

Department of Defense US Army Medical Research and Materiel Command



### Fiscal Year 2004 (FY04) Chronic Myelogenous Leukemia Research Program (CMLRP) Funded Awards List

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#### Introduction

The US Army Medical Research and Materiel Command (USAMRMC) is pleased to present the awards list of funded projects for the fiscal year 2004 (FY04) Chronic Myelogenous Leukemia Research Program (CMLRP). Therapeutic Development Award negotiations were completed on January 21, 2005; Exploration – Hypothesis Development Award (EHDA) negotiations were completed on September 30, 2005. Awards listed in this document were selected in a competitive, two-tier review process. Funding decisions were based on evaluations of scientific excellence in the first tier, followed by determinations of programmatic relevance in the second tier. These projects represent a diverse portfolio of scientific research directed toward the program's overall goal of improving: (1) the understanding of the basic science of chronic myelogenous leukemia (CML), (2) the diagnosis of CML, (3) the treatment of CML, and (4) the quality of life for individuals and their families living with CML.

Congressional direction for FY04 specified \$4.25 million for CML research. Following the receipt of funds, a programmatic strategy was developed, proposals were solicited and evaluated, award recommendations were made, and contract negotiations completed.

The FY04 programmatic strategy called for use of a Therapeutic Development Award mechanism. This award sponsors the development and evaluation of preclinical model systems and the preclinical assessment of therapeutics for CML. Of the 23 proposals received, four were funded. To best utilize remaining FY04 dollars, the CMLRP funded additional awards from proposals submitted in response to the CMLRP FY05 Exploration – Hypothesis Development Award (EHDA) program announcement. The EHDA mechanism, successfully utilized by the CMLRP previously in FY03, sponsors the investigation of novel and preliminary research that may propel the field forward toward finding a cure for CML. Three EHDA awards were funded with FY04 dollars and a fourth award was partially funded with FY04 dollars (and partially funded with FY05 dollars).

As the funded investigators embark on these projects, the Department of Defense and the US Army gratefully acknowledge the participation of their scientific, clinical, and consumer advisors. The expertise, vision, and diversity of perspective of all individuals who contributed to this program were vital to developing a sound investment strategy on behalf of all persons affect by CML. It is with great anticipation and excitement that we await the outcomes of this body of research.

# Therapeutic Development Award

Log Number	PI Last Name	PI First Name	PI Institution	Proposal Title	Final Budget
CM043013	Gottesfeld	Joel	Scripps Research Institute	Small Molecule Therapeutics for Chronic Myelogenous Leukemia	\$940,323
CM043018	Bhalla	Kapil	-	Combinations of Novel Histone Deacetylase and Bcr-Abl Inhibitors in the Therapy of Imatinib Mesylate-Sensitive and- Refractory Bcr-Abl Expressing Leukemia	\$499,014
CM043020	Pankiewicz	Krzysztof	University of Minnesota, Twin Cities	Novel Selective Inhibitors of IMP-Dehydrogenase Type II Against Chronic Myelogenous Leukemia	\$844,027
CM043036	Skorski	Tomasz	Temple University	The Use of Anti-oxidants as a Therapeutic Tool to Prevent Mutations Causing Imatinib Resistance, and Chromosomal Aberrations Associated with CML Blast Crisis	\$897,650

# **Exploration – Hypothesis Development Award**

Log Number	PI Last Name	PI First Name	PI Institution	Proposal Title	Final Budget
CM050011	Stone	Brad		Identification of Minor Histocompatibility Antigens Expressed in Dendritic Cells Using Non-Synonymous SNP Genotyping, Epitope Prediction, and ELISPOT Analysis	\$150,000
CM050037	Druker	Brian	Oregon Health & Science University	Mechanisms of Disease Persistence in Chronic Myelogenous Leukemia (CML)	\$150,000
CM050044	Jordan	Craig	University of Rochester	Properties of Leukemia Stem Cells in a Novel Model of CML Progression to Lymphoid Blast Crisis	\$149,707
CM050054	Espinosa	109/01/10		Counteracting the Oncogenic Effects of Bcr-Abl by Disrupting the p53-MDM2 Interaction in CML Cells	\$150,000

#### FY04 Chronic Myelogenous Leukemia Research Program Peer Reviewers

Peer Reviewers	Degree	Institution/Affiliation
Bouhassira, Eric	Ph.D.	Albert Einstein College of Medicine
Brown, Daniel		The Leukemia & Lymphoma Society
Cranmer, David		The Leukemia & Lymphoma Society
Cunningham, Isabel	M.D.	Jacobi Medical Center
Dorshkind, Kenneth	Ph.D.	David Geffen School of Medicine at UCLA
Gottesfeld, Joel	Ph.D.	The Scripps Research Institute
Grant, Steven	M.D.	Medical College of Virginia
Helman, Sandy	Ph.D.	Scientific Review Administrator
Jhanwar, Suresh	Ph.D.	Memorial Sloan Kettering Cancer Center
Muller-Sieburg, Christa	Ph.D.	Sidney Kimmel Cancer Center
Ness, Scott	Ph.D.	University of New Mexico Health Sciences Center
Nichols, Gwen	M.D.	Columbia University
Nucifora, Giuseppina	Ph.D.	University of Illinois, Chicago
Pankiewicz, Krysztof	Ph.D.	University of Minnesota
Perrotti, Danilo	M.D., Ph.D.	Ohio State University
Ross, Jeffrey	M.D.	McArdle Laboratory
Ryan, Shawn		The Leukemia & Lymphoma Society
Skorski, Tomasz	M.D., Ph.D.	Temple University
Smithgall, Thomas	Ph.D.	University of Pittsburgh
Wieder, Eric	Ph.D.	University of Texas M.D. Anderson Cancer Center

### FY04 Chronic Myelogenous Leukemia Research Program Integration Panel Members

Reviewers	Degree	Institution/Affiliation
Kinniburgh, Alan J.	Ph.D.	National Hemophilia Foundation
McCullough, Rose	Ph.D.	US Agency for International Development
Radich, Jerald P.	M.D.	Fred Hutchinson Cancer Research Center
Talpaz, Moshe	M.D.	University of Texas M.D. Anderson Cancer Center
Van Etten, Richard (Chair)	M.D., Ph.D.	Tufts-New England Medical Center

### FY04 Chronic Myelogenous Leukemia Research Program Ad Hoc Reviewers

Ad Hoc Reviewers	Degree	Institution/Affiliation
Bhatia, Ravi	M.D.	City of Hope National Medical Center
Dickenson, Kelvin J.		The Leukemia & Lymphoma Society

#### **Glossary of Terms**

*Therapeutic Development Award (TDA):* The intent of this award mechanism is to provide funds to sponsor the preclinical assessment of therapeutics for chronic myelogenous leukemia (CML). The award is designed to allow CML investigators to analyze preclinical efficacy of novel and existing agents and/or to generate the preclinical data necessary to conduct clinical trials after completion of the proposed research. It is anticipated that the agents, model systems, or data generated from these awards will lead to the advancement of therapeutics novel to CML with the ultimate goal of significantly moving closer to the development of new therapeutics for CML. This award is open to investigators at all levels.

*Exploration – Hypothesis Development Award (EHDA):* The intent of this award is to provide funds to support the initial exploration of innovative, untested, and potentially groundbreaking concepts in chronic myelogenous leukemia research. Results of studies conducted through an EHDA may provide the scientific rationale upon which a new hypothesis can be based or may provide initial proof of principle for an innovative hypothesis. The award is designed to provide investigators with the opportunity to pursue serendipitous observations. Some gaps in supporting rationale may exist due to a lack of available information. This award is not intended to support ongoing work. Therefore, the existence of preliminary data suggests that the research would be more appropriately submitted to a different award mechanism. Successfully completed EHDAs are expected to lead to high-risk, potentially high-gain future research endeavors for this and other funding agencies. Projects involving human subjects or specimens will not be supported unless they are exempt under 32 CFR 219.101(b)(4)<sup>1</sup> or eligible for expedited review (45 CFR 46.110, 21 CFR 56.110).<sup>2</sup> This award is open to investigators at all levels.

<sup>&</sup>lt;sup>1</sup>Title 32, Code of Federal Regulations (CFR), Part 219, Section 101(b)(4). Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, is considered to be exempt under 32 CFR 219.101(b)(4).

<sup>&</sup>lt;sup>2</sup>For additional information, refer to U.S. Department of Health and Human Services' Office of Human Research Protection website at <u>http://www.hhs.gov/ohrp</u>.