

U.S. OK's Gleevec for GIST

Novartis developed drug shows 'unprecedented efficacy' in rare tumors

The U.S. Food and Drug Administration approved the Novartis drug Gleevec® (imatinib mesylate) for the treatment of patients with c-Kit positive gastrointestinal stromal tumors (GISTs) deemed inoperable and/or having spread.

"Not only have we seen shrinkage in size and quantity of tumors, but patients are feeling better than they have in many months," said Dr. Charles Blanke, director of gastrointestinal oncology at the Oregon Health & Science University Cancer Institute. Blanke is one of the principal investigators of the initial clinical trials using Gleevec on GIST.

The Feb. 1 approval of Gleevec for GIST came 10 months after the drug was approved in the U.S. for treating chronic myeloid leukemia.

According to Dr. Daniel Vasella, chairman and CEO of Novartis, "Gleevec has already made a major difference in the lives of patients with chronic myeloid leukemia and we're extremely gratified to now make this drug available to patients with GIST."

Vasella continued, "Novartis – along with our colleagues in academia and government – continues to study Gleevec and investigate other cancers in which it may help patients – either alone or in combination with other therapies."

GIST affects some 5,000 to 10,000 Americans a year, striking any of the organs along the length of the gastro-

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Battling GIST with Gleevec (STI571)



LIFE RAFT GROUP

February 2002 — In memory of Robert Carr, Robert Lecca — Vol. 3, No. 2

Life Raft gathering is set May 3-4 in Boston

Life Rafter will get to see good friends they've never met before

GIST research, management of Gleevec side effects, an awards presentation and a candle-lighting ceremony - the first general meeting of the Life Raft Group promises to be a memorable milestone.

Yet for GIST patients who've come together in cyberspace to share victories and setbacks, pooled information and supported each other in times of sorrow, the Life Raft Group gathering will offer the chance to see good friends you've never met before.

The meeting will take place Friday and Saturday, May 3-4, at the Radisson Cambridge Hotel in Boston, Mass., U.S.A. Gary Golnik, Life Raft Group webmaster and science team member, is coordinating the two-day gathering.

"We have decided to have the entire meeting at our host hotel, the Radisson Cambridge," said Gary. "The hotel is directly across the Charles River from the Dana-Farber Cancer Institute. This will simplify the logistics and lower the costs."

The gathering will begin Friday evening around 7 starting with a dinner

reception in the hotel's Harvard Suite featuring an Italian buffet. Cost will be about \$15 per person.

Saturday's meeting will begin with registration and a welcome by Life Raft Group Coordinator Norman Scherzer, who has set four objectives of the meeting:

- To gather the Life Raft in one place; to celebrate the miracle of life that has been granted us, to honor those who have helped us, to mourn those who have left us, and to stand together in wonder at this journey we have embarked upon together.
- To decide the future mission, objectives and structure of the Life Raft Group.
- To review the latest information about the GIST-Gleevec experience.
- To develop a proactive strategy for confronting drug resistance.

"Guest invitations are going out; Dr. [George] Demetri has already accepted." Norman said,

Hours of Saturday's meeting will likely be 8 a.m. to 4 p.m. in the Harvard Suite. There will be a continental breakfast, a sandwich buffet lunch, with snacks and beverages morning and afternoon.

Planned is an awards presentation

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Gathering

From the front page

Saturday afternoon, and a candle lighting ceremony at sundown, possibly on the bank of the Charles River.

“Think about contributing something to the meeting,” Norman says: “Some time (staff our registration desk; take notes); some wine; a desert or a snack; photographs for our newsletter; decorations for our meeting room; design a keepsake; or do something creative we have not thought of.”

He adds: “If you have not yet already made up your mind to attend, consider this a defining moment in your journey and a unique opportunity to meet so many others with whom you share an experience that only other GIST patients, and their loved ones, can possibly understand.

“We know now that the battle is far from over, and that we need to find other means to cope with the specter of resistance.”

THE DETAILS

Gary has arranged a rate of \$95 per night (1-2 people, \$15 for each additional person up to 4 per room) plus tax of approximately \$12, which is very competitive for Boston. The Radisson is a very nice hotel, and the setting is lovely.

To make reservations: phone the Radisson Cambridge Hotel reservations desk at 1-800-333-3333. Identify yourself as part of the Life Raft Group and ask for the special rate.

“We have 30 rooms in our block, and I have about 20 people who have so far indicated that they need a room,” said Gary.

The rate is available Thursday through Sunday, May 2-5, for those who wish to arrive early or stay the next day. The rate will be available until April 2. After that it MAY be available but the hotel can't guarantee either room availability or rates.

“You are responsible for your own reservations — making them and

Life Rafterers 'do lunch' at Scherzer home



Life Rafter Coordinator Norman Scherzer and his wife, Anita, hosted a small luncheon gathering Jan. 10 at their home in Little Falls, New Jersey. The men, from left: Robert Stutman, Norman, Walter Josephy and Michael Josephy. The ladies, from left, with Tania Stutman, Anita, and Michael's wife Elsie Hernandez.

paying for them,” says Gary.

The hotel is located at 777 Memorial Dr., Cambridge, MA 02193. If people wish to call hotel guests, the number is 1-617-715-1772, or fax 1-617-864-0242.

For those flying in, Gary says a cab to the hotel is your best bet, as the nearest “T” (Massachusetts Bay Transportation Authority) stop is a bit of a walk with luggage.

Life Rafterers who plan to partake of Friday's buffet dinner and Saturday's meals should contact Gary as soon as possible so he can get a preliminary head count.

Life Rafterers should plan on an additional \$75 to \$90 per person to cover the cost of Friday night dinner, Saturday breakfast and lunch, and the registration fee to cover such costs as name tags, awards and guests.

“These costs are tentative, because

they depend on how many people will want to partake of the delectables,” said Gary. “More participation will lower the cost.”

So give your feedback (Are the costs reasonable? Will you partake of both days' food?) to Gary via e-mail at ggolnik@earthlink.net, or phone 1-978-887-3161.

Adds Norman: “We are only a few handfuls of people on a growing, and slightly leaky life raft, and frankly we need every one who can do so to help us navigate and row to the nearest shore.

“We also know that the ongoing struggle to survive GIST knows no institutional nor national boundary and we encourage our members from throughout the world to attend.”

Watch Life Raft Group postings and future newsletters for details.

Demetri: Gleevec a 'global collaboration'

Sarcoma guru thanks some of the many who played a role in Gleevec

I wanted to write a brief note to say thanks to everyone for the remarkable efforts made on behalf of the work in developing Gleevec (STI571, imatinib) as an effective therapy for patients with the sarcoma known as GIST.

It truly has been a global collaborative effort, and you have all been part of this. It is a remarkable story. The FDA approval of this agent for this indication fully validates what we have all seen since we began this work in late 1999 (GIST-directed laboratory studies) and 2000 (clinical).

There are so many people to thank for this. First on the list, of course, is Dr. Brian Druker; without his insights and noble cooperative spirit, this work might never have transpired at such a rapid pace. Additionally, I must note the important contributions of our laboratory colleagues Drs. Jonathan Fletcher and David Tuveson (Harvard) and Mike Heinrich (Oregon). From Novartis, the dedication of the STI571 GIST development team has been instrumental to our work, including the outstanding skills and sensitivity of Drs. Sasa Dimitrijevic (Switzerland) and Sandra Silberman (U.S.A.), who have always done so much to help our patients.

The clinical collaborative team on the academic side has been a truly wonderful working group as well, made up of the hard work from the global medical leadership team of Drs. Charles Blanke (Oregon), Heikki Joensuu (Finland) and Margaret von Mehren (Philadelphia). To this, one must add the important surgical input and leadership of Drs. Burt Eisenberg (Philadelphia), Peter Roberts (Finland), and Sam Singer (formerly of Boston, now in New York City).



Quote:

"This is just the first step. We all realize much work is yet to be done, in GIST as well as in other sarcomas (not to mention so many other types of cancer). But the lessons we have learned from the activity of Gleevec in GIST will help us to understand better the foe that is cancer, and to move the field to the next higher level."

We must also note the important insights made by our colleagues in imaging, such as Drs. Annick van den Abbeele (Boston, PET scanning) and Milos Janicek (Boston, CT scanning

interpretations). The willingness of our European academic colleagues to share experiences, anecdotes, and information has also greatly accelerated the learning curve of our efforts, and for that we must thank Drs. Allan van Oosterom (Belgium), Jaap Verweij (Netherlands), and Ian Judson (U.K.). The team at the U.S. National Cancer Institute, including Drs. Tony Murgu and Scott Saxman, has helped to move the GIST work along to the next phase, as did the tremendous support of the sarcoma and clinical trials community with leaders such as Karen Antman (New York), Bob Benjamin (Texas), Larry Baker (Michigan), Ron Blum (New York), and Ernie Borden (Cleveland).

There are many, many more names as well who played key roles in this work, and I hope those individuals will forgive me for not mentioning them. The nurses, data managers, administrators, family members, everyone did so much to make this work a success. This is true for all the Internet-savvy patients and support systems, enabled by such people as the Life Raft Group and its leaders, including Gilles Frydman and — of course — Norman Scherzer.

It has been a rare privilege to have been a part of this all. I thank you all again for the chance to do this work along with you all.

This is just the first step. We all realize much work is yet to be done, in GIST as well as in other sarcomas (not to mention so many other types of cancers). But the lessons we have learned from the activity of Gleevec in GIST will help us to understand better the foe that is cancer, and to move the field to the next higher level.

Thank you all again. I wish you all well.

Warmly,

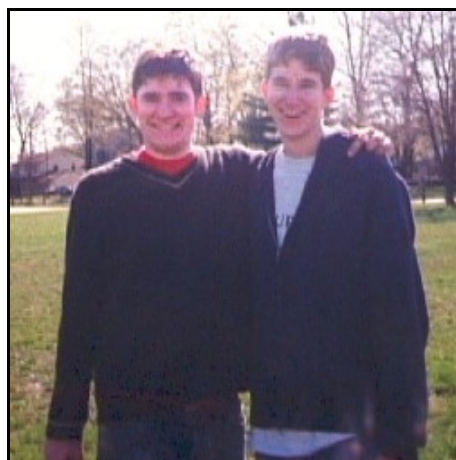
George Demetri, M.D.
Dana-Farber Cancer Institute
Boston, Mass., U.S.A.

Donation of \$2,600 made to Life Raft

Friends, family offer memorial to Jon Montague, 23

Editor's note: Most Life Raft members don't know the name Jon Montague. This young man's battle with GIST was too short for him to join the Life Raft Group. But friends and family learned of the group, and this month donated more than \$2,600 to the Life Raft Group in Jon's name.

His brother, Jamie, offered the following about his brother.



Jon Montague, left, with his brother Adam.

He was first and foremost an artist," Jamie writes. "As both an aspiring film maker and musician, he dedicated his life to his projects. He strove to become as influential as possible in both arenas, working not only on stage and in front of the camera but behind the scenes as well." To promote the projects he and his friends had done, Jon founded and operated his own record company, Arbor Records.

"Less than a month before his death, he co-wrote and starred in Arbor's annual Christmas show," Jamie says. "His best and most widely distributed work is his movie, "Long Live Rock," which is a mock documentary that he wrote, produced, directed and edited as his final project towards attaining his film degree from Philadelphia's University of the Arts, which he did in 2000.

"He was also known to many for his undying love for the perennial losers, the Philadelphia Phillies. Each spring

he was convinced that the team everyone else knew would be lucky not to finish last would make the World Series, and he was not shy about telling everyone he knew about it. He attended as many as 40 games per year, and during that time, I'm sure annoyed many with his LOUD and constant optimism. But friends and strangers alike recognized his passion was genuine, and rarely did anyone complain about his unusual behavior at the stadium."

Jon's tumor was found in early November 2001 and was diagnosed as GIST some weeks later. He had surgery to remove the tumor, which weighed some 10 pounds, right before Thanksgiving and recovered quickly enough to celebrate the holiday at home.

"He was told that the cancer was gone," Jamie says, "although he could

expect a recurrence in about 18 months, at which time he would be prescribed Gleevec."

Jon was in and out of the hospital between Christmas and New Year's with minor complications such as fluid buildup. It was confirmed during that time that the cancer was back and that a few more tumors appeared.

"He began taking Gleevec in hopes of killing the tumors," Jamie said. "He was told that he should see results in approximately 30 days."

Due to discomfort from fluid buildup and other complications, Jon was readmitted to the University of Pennsylvania hospital Jan. 6. His condition grew worse; he died the morning of Jan. 19, two weeks after starting Gleevec. Jon Montague was 23.

"Even during his last full day of life, Jon was adamant about taking his full dose of Gleevec, convinced it would save him," Jamie says. "I am sure that it would have had he not been cheated out of the time he deserved."

A native of Westmont, New Jersey, U.S.A., Jon is survived by his parents, Ray and Sheila Montague; his brothers, Jamie and Adam, and his sister, Meghan. He is also survived by both of his grandmothers and his girlfriend of three years, Nadya, along with many family and friends.

"I hope that the other members of your community are able to read about Jon and realize that he is still pulling for them," Jamie says.

Who's new in the Life Raft Group

Rob Danielson, on the clinical trial at the University of California, Los Angeles, U.S.A.

Gail Orso of Corning, New York, U.S.A., by prescription from doctors at Dana-Farber Cancer Institute, Boston, Mass., U.S.A.

Setting the record straight

Rob Ryninger's wife is named Vonda. An editing error in last month's newsletter had Rob married to a different woman.

Approval

From the front page

intestinal tract or its lining. These tumors are prone to spread to other organs and, once spread, they often are unresponsive to chemotherapy or irradiation, and invariably fatal.

Clinical trials for GIST using Gleevec began in July 2000 at OHSU, Dana-Farber Cancer Institute and Fox Chase Cancer Center.

In clinical trials, more than half of patients with GIST have gone into remission on Gleevec, and more than 90 percent of patients reported major signs of clinical improvement in their conditions.

"This is exciting news, not just because these results validate the theory of targeted therapy, but because these patients have no other options," said Blanke.

For patients with metastatic or unresectable disease, GISTs had represented an incurable malignancy with a median survival of approximately 10 to 12 months. Until now, surgery has been the only effective treatment.

The limited prevalence of GIST has resulted in the FDA designating Gleevec as an orphan drug for this indication.

GLEEVEC and GISTs

The FDA approval for GIST is supported by data from a multinational study conducted in 147 patients with unresectable or metastatic GIST. Patients were randomized to receive either 400 mg or 600 mg of Gleevec daily for up to 24 months.

Gleevec, a signal transduction inhibitor, is one of the first cancer drugs to be developed based on an understanding of how some cancer cells work. Gleevec targets the activity of certain enzymes called tyrosine kinases that play an important role within certain cancer cells. The activity of one of these tyrosine kinases, known as c-kit, is thought to drive the growth and division of most GISTs.

Novartis also has submitted a supplemental filing application for Glivec (as

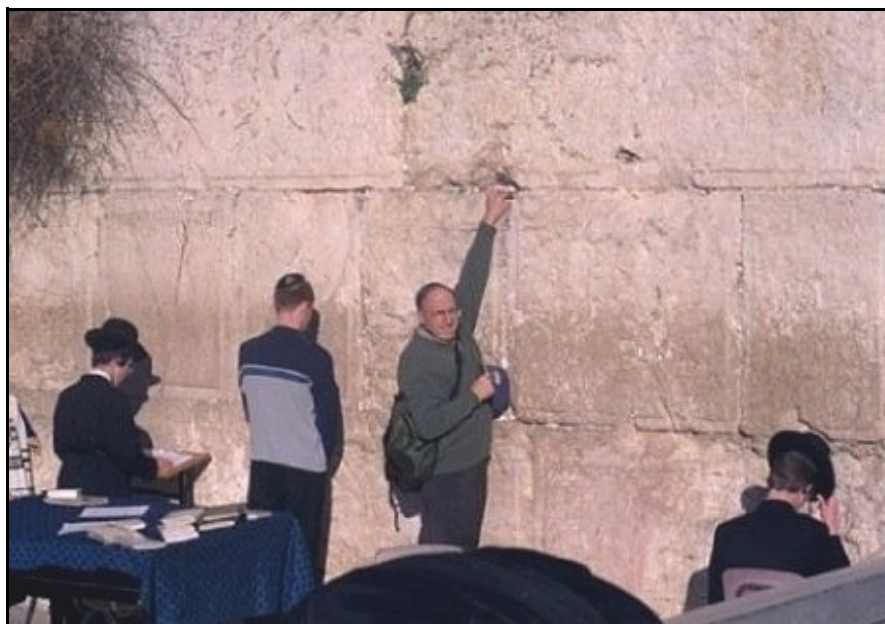


Photo by Bracha Kaplan

Life Rafter Bernie Kaplan of New York City is pictured at the Western Wall in Jerusalem, Israel, placing a written prayer for Life Rafterers and GIST patients into a crack in the wall.

Life Rafterers remembered during visit to Holy Land

Bernie Kaplan, a Life Raft member since Jan. 31, 2001, traveled to Israel last December where he remembered GIST patients at the Western Wall in Jerusalem, Judaism's holiest site.

Bernie placed a small piece of paper into a crack in the Wall; written on the paper was a prayer for the well-being of all Life Raft members and GIST patients.

The Western Wall is the oldest remaining portion of the Jewish temple that stood on this spot 2,000 years ago. As such, it is revered by Jews as a holy site and a special

place for prayer. It has become custom over time to write short requests for good health and well-being and place them in the wall's crevices.

The wall is more than 100 feet tall and originally stretched over 1,580 feet to encompass the western side of the Temple, which was destroyed by Roman soldiers in 70 CE. On the Temple Mount today in the Old City of Jerusalem stands the Al-Aksa Mosque, one of the holiest sites in Islam, and just a few hundred yards away is the Church of the Sepulcher, one of Christianity's most significant sites.

Gleevec is called outside the U.S.) to health authorities in the European Union and in Switzerland for the GIST.

SIDE EFFECTS

Although the majority of patients had adverse events reported at least once during the trial, most events were mild to moderate in severity. In the GIST

trial, drug was discontinued for adverse events in six patients (8 percent) in both dose levels studied. In this trial, seven patients (5 percent) were reported to have gastrointestinal bleeds and/or intratumoural bleeds. Gastrointestinal tumor sites may have been the source of GI bleeds.

Life Rafter get to meet in Jordan Station, Ontario, Canada



The Murphys — that's Al on the left, daughter Andrea and Sheila, got to meet Michael Josephy, Elsie Hernandez and their son Daniel when the Josephys stopped at the Murphys in Jordan Station (near Niagara Falls) on their way to Boston. After lunch they walked over to the Jordan Historical Museum; the building is an old school house that takes in classes through an authentic afternoon at the turn of the century. The covered wagon, says Sheila, is also an original from Mennonite homesteaders that arrived in this area in the 1800's.

Robert Lecca battled GIST for 9 months

Robert Lecca of Corona, Calif., U.S.A., died Jan. 28, 2002 after a nine-month battle with GIST. Being the special and unique man he was he died on his 49th birthday. He was surrounded by family and his death was very peaceful. His faith in God was everything to him, putting his family No. 1 and his work No. 2.

He is survived by his wife, Diane, sons Bobby, 23, and Mitchell, 11 and also his daughter, Kelly, 21.

Robert also was fortunate to have two beautiful grandchildren, Bobby, 3 and Gabriella, 1. He is sorely missed!

Robert Carr leaves four children

Robert Carr, a Life Raft member through his sister, Mary Lou, died Dec. 30, 2001. He was a truck driver his entire adult life, most recently with CCX Trucking.

Mary Lou spoke at his funeral, recalling what it was like to grow up with "the chief who ruled the schoolyard and I was made to feel important because I was the chief's sister."

Her brother left his mark in this world in the people whose lives he touched. "You have raised four beautiful children, Bobby, Steven, Melissa, and Scott and have a wonderful granddaughter, Kayla," said Mary Lou.

"You have instilled in them the values that you lived by. You were a man of your word, honest and forthright. You treated all with love. You were there to help anyone in need."

"You were a man who rarely asked for help and liked to do things on his own. You never wanted to put any burden on anyone," said Mary Lou. "Yet, for the past few months, you al-

lowed us to minister to you. You were never a burden but instead a great gift for which we are very grateful."

When faced with cancer, Bob began to prioritize his life. Church and the example he set for his children took on greater importance. "You gave them a strong foundation. It became quite evident in the last few days of your life as I watched them pray at your bedside, clutching the crosses you gave them for Christmas. You witnessed to them in your prayer and trust in the Lord and his promise for eternal life."

"Your greatest desire was the assurance that you would be with the Lord for all eternity and on Christmas night God gave you a glimpse of heaven."

"You were a loving son, a wonderful father, a super gramps, a great brother and an awesome uncle."

Besides his three sons, daughter and granddaughter, he is also survived by his parents, Sherman and Gertrude Carr; a brother, Thomas, and two other sisters, Jane and Elizabeth.

THE LIFE RAFT GROUP

<http://www.liferaftgroup.org>

Webmaster: Gary Golnik, ggolnik@earthlink.net

Coordinator: Norman J. Scherzer
normanjs@bellatlantic.net

List Management: Mia Byrne
mebmcb@peoplepc.com

Medical Librarian: Janet Hendrickson
delmar@mn.rr.com

Membership: Penny Duke
liferaft@cfl.rr.com

Newsletter Editor: Richard Palmer
linda@interpac.net

Treasurer: John Poss
jcpoos@swbell.net

Advocacy: Joe Stevens
jbsteven@harthosp.org

Medical/Scientific Team:

Jerry Call, team leader, Jerry_Call@msn.com; Barry Jordan, M.D., bgjordan@attglobal.net; Marina Symcox, keithsymcox@barnard.utulsa.edu; Gary Golnik, ggolnik@earthlink.net; Marvin Frazier, Marvin.Frazier@science.doe.gov; Janet Hendrickson, delmar@mn.rr.com; Penny Duke, liferaft@cfl.rr.com; Antonio Ramos, ramosdelamedina@hotmail.com; Angela Riepel, angelee@stanford.edu; Robert Donohoe, rjd@LANL.gov

Who are we and what do we do? We started as GIST patients and caregivers (spouses and others) in the Gleevec (STI571) clinical trials, and have since extended membership to all GIST patients on Gleevec/Glivec. We come together to share our experiences and support each other. We focus on symptoms, side effects and other drug-related issues. Members correspond privately to each other and to the group as appropriate.

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 listserve does not include professional members of the various study sites. However, this newsletter does serve as an out-

reach 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.

In Memoriam

There have been 10 deaths of Life Raft members 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 2, 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.

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

Life Rafterers share good news



Richard Palmer and Cindy Dunigan got to meet in Buellton, California, on Friday, Feb. 8. Over a late lunch at Anderson's Pea Soup Restaurant, they got to compare notes and GIST/Gleevec experiences. Richard and Linda Palmer live in Hilo, Hawaii but have a home and family in San Luis Obispo County, California, and got to meet Cindy while driving up the California coast. Both had just gotten good news regarding their latest CT scans, and had reason to celebrate.