PRESS RELEASE

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Troy, Michigan

FREEDOM OF ACCESS TO MEDICINES FILES FOIA REQUEST TO FDA ON AVASTIN

Today, leaders in the battle with the U.S. Food and Drug Administration to retain metastatic breast cancer (mbc) as an indication for the drug Avastin filed a Freedom of Information Act ("FOIA")request with the FDA.

The filers include noted attorney David Rivkin, (www.bakerlaw.com/davidbrivkinjr/), Frank Burroughs and Steven Walker on behalf of the Abigail Alliance for Better Access to Developmental Drugs (www.abigail-alliance.org), campaigners for increased access to experimental drugs and Terrence Kalley on behalf of Freedom of Access to Medicines (www.fameds.org), an organization dedicated to the right of women to retain Avastin as a medical option for mbc.

The filers are troubled by many actions of the FDA in its review of the drug Avastin, a drug relied upon by an estimated 17,500 women with incurable mbc. Many woman and their oncologists report great success with the drug, yet the FDA will remove the indication for mbc, subject to a final appeal by the drug's manufacturer on June 28th & 29th at the FDA's headquarters in Silver Spring, Maryland.

Terrence Kalley, founder of Freedom of Access to Medicines stated:

> The FDA has forgotten that there are an estimated 17,500 patients currently on Avastin. Since the Oncologic Drugs Advisory Committee voted to remove Avastin for mbc as an indication at its meeting in July, 2010, FDA officials have let the patients wonder what their fate will be. Not once have they indicated that they are attempting to carve out some sort of exemption for current patients or to secure coverage for current patients under Medicare or under private health insurance.
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> It is bad enough that the patients have to fight daily on the health front. Some of these patients are doing extremely well on Avastin. The thought that they will lose the benefit of this drug scares them greatly because they and their oncologists believe that they owe their very survival to Avastin.
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> The FDA has not been responsive to letters or e-mails from patients or cancer organizations expressing concern about the FDA's actions regarding Avastin for mbc. We also have not heard of the FDA responding to any letters written by members of Congress on behalf of patients. This attitude leads some to regard the FDA hierarchy as contemptuous of patients, let alone Congress.

The FDA keeps hiding behind the slogans of “we’re following the science” or “the drug is unsafe” or “the drug did not show sufficient benefits.” These are all spurious arguments by the FDA. The FDA did not find any new risk factors associated with Avastin from the earlier trials and the side effects are well-tolerated by most patients. The FDA has furthermore knowingly and deliberately overstated the risks associated with Avastin in order to justify its decision. The biggest risk to most patients is death due to not taking Avastin.

The primary endpoints for Avastin were objective response rates and progression free survival, not overall survival. Yet the Oncologic Drugs Advisory Committee (“ODAC”) spent much of its time discussing overall response rate and so do FDA officials when defending their Avastin decision. In fact, this was never a primary endpoint and so to discuss its lack of positive benefit is to mislead the public about the reasons why the FDA is taking such a negative position against Avastin for mbc.

The patients deserve the truth and in order to get it we are filing a FOIA request with the FDA. Under FOIA, the FDA must respond to us in 20 days. Failure of the FDA to provide the information sought will further jeopardize the FDA’s standing in the public eye. We trust that the FDA will come clean with the American public.