

Somers, Karen M

From: sambug [REDACTED]
Sent: Tuesday, December 03, 2002 9:27 PM
To: SomersK@cder.fda.gov
Subject: Bexxar

Dr. Somers:

I would like for my name to be counted for the approval of Bexxar.

I received treatment in a clinical trial in Charlotte, NC in February of 1999. I have been in complete remission since. I had transformed low-grade, B-cell non-Hodgkin's lymphoma.

If this e-mail will not serve that purpose, please let me know and I will write a letter.

Thank you!

Faye B. Poole

I was diagnosed with low grade BCell Non-Hodgkins Lymphoma in June 1988. I presented with enlarged inguinal and axillary lymph nodes. Treatment commenced with a six month course of chemotherapy prescribed by my oncologist, Dr. Morton Coleman. The enlarged nodes disappeared after the first month of treatment. However, within three months after completing the full course the enlarged lymph nodes reappeared.

In 1993 I underwent a bone marrow transplant at North Shore University Hospital in Long Island under the supervision of Dr. Michael Schuster. Within one year C-T scans indicated evidence of active disease.

In late 1993 my daughter's father-in-law sent me an article published in the Baltimore Sun regarding a study of nine patients with BCell Non-Hodgkins Lymphoma who had all been successfully treated with monoclonal antibodies at the University of Michigan Hospital in Ann Arbor by Dr. Mark Kaminski. After reading Dr. Kaminski's study in a medical journal I felt that the therapy might be appropriate for me. I mentioned this to Dr. Coleman who contacted Dr. Kaminski regarding my suitability as a possible candidate. I was urged to visit Dr. Kaminski and did so in November. At that time I was informed that I would be an ideal candidate for the monoclonal antibody treatment, which I later learned, was known as Bexar.

I was scheduled for treatment in March 1994. However, in the interim I developed back pain with weight-bearing. A C-T scan revealed enlarged lymph nodes on my sacrum. Dr. Coleman placed me on a short course of steroids which fortunately eliminated the pain.

On March 14, 1994 I received the Bexar. I experienced absolutely no side effects during or at any time since receiving the intravenous treatment. All C-T scans since then have revealed no active disease and I have been symptom-free and in remission for eight years and eight months.

I am extremely grateful to Dr. Kaminski for his pioneering work with Bexar and to Dr. Coleman for his role in facilitating my access to Dr. Kaminski. Since my experience Dr. Coleman has sent many patients to Dr. Kaminski. I am especially gratified that my success opened the doors to others.

S. Nancy Sanders
[REDACTED]

My Experiences with Bexxar
by Susan Day
December 8, 2002

I can't be there in person to tell about my experience with Bexxar, so I hope it will be read. It seems important to me to tell what led up to why I really needed to have this treatment.

In March of 1988, when I was 35, the diagnosis was low grade, nodular, mixed cell, non-Hodgkin's lymphoma, most likely stage I or II. I was asymptomatic and had an inguinal lymph node biopsy that showed malignancy. Later my CT scan showed retroperitoneal involvement. I underwent an aggressive chemotherapy called ProMace Cytobom with the hope of being cured. The thought of sitting around waiting for progression didn't agree with my way of thinking. I was symptom free for three years until 1991 when a low grade, small cell type appeared. Apparently, the chemotherapy removed the large cell component of the initial diagnosis, but the small cell component resisted the treatment. I had no problem watching and waiting this time. In 1996 things started changing. I had involved lymph nodes in several places, stage III by the standard staging criteria. I didn't know at that time if there was any bone marrow involvement, but it was still low grade. The thought of more chemotherapy or a stem cell rescue was extremely unpleasant to me. I even spent my savings to go to Germany to explore more natural, non-toxic treatment. During the summer of '96 I gave in to Fludarabine for three months, but it didn't stimulate any change. My oncologist is the best, but I had to keep searching for alternatives to having additional chemotherapy, especially since Fludarabine didn't work. My friend and previous biology professor referred me to his colleague in biology and research medicine. She led me to a clinical oncologist who was interested in research. He reviewed my history, and he recommended that I check into the clinical trials led by Dr. Julie Vose at the UNMC. I contacted several university hospitals in the U.S. that had clinical trials using non-radiolabeled and radiolabeled monoclonal antibodies. It seemed to make sense that the radiolabeled antibody was the treatment I should try for, and the UNMC was the place to go, if possible.

Getting the process going was more difficult than having the treatment. The final protocol approval had been delayed a few times. That was disappointing. I was concerned that by the time the new protocol was approved that my health status would no longer fit the strict criteria. My husband and I arrived in Omaha on Sunday hoping that there wouldn't be another delay with the approval on Monday. What a relief! On Monday it was a "GO".

The day to begin treatment finally came. The whole process went as smoothly as it could have gone. I was isolated for only about three days. There weren't any allergic reactions or any side effects out of the ordinary. I think I just felt a little queasy from the thyroid SSKI. There were no illnesses, no hair loss, and only two infusions —the tracer dose and the treatment dose. Over the next six months my blood counts went down causing fatigue, but never dangerously low. Hey, I had a complete response to treatment, so no

big deal. They gradually increased again over the next year. My WBC count was the only one that remained lower than normal, but in the past year or so, they have been in the normal range again.

How could I be so fortunate to have Anti-B1 radioimmunotherapy available to me at this place in time (in Omaha, not so far from Denver, and right when I needed an alternative to chemotherapy). How could I be so lucky to have the CD20 antibodies in my cells? How could I be so lucky to have just the right amount of bone marrow involvement to fit the criteria for the Bexxar treatment? How could I be so fortunate to perfectly fit the study criteria and to escape the ravages of chemotherapy? How could I be so lucky to have a supportive oncologist at home, such a competent and compassionate nurse coordinator, and a talented research physician and support team all at the same time? It wasn't easy, but I was also lucky enough to be able to convince my HMO that their share of this treatment would save them money in the long run. I was given the gift of all gifts. It felt like such an honor to be given a new chance to extend my life in a more gentle way, and to help other lymphoma patients coming along behind me.

Here I am, six fantastic years later, still in remission. I just had a routine PET scan two weeks ago. It showed "no evidence of lymphoma". How lucky is that? Luck is certainly part of it, **but without good medical research, I would be, you know, SOL.**

Thank you for listening to my story.

To: Karen M. Templeton-Somers, PhD
Supervisory Health Science Administrator

From: Pat Hare
[REDACTED]
Auburn, Me., 48611
[REDACTED]

Subject: Bexxar

Karen, This was sent back in March to Patty Delaney, Public Health Specialist. And I thought we could use this for the Dec. 17th Open Public Hearing of the Oncologic Drugs Advisory Committee. It takes approx. 2 mins to read as is. What are your thoughts on this? Should paragraph 3 be omitted? Please critique and get back with me

In 1985 I was diagnosed with NHL & underwent 8 years of Chemo, Radiation, & Massive doses of vitamin A. With these treatments I experienced several hair losses, blood transfusions, weakness, mental & physical exhaustion, hospitalization, all of this and more over 8 years with no end in sight, and no other options until I was offered the chance of a life time to try **BEXXAR**.

In April of 1993 I underwent an experimental treatment at Ann Arbor under Dr. Mark S Kaminski, Professor of Internal Medicine. I was the 20th patient to undergo this procedure. This treatment lasted 4 weeks and I absolutely had **no side effects**. Although I had to stay in the hospital, I was only confined in my room a half a day per week (And I realize that this has now changed). I could come and go as I wished, the Dr. had to leave me notes, because I was too busy shopping, walking, and visiting. It's been 9 years and this treatment gave me back my life. I continue to go back annually for an exam and thanks to this wonderful treatment I'm here, because without it I would not be.

This disease needs action taken, it's been too long and too many people have suffered, died without the opportunity to get their lives back. Please hurry and save as many as possible, give them the right to life. New treatment is needed for NHL, talk to the people, go see the people and you will then realize how important/needed these actions are. Please approve this much-needed drug.

This treatment is a miracle to me if only it would have been available when I first started. My first chemo treatment left me with 35% heart function and other long-term health problems. All this could have been avoided. But, I thank BEXXAR for my life today.

Somers, Karen M

m: Teresa Singh [REDACTED]
sent: Thursday, December 05, 2002 8:18 AM
To: SomersK@cder.fda.gov
Subject: Dec 17 ODAC meeting statement

Dr. K. M. Templeton-Somers
FDA

Dec. 5, 2002

Dear Dr. Templeton-Somers,

As I cannot attend the Dec. 17 ODAC meeting, I would like to submit the following statement.

Please take a moment to read about my experience with Bexxar.

In June of 1996 I was diagnosed with "Non-Hodgkin's Lymphoma." At that time, the literature offered little hope:

~6-9% survival rate over 5 years

~high likelihood of remission within 18 months of treatment

~no known cure

Surgery for biopsy confirmed low-grade NHL, stage III, B-cell involvement. The tumors were twisted around vessels making surgical removal impossible. The total mass of the tumors was the size of a cantaloupe.

I entered the first "batch" of newly diagnosed patients to receive the yet unnamed Bexxar.

Even though this treatment was not yet FDA approved I voluntarily submitted to it!

Dr. Kaminski and "Bexxar" were my hope.

To my knowledge, the only side-effect I experienced was to my thyroid gland. I am now on a daily synthetic thyroid pill. The "gnarly lumps" were invisible the MORNING AFTER my treatment. Follow-up CT scans confirmed their disappearance. I am healthy!

After more than SIX YEARS of being "Cancer-free" I can say I am amazed at Bexxar's capabilities.

We owe it to our fellow citizens who are facing the terror of a diagnosis of Non-Hodgkin's Lymphoma the choice of a new treatment; a treatment I know for a fact has saved me and my family from agony.

PLEASE APPROVE BEXXAR. Let more patients feel the hope that I feel.

Thank you,

Teresa Singh
Ann Arbor, Michigan
Email: [REDACTED]