

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

M.D.L. No. 1430
Civil Action No. 01-10861

MEMORANDUM AND ORDER ON A. DAVID MAZZONE
RESEARCH AWARDS PROGRAM FIRST ANNUAL PROGRESS and
ACCOUNTING REPORT # 4

April 19, 2013

STEARNS, D.J.

On March 14, 2013, Dr. Philip Kantoff of the Dana-Farber/Harvard Cancer Center (DF/HCC), the principal investigator for the A. David Mazzone Research Awards Program,¹ and co-principal investigator, Dr. Jonathan Simon, President of the Prostate Cancer Foundation (PCF), submitted for the court's review Report #4 for the program period July 1, 2012, to December 31, 2012. Now in its third year, the Program supports a total of 93 investigators working on 28 prostate cancer and related

¹ The Research Awards Program is named in the memory of the Honorable A. David Mazzone, a much-revered United States District Court Judge who for nineteen years oversaw the federally-mandated clean up of the Boston Harbor and who died prematurely of prostate cancer. The Program is funded from a pool of unclaimed consumer class funds created as part of the settlement of a national class action lawsuit involving overpricing of the prostate cancer drug Lupron®. *See In re Lupron® Mktg. and Sales Practices Litig.*, 729 F. Supp. 2d 492 (D. Mass. 2010). The Program is administered jointly by the DF/HCC and the PCF under supervision of the court.

research projects. The following are milestones compiled during the six months following the last report.

- (1) A “High Impact Clinical Trial Award” developed by Dr. Kantoff will support an early phase, multi-institutional clinical trial. Dr. Kantoff expects the award to have a significant impact on prostate cancer drug development and testing.
- (2) The Lupron Treatable Diseases and Conditions Mechanism awarded its three available grants during the 2012 funding period (Stacey Missmer, ScD - *Cancer and endometriosis*; Jose Teixeira, PhD - *Pre-clinical in vivo studies investigating the efficacy of mTOR inhibitors for uterine fibroids*; and Elizabeth Henske, MD - *Targeting estrogen-dependent mechanisms in lymphangiomyomatosis LAM*). As the designate funds have been exhausted, there will be no additional awards in 2013.
- (3) In 2012, the Program experimented with a new training award mechanism to support pre- and post-doctoral fellows working in prostate cancer research laboratories. However, the Program review panel concluded that the applications received in 2012 did not provide significant added value to the career development awards. In collaboration with the court representatives, the Program decided to terminate the pre-post-doctoral fellowship funding mechanism for 2013. The court is appreciative of the determination of the

principal investigators and the Scientific Advisory Board (SAB) in ensuring the financial and scientific integrity of the Program.

The Report also details the 2013 Request For Application (RFAs). In the 2013 cycle, DF/HCC will offer six investigative awards and PCF will continue to offer the Special Challenge Award. The deadline for Letters of Intent (LIT) was March 8, 2013. The Program leadership board decided to offer the RFA for High Impact Trials for a second time for year 2013. The Mazzone Program received 90 LITs involving 212 researchers at 87 institutions. The application deadline was April 5, 2013. After ranking and review, the SAB will make its final funding decisions on or before June 15, 2013.

The Report also highlights the Mazzone Awards recipients participation in the Sixth Annual Prostate Cancer Program conference held March 18-20. The event, co-sponsored by Memorial Sloan-Kettering Cancer Center, Dana-Farber/Harvard Cancer Center, Johns Hopkins Hospital, and the University of Michigan, featured Mazzone Award investigators Lorelei Mucci, ScD; Myles Brown, MD; Steven Balk, MD, PhD; Bill Nelson, MD, PhD; and Massimo Loda, MD, as sessions moderators for panels on *Genomics and Biology*; *Prognostic and Predictive Markers*; *Population Science to inform on prostate cancer etiology: Genetics*; and *Androgen Receptors*.

The 2011 DF/HCC and PCF award recipients will complete their second year

of research activities in July of 2013. Simultaneously, 2012 DF/HCC and PCF award recipients will complete their first year of research activities. Each award recipient will submit an annual scientific progress report and financial report. Progress reports will be reviewed by Dr. Kantoff and the SAB, and the court if necessary. The court will receive a further progress report on or before September 30, 2013 .

ORDER

The principal investigator of the A. David Mazzone Research Awards Program, Dr. Kantoff, and the co-principal investigator, Dr. Simons, are requested to submit to the court the required research progress and accounting report for all grants (Annual Report # 5) on or before September 30, 2013.

SO ORDERED.

/s/ Hon. Richard G. Stearns

United States District Judge