innovation.

The international Galien Prize is awarded every two years. The award recognizes innovative therapeutic drugs that have made a substantial improvement in therapy.

Drugs that have already won a prize on a national level compete for the in-

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NICE

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suggested that NHS patients should not get Glivec unless their disease had already gone into the accelerated phase.

The drug costs between £19,000 and £28,500 (\$28,450-\$42,700) per patient per year. But the results on first chronic myeloid leukemia and now gastrointestinal stromal tumors suggest it is a life-saver.

A group of specialists led by John Goldman of the Hammersmith Hospital in London have written to The Lancet, protesting the position the institute has taken.

Professor Goldman, who has treated many chronic myeloid leukemia patients with the drug in trials, said that the decision was “mad.”

“If they had existed in 1939, they would have delayed the introduction of penicillin by at least five years,” he said. “To ignore the unanimous body of medical opinion is grotesque.”

Dr. Cook wrote to Alan Milburn, the Health Secretary, protesting at the institute’s assessment, now the subject of an appeal. “I would be astonished if the drug were not available as needed on the NHS,” he wrote.

Glivec does not have a license in Britain for treating gastrointestinal stromal tumors, but some patients, like Dr. Cook, have been able to get it as part of a trial. The disease is marked by a proliferation of tumors in the gut which are resistant to all normal cancer drugs. Before Glivec, surgery was the only option but even if all visible tumors were removed they generally recurred and typical survival was less than two years.

At last month’s U.S. oncology society meeting, data on 147 patients with gastrointestinal stromal tumors was reported. After a year on the drug, 67 percent saw their tumors shrink 50 percent or more, and another 20 percent had tumors that had shrunk to a lesser degree. Dr. Margaret von Me-

Cordelia and the CEO



Photo by Paul Zalewski, RavenwoodPhoto.com

Dr. Dan Vasella, chairman and CEO of Novartis, maker of Gleevec, appears to be delighted to meet Life Rafter Cordelia Salas of Mexico at the May 3 Life Raft Group meeting in Boston — and who wouldn’t be. The mother of five (yes, you can be the mother of five, have cancer, and still look like a movie star) was among several international patients to attend the first-ever gathering of the Life Raft.

Quote:

“If they [NICE] had existed in 1939, they would have delayed the introduction of penicillin by at least five years.”

— Professor John Goldman,
Hammersmith Hospital, London

hren, one of the team that presented the results, said: “Before Glivec, more than half the patients would have been dead.” Doctors at the meeting were also told that the brain tumors of 14 out of 31 patients that had come back

after previous treatment had been stabilized on Glivec.

Glivec works by disabling an enzyme that functions only in the tumor and not in healthy tissue. So unlike most chemotherapy it does not have such severe side effects. It has been approved in more than 65 countries for chronic myeloid leukemia treatment. At least 10,000 patients were given the drug in trials.

NICE has made clear that its assessment is not its final word. Andrew Dillon, the chief executive, said that the document in its Web site “contains preliminary views that may change after consultation.” The reason for its skepticism, he said, was a lack of evidence that Glivec was clinically effective and cost-effective in chronic myeloid leukemia as a first-line therapy.

Small tumours make for large doses

A Life Rafter learns the importance of a wife's concern, early diagnosis

By Dave Cook

My story is, like so many others perhaps, one of being saved by my wife.

In my late 50s, Irene decided that I should make an effort to be fit (the usual reply "fit for what?" didn't work this time); so I decided to walk up four floors to my office instead of taking the lift (aka elevator). After about a week of this I was completely exhausted so (again!) Irene sent me to the family doctor to find out what was wrong.

I was anaemic and, if you are anaemic, you are bleeding somewhere and so I was referred to the Royal Hallamshire Hospital here in Sheffield — a prestigious medical establishment but a 1960's architectural disaster. One of the things that is not allowed in the Hallamshire is internal bleeding; it is completely forbidden and they are going to stamp it out. So what followed is familiar to all members of the Life Raft; from beginning-oscropy to endoscopy with no result. So, then it was X-rays in earnest, looking at the small intestine where an ace radiographer noticed a narrowing. I was whooshed off to the ultra-sound scanner and jumped the queue ahead of some startled expectant mothers waiting for their routine scans! Sure enough, there was a golf ball-sized suspicious object which was the cause of the problem.

Less than a week later (July 1999) I was back in the surgical ward of the Hallamshire having the object removed, which turned out to be a GIST. Life Raft members will all be familiar with abdominal surgery but it was all news to me.



AT HOME IN THE U.K.: Dave Cook is shown with his wife, Irene, left, and their daughter, Laura. Dave was diagnosed with GIST nearly three years ago, and has been on Glivec since last September.

Another thing which is not allowed in the Hallamshire is post-operative pain so I was on a self-controlled morphine drip which worked very well but generated some spectacular hallucinations (do people really take this stuff for pleasure?).

On day two when one is feeling that perhaps death was the better option, the physios came in: "Hello, David (first name terms only in the Hallamshire), time for breathing exercises and a walk."

EXERCISES!?! WALK!?! Help!

The surgeon was confident that he had got the lot and there was no evidence of malignancy in the joined region of intestine. I was put under the care of oncology in the nearby Weston Park Cancer Hospital; monthly "how are you" appointments and three-monthly CT scans. During this time Irene found out about Glivec through a newspaper article so this looked like insurance against a recurrence.

Almost exactly two years later (July 2001) one of these CT scans showed another GIST of a similar size to the

first one. So off to the Hallamshire again and Chris Stoddard went in (through the same scar) and, this time, fished out the GIST seen on the scan PLUS five much smaller ones each about a centimetre. I was growing GISTs like other people grow courgettes! Surgery was completely successful with me a lot more relaxed about the whole procedure -- the experienced patient.

Same drill at the cancer hospital; a CT scan in September revealed two more small suspicious objects.

This was Sept. 11th (yes, *the* Sept. 11th) and I was watching the Twin Towers burn live on TV while waiting for the appointment. So, "let's get onto the Gleevec trial" says everybody; come back on Thursday (the 13th) and we'll set you up." Now I knew that the trial closed for new members on Sept. 14, so I was pretty uptight on the appointment on the 13th. My blood pressure was so high that the oncologist was very alarmed.

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Glivec OK'd

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chairman and CEO of Novartis.

“Glivec has already had a significant impact on the lives of people with CML and GISTs, and we are continuing to study it in other cancers to determine if it has the potential to help patients, either alone or in combination with other therapies.”

GISTs are the most common malignant form of sarcoma that arise in the gastrointestinal tract. Worldwide, there are some 12,000 new cases each year. It primarily strikes those age 30 to 60.

The EC approval of Glivec for GIST was supported by data from an multinational study of 147 patients with Kit-positive inoperable and/or metastatic malignant GISTs. Patients randomly received either 400 mg or 600 mg of Glivec daily. Forty percent of patients responded or had stable disease at the time of the data cut-off for the submission.

Data which emerged since the submission for approval were presented in May at the 38th annual meeting of the American Society of Clinical Oncology (ASCO) in Orlando, Florida, U.S. In this study, more than 60 percent of GIST patients responded to Glivec,

and an additional 20 percent attained some degree of tumor shrinkage or stabilization of their disease.

The U.S. Food and Drug Administration (FDA) was the first to approve Glivec for GIST, giving it “orphan drug” status in February.

An orphan drug is one designed to treat a disease that affects fewer than 200,000 U.S. citizens; designating Gleevec an orphan drug will allow Novartis to claim a 50 percent tax credit for clinical testing expenses for drug.

Switzerland approved Glivec for GIST in April. To date, Novartis has received marketing clearance for Glivec for CML worldwide.

Cook: His next-door neighbour takes Glivec for CML

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I got onto the trial and was given the highest dose (by the random choice method) 800 mg. a day.

The first CT scan two months later showed some shrinkage of one object and no growth of the other. Next scan showed the shrinkage continuing with one object almost undetectable; the next two scans showed no trace of tumours. In fact, these last two scans had the report “no evidence of abnormality.”

This is, of course, fantastic news for me and my family, particularly since, as the tumours were so small, I had never been actually ill and the whole business had a rather unreal air; friends, family and colleagues kept saying “you look so well.”

I am now feeling good, still taking the orange tablets at the high dose. Side effects? Initially, I felt rather tired and often had to have a sleep in the afternoon (I am still working). I have a small problem with slight oedema in the eyes and eyelids but nothing serious. In retrospect, I think that much of the tiredness was delayed surgical shock after talking to some people who have had abdominal surgery for other reasons but this is just conjecture.

What my story shows is the advantage of:

- Early diagnosis
- Wifely concern in any health problem.

Quote:

“One curious coincidence: My next-door neighbour, John, has been on the Gleevec trial for CML for the last year. It has absolutely transformed his life ... his main side effects seems to be chronic gardening and holiday making — cruises in the Caribbean, tours of Italy ...”

One curious coincidence: my next-door neighbour, John, has been on the Glivec trial for CML for the last year.

Glivec has now been licensed for CML in the U.K. and John is now on routine Glivec. It has absolutely transformed his life: no more midnight ambulances for blood transfusions, etc., etc. John has some oedema around the eyes but his main side effects seem to be chronic gardening and holiday making — cruises in the Caribbean, tours of Italy ...

U.S. Life Rafterers may be interested to know that all this treatment was done by the much-maligned U.K. National Health Service (NHS), which is funded by taxation and free for all U.K. residents. All the scans, investigations, surgery, outpatient backup, oncology services, blood tests, etc., have not cost me a penny (except for a lifetime of income tax!). Of course, the Glivec on the trial is paid for by Novartis but when the trial is over, the NHS will fund the drug for as long as I need it.

There is much current criticism of the NHS within the U.K. for the long waits for certain types of “non-urgent” treatment; but for my acute condition I could not have wished for better treatment.

Jerry Pat Rylant, father of four, grandfather to 10

Jerry Pat Rylant, 61, died May 5, 2002 in Mesquite, Texas.

He was born Jan. 15, 1941 in Edgewood, Texas.

He was a member of International Brotherhood of Electrical Workers, Local 20 for 30 years. He was a loving husband, father, grandfather and will be deeply missed.

He is survived by his wife, Pamela Rylant; two sons, Ray Lambert and Timothy Lambert; two daughters, Teresa Franks and Kimberly Holloman; 10 grandchildren, Ryan Hester, Amy Franks, Gatlin Lambert, Eric McKensey, Tanner Lambert, Carlie Lambert, Cody Lambert, Austin Holloman, Vance Holloman and Cale Holloman; a brother, Don Rylant; a sister, Doris Ross, and several nieces and nephews. He was preceded in death by a son, Greg Rylant.

Services were held May 8 at First Presbyterian Church in Dallas, Texas. Memorials may be made to the American Cancer Society, 8900 Carpenter Freeway, Dallas, Texas 75247.

In Memoriam

There have been 17 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, 2001, 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, when she married Stan. Since her death, people have been leaving cards and flowers at her boutique for babies, Mi Bebe. One note said, "Dearest Ana, I have only known you for a short time, but I feel like I have known you forever. I will miss the beautiful person that I finally met in December. You had the heart of a lion and the soul of an angel."

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.

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.

Galien: The prize will be awarded Oct. 17 in Madrid

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international prize. This year, Glivec was awarded with the national Galien Prize in Belgium, Canada, France, Luxembourg, Netherlands and Portugal.

The deliberation meeting for the international Galien Prize was held in Madrid, under the aegis of the press group MediMedia Spain. The international jury brought together 13 renowned scientists who represented the national juries. The prize will be awarded Oct. 17 in Madrid.

According to Dr. Daniel Vasella, chairman and CEO of Novartis, "This

prestigious award is a testament to the success of our research and development efforts, and the tremendous medical and scientific potential of Glivec. We are pleased that eminent professors from all the partner countries of the Galien Prize have recognized once again this drug which has opened new horizons in oncology."

This award follows on the heels of additional encouraging research results presented at the 2002 meeting of the American Society of Clinical Oncology in Orlando, Florida, U.S. and the approval of the European Commission

for the treatment of patients with inoperable and/or metastatic malignant gastrointestinal stromal tumors (GIST).

Since 1970, Novartis has received 12 national Prix Galien in six countries for innovative therapies. Further, research into Glivec has garnered additional prizes including the Bruce F. Cain Award from the American Association for Cancer Research (AACR) in April of this year, and the Warren Alpert Foundation Scientific Prize, awarded by Harvard Medical School in May.



Life Rafter Tuomas of Finland probably didn't think he'd be modeling a T-shirt like this at the Life Raft gathering in Boston, but he was more than willing to help out with this presentation to Life Rafter Marina Symcox. "Hugs" Andrea is at left, while Marina is off camera to the right.

Photo by Richard Palmer

Life Raft goes *haute couture* as Finn models Okie's T-shirt

It was a conspiracy started by Penny Duke, who found ready co-conspirators in "Hugs" Andrea and Cynthia Whitson.

Penny wanted to do something to/for Marina Symcox of Oklahoma, U.S.A. "We had never met Marina but we knew she had a great sense of humor," says Cynthia.

Andrea came up with the idea of a T-shirt imprinted with the image of a well-endowed, trim-tummied woman in a bikini. The T-shirt was inspired by none other than Marina herself.

For a person who spent eight months in hospice before Gleevec, Marina has a cast iron stomach. She takes her

Gleevec on an empty stomach and will often lie down after — a direct reversal of the way Gleevec is supposed to be taken.

Marina has had so little problem taking Gleevec she even tried to create a problem by taking pills, then doing a headstand on her bed.

The way Marina told it in her e-mail to the group, her flabby Gleevec-belly shifted, cutting off her air and causing her to faint.

At any rate, to honor this amazing tale, Cynthia found a suitable T-shirt at the beach and brought it to the Boston gathering of the Life Raft Group. By Saturday's lunch, "Tuomas (of

Finland) had become a great friend and shown that he was full of fun and a good sport," Cynthia says. He agreed to model the T-shirt as Hugs was presenting it to Marina.

The above photo shows Tuomas modeling the shirt as Hugs, at left, recounts Marina's episode. The recipient is off camera to the right.

"Tuomas was a wonderful model — he missed his calling — and we all had a good laugh," says Cynthia. "I wasn't able to get a clear picture of Tuomas but I'm hoping that Richard did and we can enjoy seeing it in the newsletter."

And Cynthia, here it is.

Money matters: Life Raft treasury tops \$7,000

During the second day of the May 3-4 Boston gathering, Life Raft Group Treasurer John Poss reported that the Life Raft Group has spent \$363 as of April 30, while donations reached \$7,743, leaving a balance of \$7,380.

Since the group's account was opened Jan. 28, 2001, donations have totaled \$2,920, while \$4,800 has come in the form of memorial gifts in memory of Jonathan Montague, Jacob Waller and Mary Golnik.

In a post-meeting report to the group, Gary Golnik said the Boston meeting paid for itself. The bill at the Radisson hotel, mostly for food, was \$5,663. That was covered by the fees (\$4,952) and donations (\$711) paid by members, so the net impact on the Life Raft treasury was zero.

On a side note, Gilles Frydman, president of the Association of Cancer Online Resources, said during Saturday's meeting that ACOR's expenses

reached \$55,000 last year, but relatively few of the some 60,000 people who use its lists make donations.

People give money to their own particular cancer, he said, but forget something like ACOR. Perhaps, he said, "if the system shut down, people would realize how valuable it is."

To donate to ACOR, go to ww.acor.org and follow the links. Or snail mail your donation to 173 Duane St., Suite 3A, New York NY 10013-3334

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Who are we and what do we do? We started in July of 2000 as GIST patients and caregivers in the Gleevec (STI571) clinical trials, and have since extended membership to all GIST patients. We share our experiences and support each other. We focus on symptoms, side effects and drug-related issues. Members correspond privately to each other and to the group as appropriate. If you are interested in joining, contact membership coordinator Penny Duke at liferaft@cfl.rr.com, or download an application at www.liferaftgroup.org.

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. To assist in that goal, the secure e-mail listserv does not include medical professionals. How-

ever, this newsletter does serve as an outreach and is widely distributed. Hence, all items in the newsletter are edited to maintain the anonymity of members, unless members have granted publication of more detailed information.

Method: Our primary means of communication is through a confidential, secure listserv operated by the Association of Cancer Online Resources, ACOR (www.acor.org).

Disclaimer: We are patients and caregivers, not doctors. Any information shared among the group should be used with caution, and is not a substitute for careful discussion with your doctor.

Newsletter note: Read at your own risk! Every effort to achieve accuracy is made, but we are human and errors occur. Please advise the newsletter editor of any errors you may find.

Jill Meyer, a 'child of the '60s,' survived by a daughter

Jill Bernice Meyer, 53, passed into another life at 3:30 a.m. June 9, 2002, in St. Mary's Hospital in Wisconsin.

Jill was a "child of the '60s" in every way. She loved life, people, and all of the earth's creatures in equal measure. When she was well off, she was generous to a fault, and when misfortune struck, she was always generous in spirit. For more than 10 years she volunteered with A Safe Place, working for the rights of battered women and their children and gave herself tirelessly to that cause.

After the birth of her daughter, Jill advocated for the rights of the deaf, testifying before public committees of inquiry and occasionally providing her skills as a sign language interpreter for Chicago area television programs.

She subsequently returned to Lake Forest College in Illinois to obtain her degree in psychology, graduating with honors in 1986.

After her graduation, she worked for a short time for the American Red Cross and later became a drug and alcohol counselor for the Northern Illinois Center for Substance and Alcohol Abuse, where she continued to transform the lives of all of those she encountered.

She is survived by her only daughter Aliza, her former husband Allen Meyer, and her soulmate, John McCoy. She is also survived by a younger sister, Jaclyn (Gier) Viskovattoff (her liason to the Life Raft Group), her mother, Bernice Gier, a brother, Jeffrey Gier and by four cats that she rescued and adopted.

Graveside services were held June 12th at the historic Green Ridge Cemetery in Kenosha, Wisconsin, where family and friends laid her to rest under an old tree. Her daughter wrote and signed the eulogy and a favorite verse from Shakespeare's play,

"The Tempest," Prospero's last speech, was read:

And now my charms are all o'er-thrown

And what strength I have 's mine own

*Which is most faint: now 't is true
I must here be released by you*

*But release me from my bands
With the help of your good hands
Gentle breath of yours my sails
Must fill, or else my project fails,*

*Which was to please. Now I want
Spirits to enforce, art to enchant
And my ending is despair,
Unless I be relieved by prayer*

*Which pierces so that it assaults
Mercy itself and frees all faults
As you from your crimes would
pardon'd be
Let your indulgence set me free.*