

FOR IMMEDIATE RELEASE

Prostate Cancer Roundtable Issues a “Red Alert” – MEDCAC Meeting Tomorrow

November 16, 2010 - Tomorrow is a landmark day for men with advanced prostate cancer and the millions of families and loved ones who are profoundly affected. Provenge, a new prostate cancer treatment option, will be considered by the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC). MEDCAC was established to provide independent guidance and advice to the Centers for Medicare and Medicaid Services (CMS). MEDCAC is supposed to supplement CMS' internal expertise and to allow an unbiased and current deliberation of "state of the art" technology and science. Medicare is not supposed to take cost into consideration when making such decisions and rulings.

"If you are concerned about price, lets have a discussion about costs of care," said Skip Lockwood, President/CEO of ZERO – the Project to End Prostate Cancer. "This conversation clearly isn't about the clinical effectiveness of Provenge, which has already been established."

Provenge was recently approved by the FDA after almost 15 years of development, \$1 billion of funding, and more than 15 studies evaluating its safety and efficacy. We were surprised to see CMS initiate the National Coverage Decision (NCD) process. We were very encouraged by many scientific and clinical experts at both the FDA and the National Comprehensive Cancer Network who support the use of Provenge for asymptomatic or minimally symptomatic metastatic castrate resistant (hormone refractory) prostate cancer.

Joel Nowak, Director of Advanced Prostate Cancer Programs for Malecare, who is a survivor of advanced metastatic prostate cancer, has found the most common question he is asked is whether the cost of Provenge is worth the additional survival time? His simple answer is YES, especially when you compare it to the real cost of the main chemotherapy currently funded by Medicare.

Based on consistent results from multiple Phase III trials which showed this therapy improved a patient's chances of being alive at the milestone 3-year mark by 38% and, for the first time ever in this advanced prostate cancer patient population, demonstrated that patients on treatment had a median life expectancy beyond two years (25.8 months), full FDA approval was granted on April 29th of this year.

A few short weeks later, the prostate cancer panel experts of the National Comprehensive Cancer Network designated this therapy as a Category 1 treatment. This is defined as "supported by high-level evidence (e.g. randomized clinical trials)" and for which there is "uniform NCCN consensus" among experts in prostate cancer treatment. Only 18% of all products reviewed receive Category 1 designation, demonstrating the value and importance of such a designation.

We welcome a full, honest, and transparent discussion on the value of innovation in our fight against cancer, including how patients perceive benefits, risks, and costs. We second Dr. Allen Lichter, head of the American Society of Clinical Oncology, comment that it is "extremely chilling" to innovation in cancer research if new FDA-approved treatments against cancer must now go through a second round of efficacy and safety review from CMS, even for their use "on-label".

We note that in metastatic cancers of any kind, only 3 other drugs have ever been approved with a four month or greater survival benefit, and that each (Herceptin, Avastin, and Alimta) has revolutionized the treatment of that cancer. Men with prostate cancer deserve to have this opportunity, too. A recent Milliman Consulting report (May 2010) shows the average annual cost of chemotherapy is \$111,000. Provenge's total cost is approximately \$93,000. We are concerned that

CMS might ration access to Provenge and other life-saving cancer therapies in the future. This could adversely impact those who don't have the personal resources to afford the treatment.

"There is an epidemic of prostate cancer amongst African American men. If CMS doesn't approve this, then this treatment becomes an exclusive kind of treatment for men who can afford it out of pocket," said Thomas Farrington, President, Prostate Health Education Network.

There is an immense need for innovative treatments like Provenge and awareness about the plight of men with advanced prostate cancer. With Provenge, men now have an opportunity to engage in a conversation with their health care provider about this new innovative immunotherapy to potentially extend and improve their quality of life.

According to Merel Nissenberg, National Alliance of State Prostate Cancer Coalitions, "This hearing is to determine the coverage of costs for Provenge for a clearly defined population. Reimbursement issues affect poor and underserved men as well as all men who are currently being treated or who want to be treated with Provenge."

Prostate cancer is a complex and problematic disease that affects not only the male patient, but also his wife or partner and other family members over many years.

The early detection and appropriate treatment of clinically significant and potentially lethal prostate cancer remains a critical priority, especially among men at high risk because of family history, ethnicity, or other factors that define such risk.

About the Prostate Cancer Roundtable:

Prostate cancer is the most prevalent form of cancer among American males. Nearly 220,000 men will be diagnosed with prostate cancer in 2010, and about 32,000 will die from this disease. This group of independent, not-for-profit organizations cooperates to foster the development of policies that support the early detection of clinically significant prostate cancer, the effective treatment of men with this disease, and the appropriate education of all men at risk for this disease.

The above statement has been issued on behalf of and endorsed by

American Urological Association Foundation – www.auafoundation.org

Ed Randall's Fans for the Cure – www.batforthe cure.org

Malecare Prostate Cancer Support – www.malecare.org

Men's Health Network – www.menshealthnetwork.org

National Alliance of State Prostate Cancer Coalitions – www.nasppcc.org

Prostate Conditions Education Council – www.prostateconditions.org

Prostate Cancer Foundation – www.prostatecancerfoundation.org

Prostate Health Education Network – www.prostatehealthed.org

Prostate Net – www.prostatenet.org

Us TOO International Prostate Cancer Education and Support Network – www.ustoo.org

Women Against Prostate Cancer – www.womenagainstprostatecancer.org

ZERO – The Project to End Prostate Cancer – www.zerocancer.org

The following organizations join in support of this press release:

Prostate Cancer Research Institute – www.pcri.org

RetireSafe – www.retiresafe.org

Veterans Health Council – www.veteranshealth.org