

DYSFUNCTION AT THE FDA

Prostate Cancer Victims Face Needless Suffering and Premature Death

FACTS

- In the United States alone, nearly 30,000 men die annually of prostate cancer.
- Today, chemotherapy (which may have severe side effects) is the only approved treatment for androgen independent prostate cancer (AIPC), which is the terminal stage of prostate cancer.
- The FDA selected an Advisory Committee of renowned experts to review Provenge®, an immunotherapeutic “cancer vaccine” developed for men dying from AIPC. On March 29, 2007 the Advisory Committee voted 17-0 that Provenge is safe. They also voted 13-4 that Provenge demonstrated substantial evidence of efficacy (the federally mandated standard).
Put another way, the experts found Provenge works.
- In a rare rejection of its own Advisory Committee’s recommendation, the FDA, on May 8, 2007, denied approval of Provenge, requesting additional data.
- Provenge has been demonstrated to be safe in more than six clinical trials. The most common complaint is 2-4 days of flu-like symptoms following each of the three, 2-hour infusions. Again, the expert panel voted 17-0 that Provenge is safe.
- Provenge demonstrated a statistically significant ($p=.01$) overall median survival benefit of 4.5 months in its D9901 Phase 3 trial. Three year survival benefit was also statistically significant ($p=.0046$), with 34% of Provenge recipients still alive at 36 months compared to only 11% of controls. A second trial, D9902A, showed a 3 year survival benefit (32% vs. 21%), and the two studies combined showed a three year survival benefit (33% vs. 15%).
- Provenge stimulates the immune system to fight cancer cells continuously, month after month, year after year. Some Provenge recipients have lived over 6 years following initial treatment, an impressive feat considering average life expectancy of AIPC patients is about 20 months.
- On July 1, 2007 a review article coauthored by National Cancer Institute experts and published in a prestigious journal of the American Association for Cancer Research found that certain cancer vaccines enhance patient outcome. The authors said, regarding the Provenge D9901 trial, “Overall survival ... was statistically significant ...” and, regarding it and the D9902A trial “[I]ntegrated analysis of both ... showed a statistically significant increase in overall survival” Regarding a combination therapy trial using Provenge, they said, “There was a statistically significant increase in survival ... when patients received [Provenge].” Schlom et al Cancer Vaccines: Moving Beyond Current Paradigms. *Clinical Cancer Research* 2007; 13: 3776-3782

- It may take 2-3 years to acquire (through an additional clinical trial), analyze and submit the additional data for Provenge that the FDA has requested. In that time, 60,000 to 90,000 men, many of whose lives could be extended without severe side effects from Provenge, will die.
- The FDA could have approved Provenge and requested post-approval studies, thereby allowing these dying men the chance to benefit from Provenge while further studies are conducted.

QUESTIONS

1. Why did the FDA reject its own expert Advisory Committee's overwhelming recommendation and turn its back on tens of thousands of dying men who could have a chance to benefit NOW from this safe, effective drug? There is no explanation.
2. Did highly unusual events and conflicts of interest with certain Advisory Committee members exist that could have tainted the fairness and objectivity of the FDA process? A thorough investigation would reveal the answer.
3. Was the FDA's denial reasonable? **NO. Please ask your Senators and Representatives to demand a reconsideration.**

**The FDA wants to wait as much as 2-3 years for more data.
Men dying of prostate cancer don't have that luxury.**

**All citizens, especially prostate cancer victims and family members,
should immediately contact Congressional representatives, urging
them to ensure this travesty is reversed.**

APPROVE PROVENGE NOW!

For further info on efforts to make Provenge available NOW visit
www.caretolive.com
www.abigail-alliance.org
www.provenge.blogspot.com

*Arnie Mass, prostate cancer patients, their family members, activists, investors,
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