

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

M.D.L. NO. 1430
CIVIL ACTION NO. 01-10861

IN RE LUPRON® MARKETING AND
SALES PRACTICES LITIGATION

MEMORANDUM ACKNOWLEDGING THE RECEIPT AND
REVIEW OF THE A. DAVID MAZZONE SECOND ANNUAL RESEARCH
AWARDS PROGRESS and ACCOUNTING REPORT #6

March 31, 2014

STEARNS, DJ.

The A. David Mazzone Research Awards Program is now concluding its third year. The Program was made possible by a *cy pres* distribution of unclaimed settlement funds from a national class action involving the pricing of the prostate cancer treatment drug Lupron®. *See In re Lupron Mktg. and Sales Practices Litig.*, 677 F.3d 21 (1st Cir. 2012). The five-year Program, which is dedicated to finding a cure and more effective treatments for prostate cancer and related diseases, now supports the work of 137 investigators involved in thirty-eight separate research projects.

On March 5, 2014, Dr. Philip Kantoff of the Dana-Farber/Harvard Cancer Center (DF/HCC), the principal investigator for the Program, and co-principal investigator, Dr. Jonathan Simon, President of the Prostate Cancer Foundation (PCF), submitted the sixth in a series of Progress and

Accounting Reports for the court's review.¹ This Report covers the period from July 1, 2013 to December 31, 2013.

Drs. Kantoff and Simon report that for the 2013 Fall semester, the Mazzone Program received 90 letters of intent in response to its RFAs submitted on behalf of 212 researchers at 87 hospitals and medical schools. Table 1 of Report No. 6 provides a detailed summary of the applications received and evaluated by DF/HCC and PCF during the May and June of 2013 peer process. The Fall of 2013 award recipients were named in August of 2013.

PCF selected the following project for funding in 2013.

Synergistic Immune and Lipid Metabolism Targeting for Metastatic Prostate Cancer Therapy

Principal Investigator: Jennifer Wu, PhD, (Medical University of South Carolina) *Collaborators:* James S Norris, PhD (Medical University of South Carolina); Michael Lilly, MD (Medical University of South Carolina); Xiang Liu, MD, PhD (Medical University of South Carolina); Ali Goshayan, MD (Medical University of South Carolina); Richard Drake, PhD (Medical University of South Carolina); Ann-Marie Broome, PhD (Medical University of South Carolina); Elizabeth Garrett-Mayer, PhD (Medical University of South Carolina)

¹ Of the current thirty-eight research initiatives, thirty-three are funded by DF/HCC and five by PCF Challenge Awards.

Carolina).

PCF is soliciting RFAs this year (2014) for a final Special Challenge Award of \$500,000. See Appendix 4 of Report No. 6..

DF/HCC made the following awards from the 2013 applications:

Co-targeting AR and ERG to Treat Advanced Prostate Cancer

Principal Investigator: Karen Knudsen, PhD (Thomas Jefferson University).
Collaborators: Felix Feng, MD (University of Michigan); Myles Brown, MD (Dana-Farber Cancer Institute).

Defining the Spectrum of Resistance to Androgen Ablation Therapy in Prostate Cancer

Principal Investigator: Levi Garraway (Dana-Farber Cancer Institute)
Collaborators: William Hahn (Dana-Farber Cancer Institute), Mark Rubin (Weill Cornell Medical College).

Genome-wide Analysis of Response to Androgen Deprivation Therapy

Principal Investigator: Mark Pomerantz, MD (Dana-Farber Cancer Institute)
Collaborators: Matthew Freedman, MD (Dana-Farber Cancer Institute); Christopher Sweeney, MBBS (Dana-Farber Cancer Institute); Manish Kohli, MBBS (Mayo Clinic); Svitlana Tyekucheva, PhD (Dana-Farber Cancer Institute).

Targeting Androgen Receptor Pathway-Independent Prostate Cancer (APIPC)

Principal Investigator: Peter Nelson, MD (Fred Hutchinson Cancer Research Center). *Collaborators:* Marc Vidal, PhD (Dana Farber Cancer Institute); Muneesh Tewari, MD, PhD (Fred Hutchinson Cancer Research Center).

Clinical Trials Assessing Mechanisms Mediating Sensitivity and Resistance to Enzalutamide

Principal Investigator: Mary-Ellen Taplin, MD (Dana Farber Cancer Center).
Collaborators: Bruce Montgomery, MD (University of Washington); Elahe Mostaghel, MD, PhD (Fred Hutchinson Cancer Research Center); Xin Yuan, MD, DSc (Beth Israel Deaconess Medical Center); Steven Balk, MD, PhD (Beth Israel Deaconess Medical Center); Glenn Bublely, MD (Beth Israel Deaconess Medical Center); Mark Pomerantz, MD (Dana Farber Cancer Center); Colm Morrissey, PhD (University of Washington).

Developing Novel Targeted Therapies for Advanced Prostate Cancer

Principal Investigator: Karen Cichowski, PhD (Brigham and Women's Hospital).

Targeting the Co-Activator Site on the Androgen Receptor

Principal Investigator: Gregory Verdine, BS, PhD (Harvard University – Chemistry Department) *Collaborator:* Levi Garraway, MD (Dana-Farber Cancer Institute).

Chronic Stress and Racial Disparities in Prostate Cancer

Principal Investigator: Lisa Signorello, ScD (Harvard School of Public Health).
Collaborators: Jennifer Rider, ScD (Harvard School of Public Health); Sebastien Haneuse, PhD (Harvard School of Public Health); Unnur Valdimarsdottir, PhD (University of Iceland).

Shared Medical Appointments: An Innovative Approach to Prostate Cancer Survivorship Care

Principal Investigator: Larissa Nekhlyudov, MD, MPH (Harvard Vanguard Medical Associates). *Collaborators:* Ann Partridge, MD, MPH (Dana-Farber Cancer Institute); Wilmer Roberts, MD, PhD (Harvard Vanguard Medical Associates); Michael Pistiner, MD, MMSc (Harvard Vanguard Medical Associates); Aymen Elfiky, MD, MPH (Dana-Farber Cancer Institute); Christopher Recklitis, PhD, MPH (Dana-Farber Cancer Institute); Sarah Reed, MPH, MSW (Dana-Farber Cancer Institute).

The court makes special note of the forum organized by DF/HCC and

PCF, to be held in Boston on May 6, 2014, that will showcase presentations by the 2011 and 2012 Mazzone Program grantees. All Mazzone Awards recipients have been invited to attend. The event will offer the opportunity not only to share the scientific progress achieved to date, but also to take interim measure of the success of high-impact funding on a critical area of medical research.

CONCLUSION

The court expresses its appreciation for the meticulous stewardship of Dr. Kantoff and Dr. Simons and the efforts they have made, as reflected in Report No. 6, to establish the A. David Mazzone Research Awards Program as a contributing presence in the international cancer research community. The results have been a fitting tribute, as the court intended, to the victims of what it is confident will someday, and perhaps sooner thanks to the efforts of the Mazzone Program investigators, prove to be a curable disease. The court looks forward to the September 30, 2014 Annual Progress Report.²

² Under separate cover, Dr. Kantoff requested authorization to utilize the remaining \$160,000 in unallocated funds to issue a final 2014 RFA to solicit applications for further Community Outreach and Disparities research. This will enable the funding of two additional grants of up to \$70,000 each in 2014. Dr. Kantoff also asked to allocate the remaining \$20,000 to provide additional funding to the Student Training mechanism through the DF/HCC Cure Program. In an Order dated March 20, 2014, the court granted these requests.

/s/ Richard G. Steams

United States District Judge