

Good afternoon. My name is Al Musella, and I am the President of the Musella Foundation For Brain Tumor Research & Information, Inc. Our organization is dedicated to helping families deal with the diagnosis of a brain tumor, and speeding up the search for the cure.

I have no direct personal financial interest with Genentech, maker of Avastin. My organization has received insignificant donations from Genetech, which are detailed in my letter, which is the first one on the CD which I gave to the committee.

1,702 of my members gave me explicit permission to speak for them at this meeting in favor of approval of Avastin. I will provide some important details on them for you in a minute. .

Over **1,300** members have submitted letters in support of approval. I put them together into one .pdf file on a CD and have given copies to the committee.

We monitor some of our members in a patient registry we call the Brain Tumor Virtual Trial. I checked our ongoing results to see how Avastin has faired. We have 31 GBM patients who took Avastin and our results were better than that reported for Avastin by Vredenburgh et al. 2007. This data just confirms that Avastin works in the real world. I submitted more details to the committee in a separate handout.

I would like to read excerpts from the first few letters. I encourage the committee members to read all of the letters, if they are considering voting against approval. The full text of each letter is on the CD.

Here is the first letter:

My name is Catherine. I am 49 and have 3 children. I also have a Glioblastoma and was told I had 6 months to a year to live. I failed on current standard therapy which included: Temodar, Radiation, and Gliadel wafers... all within a year and a half. I was then put on Avastin, and the next scan was clean. I was on it for a year, then my doctor decided to take me off of it and I have had clean scans for 14 months with no sign of tumor. Please approve Avastin - I may need it again!!!! It has given me more precious time with my children.

Here is the second letter.

My daughter, Monika, was diagnosed with a low grade brain tumor which progressed to a GBM 9 years later. She had 3 surgeries, standard radiation, gamma knife, Temodar, high dose chemo with bone marrow transplant and several other chemotherapies, but

Monika's condition was deteriorating and her doctors did not think she would survive much longer. Within weeks of starting Avastin she had a remarkable response and was once again strong and vibrant. The tumor shrunk significantly, very quickly on Avastin, and my beautiful daughter's quality of life improved to the point of her becoming fully functional again. However, since Avastin wasn't approved for brain tumors, we had trouble with her insurance paying for it and we were forced to stop using it. She died soon afterwards. I don't want this to happen to other families.

And finally the third letter:

My daughter Lori battled a glioblastoma multiforme for 22 months. She failed the standard treatments of surgery, radiation and chemotherapy. We were attempting to put her on Avastin but her insurance would not pay for it. Before we were able to come up with the money, she passed away. If we would have been lucky enough to have her insurance pay for it, she could possibly still be with us.

In summary, I would like to ask the committee members to consider what you would choose if you were in the situation of having a recurrent GBM after failing Temodar. Avastin is the logical drug of choice. It is not perfect, but it is the best of the current alternatives. Your approval will allow brain tumor patients better access to this promising treatment.

I would also add, that approval may also allow better access to the drug for researchers looking for better ways of using the drug, without having ties to the drug company.

Thank you for allowing me to speak on this matter.

Brain Tumor Virtual Trial: Preliminary Experiences with Avastin

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Purpose:

The Brain Tumor Virtual Trial is an internet based patient registry that records patient self reported information on their tumor type, the treatments they do and the outcome. We do not tell patients what to do, we only record and analyze them. We report the interim results on glioblastoma patients who have reported using the drug Avastin at some point in their treatments.

Patients and Methods: 731 patients have registered in the brain tumor virtual trial at virtualtrials.com. Of these, 348 have a glioblastoma multiforme (GBM), and 31 of these GBM patients reported using Avastin at some point in their treatment. Patients submit copies of their pathology reports and MRI reports for verification and post an update once a month. We email them reminders to post updates, and if an update is missed, we call them or their alternate contact person to get the missing data point.

Since we are not physically examining the patients, our main endpoint is overall survival. We also report on the number of months each patient took Avastin, and how long they survived after starting Avastin.

Results:

A total of 31 patients with glioblastoma multiforme who have used Avastin have enrolled in the brain tumor virtual trial.

Of these patients, **16** are still alive, **15** have died.

2 Patients were newly diagnosed when Avastin was started

29 Patients had recurrent GBM when Avastin was started.

For ALL patients, Newly diagnosed and recurrent GBM:

Average months taking Avastin = **7** months

Average Overall Survival (from Diagnosis)= **29** months

Average Survival After starting Avastin= **10** months

For ONLY Recurrent GBMs:

Average months taking Avastin = **7** months

Average Overall Survival = **31** months

Average Survival After starting Avastin= **10** months

Patient ID	GBM status When Avastin Started	Months On Avastin	Alive?	Still Taking it?	Age	Overall Survival (months)	Survival after starting Avastin (Months)
1481	Reccurent GBM	19	Dead	N	53	37	22
1625	Reccurent GBM	19	Alive	N	40	27+	22+
1703	Reccurent GBM	19	Alive	Y	52	24+	19+
1737	Reccurent GBM	15	Alive	N	56	24+	16+
1718	Newly Diagnosed GBM	14	Alive	Y	57	15+	14+
1622	Reccurent GBM	13	Dead	N	61	25	17
1623	Reccurent GBM	13	Alive	Y	73	26+	13+
1562	Reccurent GBM	13	Dead	N	60	46	13
1440	Reccurent GBM	13	Dead	N	48	36	13
1498	Reccurent GBM	11	Dead	N	63	63	23
1646	Reccurent GBM	11	Alive	N	65	22+	17+
1655	Reccurent GBM	11	Alive	Y	53	19+	11+
1654	Reccurent GBM	10	Alive	Y	60	20+	10+
1556	Reccurent GBM	7	Dead	N	41	32	7
1671	Reccurent GBM	7	Dead	N	59	17	11
1620	Reccurent GBM	6	Alive	N	38	30+	18+
1621	Reccurent GBM	5	Alive	Y	52	18+	5+
1727	Reccurent GBM	5	Alive	N	64	21+	11+
1627	Reccurent GBM	3	Dead	N	81	11	5
1478	Reccurent GBM	3	Alive	Y	49	49+	3+
1509	Reccurent GBM	2	Dead	N	59	49	5
1715	Reccurent GBM	2	Dead	N	52	21	4
1656	Reccurent GBM	2	Alive	Y	55	19+	2+
1689	Reccurent GBM	1	Alive	N	69	13+	8+
1742	Newly Diagnosed GBM	1	Alive	N	54	6+	4+
1554	Reccurent GBM	1	Dead	N	57	17	2
1506	Reccurent GBM	1	Dead	N	56	24	3
1495	Reccurent GBM	1	Dead	N	56	31	1

1257	Reccurent GBM	0	Alive	N	47	118+	5+
1425	Reccurent GBM	0	Dead	N	29	22	0
1650	Reccurent GBM	0	Dead	Y	54	26	0

Conclusions: The reported survival after starting Avastin by Vredenburgh et al. 2007 was 9.7 months. Our patients have already done slightly better than that already, and more than half of the patients are still alive. Although not rigidly controlled as the Vredenburgh et a trial, this represents how Avastin is doing in the “real world”.