

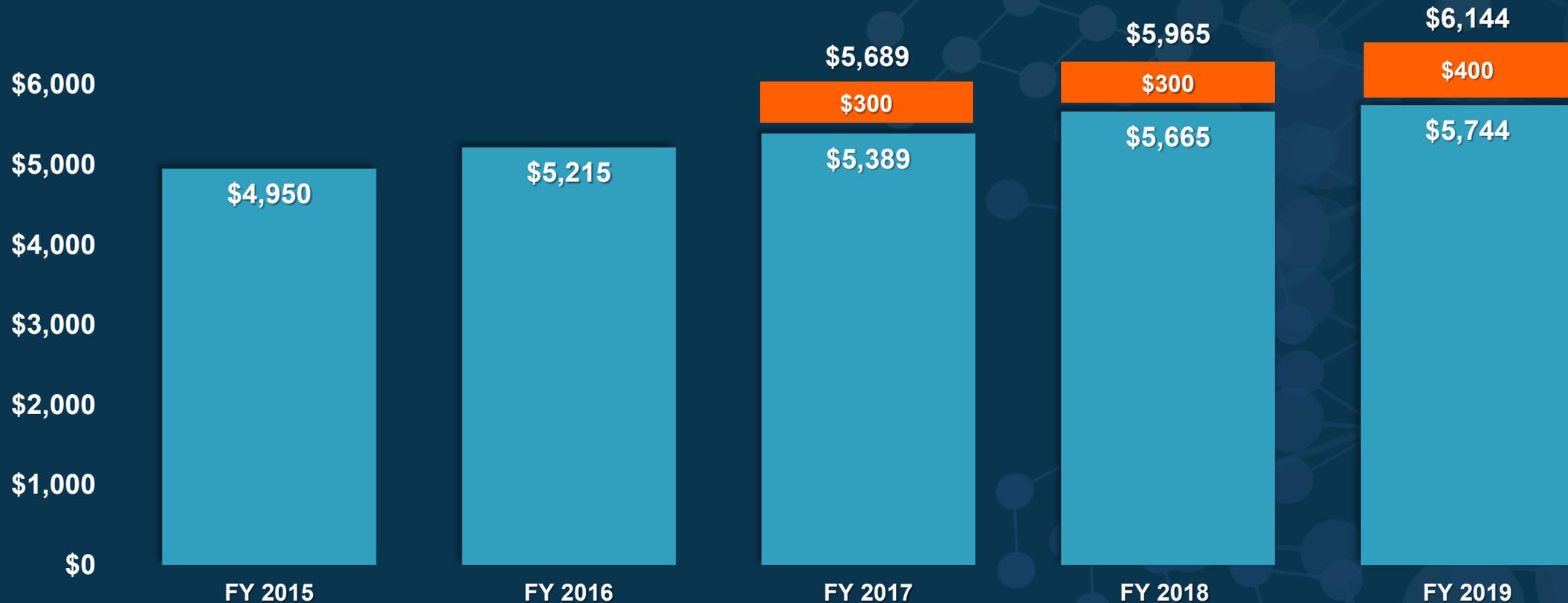
NCI Director's Update

Joint NCAB-BSA Meeting

Norman E. Sharpless, M.D.
December 4, 2018

NCI Appropriations FY 2015 - 2019 (in millions)

*21st Century Cures
Act funding shown
in orange.*



**FY 2018
RPG FUNDING**



Largest
increase since
FY 2003

FY 2018 ESIs



NCI exceeded
its goal of funding
25% more Early-
Stage Investigators

**FY 2018
NEW RPGs**

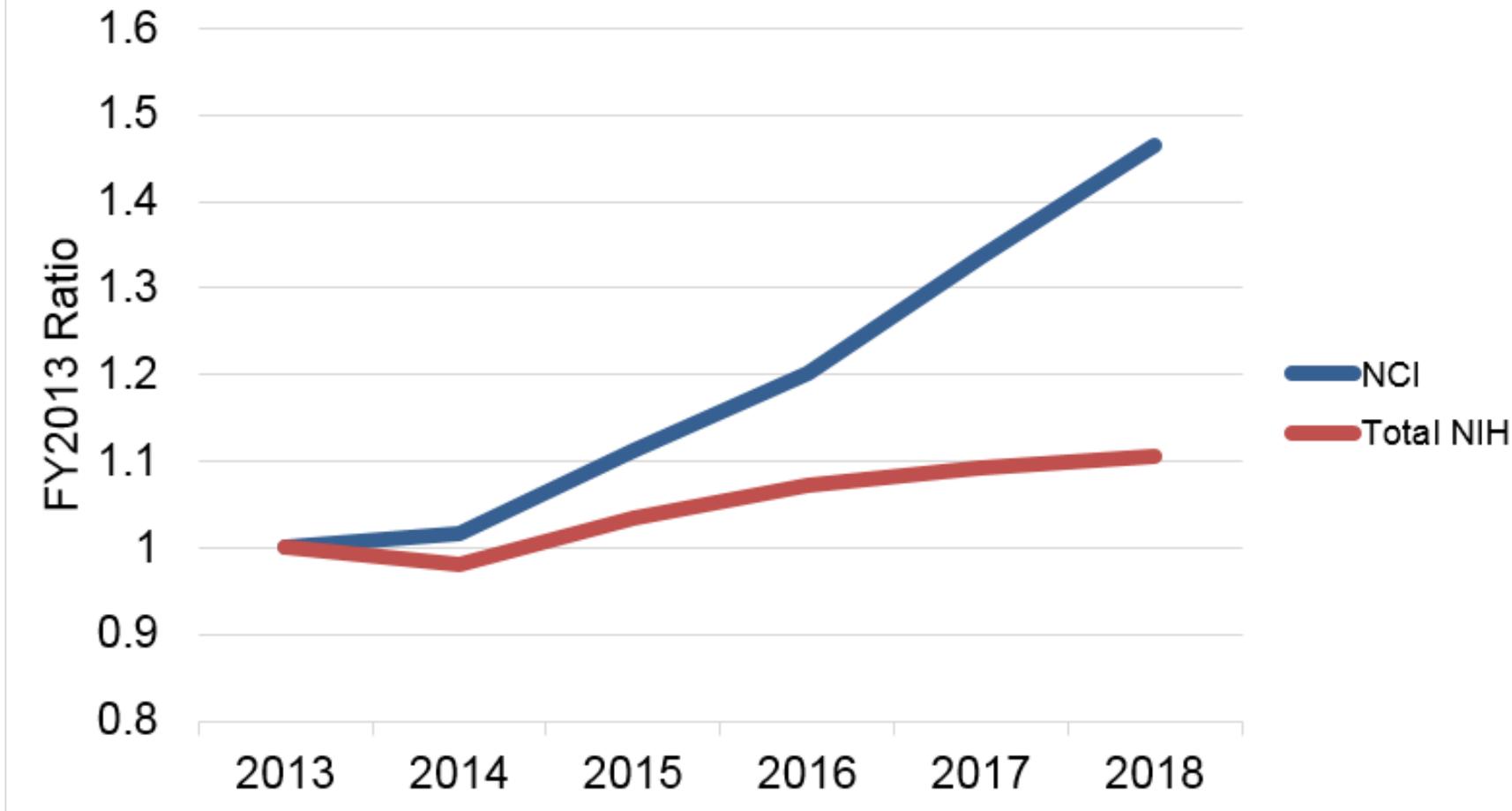


Total number of
awards up from
FY 2017

FY19 Realities: Increasing Costs

- Rent and utilities
- Mandatory assessments and transfers
- NRSA stipend increases
- Increasing award sizes
- Non-competing commitments to RPGs

Competing R01 Applications



Fiscal Year	2013	2014	2015	2016	2017	2018
NCI	4,175	4,240	4,640	5,019	5,572	6,113
NIH Total	27,939	27,399	28,873	29,968	30,516	30,874

Guiding Principles for FY19

1.

**Preserve
the RPG
Pool**

2.

**Stay true
to the
Moonshot
Vision**

3.

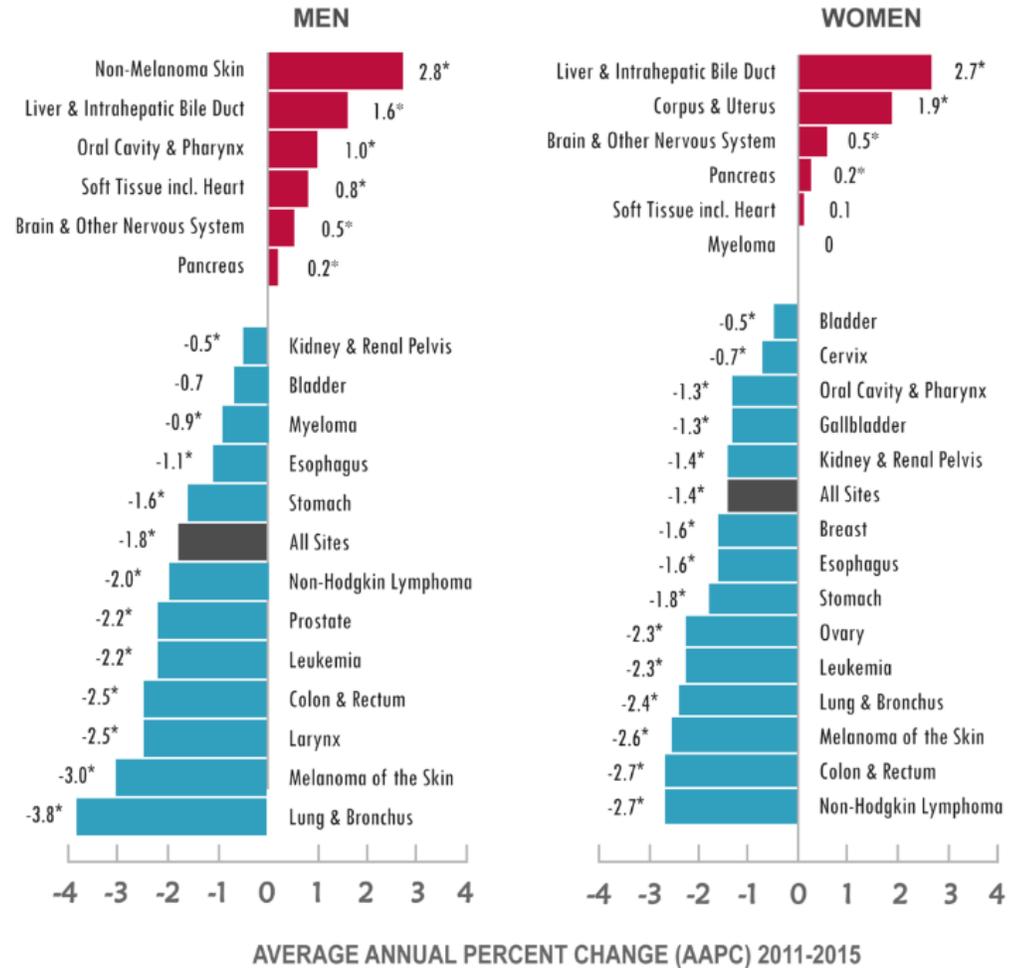
**Continue
to
Prioritize
ESIs**

ANNUAL REPORT TO THE NATION ON THE STATUS OF CANCER

1999 — 2015
**CANCER
DEATH RATES
DECLINED**

FOR MEN, WOMEN, & CHILDREN

NATIONAL TRENDS IN CANCER DEATH RATES



Annual Plan & Budget Proposal

FOR FISCAL YEAR 2020

As director of the National Cancer Institute (NCI), I am pleased to share our *Annual Plan and Budget Proposal for Fiscal Year 2020*.

Having been sworn in to my position a little less than a year ago, this marks my first opportunity to present, in this form, the promising results of our country's investments in biomedical research. This plan directs attention to areas where additional support has unique potential to improve cancer prevention, detection, and treatment.

To place the plan's focus squarely on those most likely to benefit from NCI research, we have included stories of patients. While each story is unique, they are not that different from that of Mike, a patient I treated for acute leukemia.

Mike started feeling poorly in 2016, and a bone marrow biopsy revealed acute myeloid leukemia (AML). I began his initial treatment with aggressive chemotherapy, which caused difficult side effects and required him to spend more than a month in the hospital. After further therapy, Mike fully recovered, and he has been in remission for more than 2 years.



Norman E. Sharpless, M.D., with former patient Mike, whom he treated for acute leukemia in 2016.

cancer research. In addition, NCI has benefitted from concerted, sustained, and bipartisan support from



DIRECTOR'S MESSAGE: A TIME OF GREAT HOPE AND GREAT CHALLENGE



LEADING THE NATION'S PROGRESS AGAINST CANCER



UNDERSTANDING THE MECHANISMS OF CANCER



PREVENTING CANCER



DETECTING & DIAGNOSING CANCER



TREATING CANCER



ADVANCING PUBLIC HEALTH IN CANCER



STRENGTHENING THE CANCER RESEARCH ENTERPRISE



PROFESSIONAL JUDGMENT BUDGET PROPOSAL

The Washington Post
Democracy Dies in Darkness

Researchers use immune-cell 'army' to battle another tough cancer

By Laurie McGinley June 4 [Email the author](#)

Newsweek

HEALTH

WHAT IS IMMUNOTHERAPY?: WOMAN WITH TERMINAL BREAST CANCER SAVED BY PIONEERING TREATMENT

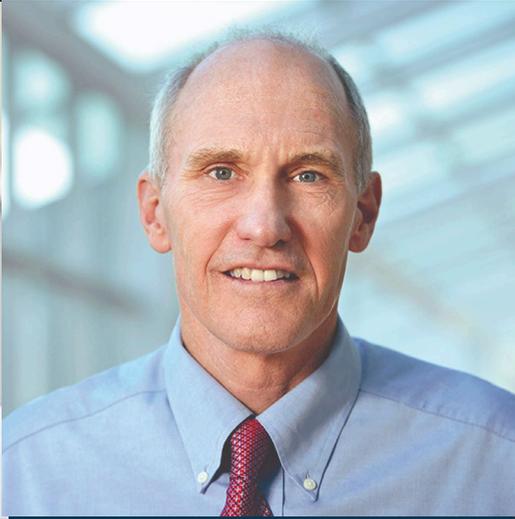
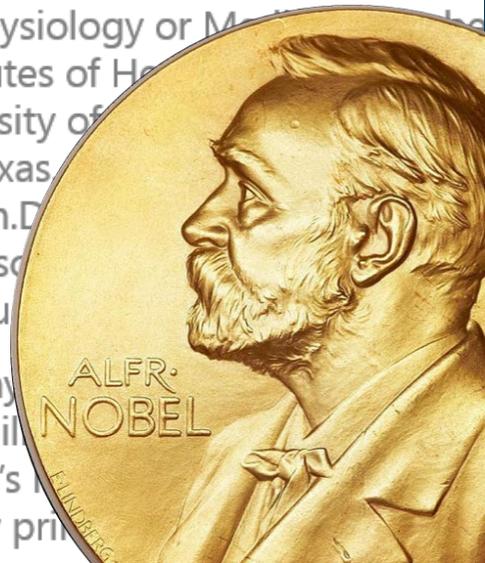
BY KASHMIRA GANDER ON 6/5/18 AT 7:03 AM

Monday, October 1, 2018

NIH grantee wins 2018 Nobel Prize in Physiology or Medicine

The 2018 Nobel Prize in Physiology or Medicine was awarded to National Institutes of Health grantee James Allison, Ph.D., of the University of Texas MD Anderson Cancer Center, Houston, Texas, with Tasuku Honjo, M.D., Ph.D., of the Kyoto Institute, Japan, for their discovery of the inhibition of negative immune checkpoints.

The Royal Swedish Academy of Sciences announced that Allison and Honjo were awarded the prize for "stimulating the inherent ability of the immune system to attack tumor cells this year's Nobel Prize in Physiology or Medicine." Allison established an entirely new principle of cancer treatment.



FDA Approval of Moxetumomab

Moxetumomab Approved by FDA for Hairy Cell Leukemia

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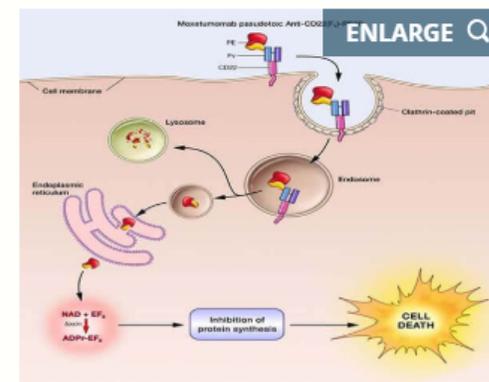
September 14, 2018, by NCI Staff

The Food and Drug Administration (FDA) has approved moxetumomab pasudotox (Lumoxiti), a bacterial toxin-based drug, for the treatment of some patients with hairy cell leukemia (HCL). The approval covers the use of moxetumomab in patients with HCL who have already undergone at least two lines of standard treatments.

The action by FDA makes moxetumomab the first treatment approved for this group of patients. The approval was based on the findings from an 80-patient clinical trial sponsored by the drug's manufacturer, MedImmune.

In the trial, approximately 30% of patients had a complete disappearance of their cancer (complete response) that lasted for a long period, and side effects from the therapy were few and mostly minor. Overall, 75% of patients in the trial had either a partial response or complete response.

Moxetumomab was originally discovered by Ira Pastan, M.D., and colleagues in NCI's [Center for Cancer Research \(CCR\)](#), and later licensed to MedImmune/AstraZeneca for clinical development.



Moxetumomab pasudotox (Moxe) binds CD22 receptors on the surface of cancerous B cells, where it is internalized and processed to release its toxic payload.

Credit: National Cancer Institute

ASpirin in Reducing Events in the Elderly

ASPREE

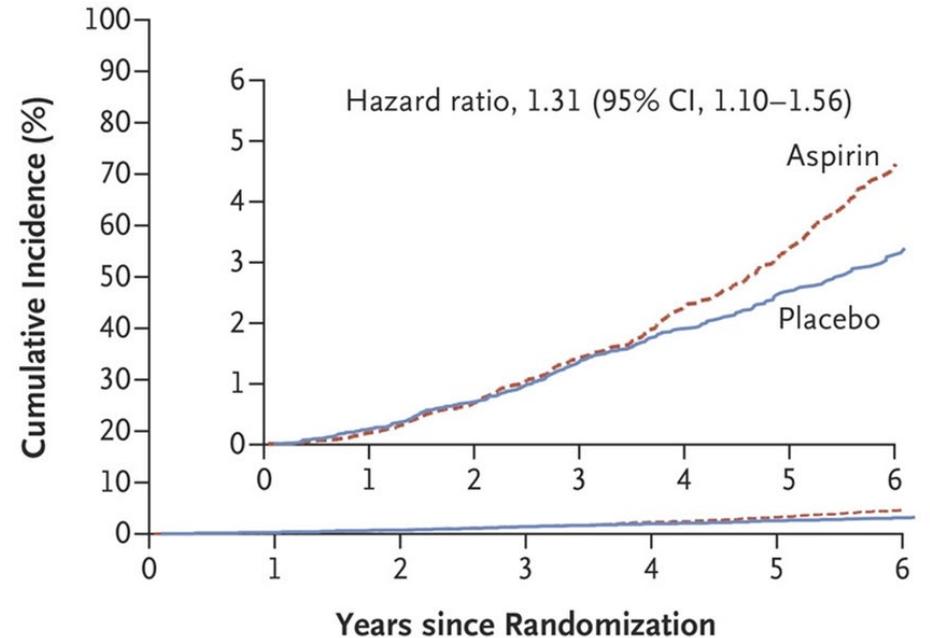
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effect of Aspirin on All-Cause Mortality in the Healthy Elderly

J.J. McNeil, M.R. Nelson, R.L. Woods, J.E. Lockery, R. Wolfe, C.M. Reid, B. Kirpach, R.C. Shah, D.G. Ives, E. Storey, J. Ryan, A.M. Tonkin, A.B. Newman, J.D. Williamson, K.L. Margolis, M.E. Ernst, W.P. Abhayaratna, N. Stocks, S.M. Fitzgerald, S.G. Orchard, R.E. Trevaks, L.J. Beilin, G.A. Donnan, P. Gibbs, C.I. Johnston, B. Radziszewska, R. Grimm, and A.M. Murray, for the ASPREE Investigator Group*

A Death Related to Cancer



No. at Risk

Aspirin	9525	9481	9408	8286	6291	4016	1495
Placebo	9589	9545	9466	8369	6367	4077	1476

FDA approves larotrectinib for solid tumors with NTRK gene fusions

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On November 26, 2018, the Food and Drug Administration granted accelerated approval to larotrectinib (VITRAKVI, Loxo Oncology Inc. and Bayer) for adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, that are either metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or whose cancer has progressed following treatment.

This is the second tissue-agnostic FDA approval for the treatment of cancer.



TCL
THE CANCER LETTER

Inside information on cancer research and drug development

Vol. **44** No. **44**

NOVEMBER 30, 2018

www.cancerletter.com

FDA APPROVES SECOND DRUG FOR A SITE-AGNOSTIC INDICATION; LAROTRECTINIB WAS TESTED ACROSS 17 CANCER TYPES

Vitakvi (larotrectinib) aims to treat a very small group of people—some say fewer than 3,000 new patients a year in the U.S. And since these patients have diseases that soan multiple tumor sites, finding them isn't easy.

→ PAGE 4

HOW WE ISOLATED THE TRK ONCOGENE

→ PAGE 9

HYMAN: "THIS APPROVAL ADDS TO THE GROWING UTILITY OF SEQUENCING IN PATIENTS WITH CANCER"

→ PAGE 12

CANCER GROUPS: CMS PROPOSAL TO LOWER DRUG PRICES WOULD LIMIT ACCESS FOR PATIENTS IN "PROTECTED CLASSES"

→ PAGE 16

REASONS FOR HOPE FOR ACUTE MYELOID LEUKEMIA PATIENTS

→ PAGE 19

6 Ibrutinib Alone or in Combination with Rituximab Produces Superior Progression Free Survival (PFS) Compared with Bendamustine Plus Rituximab in Untreated Older Patients with Chronic Lymphocytic Leukemia (CLL): Results of Alliance North American Intergroup Study A041202

Program: General Sessions

Session: Plenary Scientific Session

Hematology Disease Topics & Pathways:

Diseases, Leukemia, Biological, CLL, Therapies, Elderly, Study relevant, TKI

Sunday, December 2, 2018, 2:00 PM-4:00 PM

Hall AB (San Diego Convention Center)

Jennifer A. Woyach, MD¹, Amy S. Ruppert, MAS, PhD^{2*}, Nyla M Booth^{4*}, Wei Ding, MD, PhD⁵, Nancy L. Bartlett, MD⁶, Daniele Rogers, MD¹⁰, Sameer A. Parikh, MD¹¹, Steven Coutre, MD¹², Nattam, MD¹⁵, Richard A. Larson, MD¹⁶, Harry P. Erba, MD, PhD¹⁷, FRCPC¹⁸, Jim Atkins^{19*}, Jeremy S. Abramson, MD, MMSc²⁰, Richard M. Stone, MD²³, Sumithra J Mandrekar, PhD^{4*} and Joh

LBA-4 A Randomized Phase III Study of Ibrutinib (PCI-32765)-Based Therapy Vs. Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemoimmunotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL): A Trial of the ECOG-ACRIN Cancer Research Group (E1912)

Program: General Sessions

Session: Late-Breaking Abstracts Session

Hematology Disease Topics & Pathways:

survivorship, Leukemia, Diseases, Therapies, CLL, Combinations, Clinically relevant, Lymphoid Malignancies, Quality Improvement

Tuesday, December 4, 2018, 7:30 AM-9:15 AM

Hall AB (San Diego Convention Center)

Tait D. Shanafelt, MD¹, Victoria Wang^{2*}, Neil E. Kay, MD³, Curtis A. Hanson, MD⁴, Susan M. O'Brien, MD⁵, Jacqueline C Barrientos, MD⁶, Harry P. Erba, MD, PhD⁷, Richard M. Stone, MD⁸, Mark R. Litzow, MD³ and Martin S. Tallman, MD⁹

¹Stanford University, Stanford, CA

²Harvard, Boston, MA

³Division of Hematology, Mayo Clinic, Rochester, MN

⁴Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN

⁵UCI Cancer Center, Orange, CA

⁶Department of Medicine, Hofstra North Shore – LIJ School of Medicine, Great Neck, NY

⁷University of Alabama at Birmingham Comprehensive Cancer Center, Birmingham, AL

⁸Dana-Farber Cancer Institute, Boston, MA

⁹Leukemia Service, Department of Medicine, Memorial Sloan-Kettering Cancer Center, New York, NY

Pediatric and AYA Cancer Research

Recent Advances and Ongoing Studies



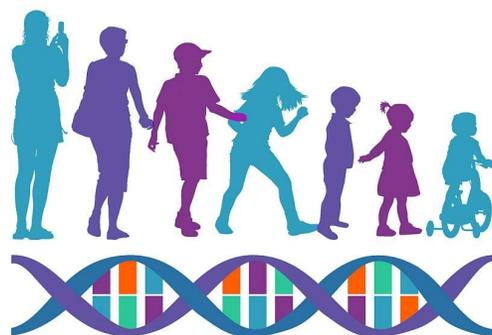
Accelerated Approval for Larotrectinib

Phase II Trial Results: Selumetinib for NF and Plexiform Neurofibromas

NCI-COG Pediatric MATCH

NCI POB Phase 1 Trial: CD19/CD22 CAR T

New Networks and Projects



Pediatric Immunotherapy Discovery and Development Network

Fusion Oncoproteins in Childhood Cancers Consortium

Pediatric Cancer Control Research Across the Lifespan

Relevant Legislation and Implementation



Childhood Cancer STAR Act

RACE for Children Act/FDA Reauthorization Act of 2017



CANCER MOONSHOT

RESEARCH INITIATIVES

Cancer Moonshot Funding Authorized Under the 21st Century Cures Act (dollars in millions)



CTAC *Ad Hoc* Working groups

Glioblastoma

Co-Chairs:

Walter J. Curran, Jr.
M.D., F.A.C.R.

Chi V. Dang, M.D., Ph.D.

Radiation Oncology

- Roster in development
- Kickoff meeting ~Spring 2019

Leadership transitions

- Director, Center for Global Health (CGH)
- Director, Center for Bioinformatics and Information Technology (CBIIT)
- Director, Cancer Therapy Evaluation Program (CTEP)
- Director, Division of Cancer Prevention (DCP)
- Associate Director, Frederick

Key Focus Areas

WORKFORCE DEVELOPMENT

Support the cancer research enterprise by focusing on the workforce of cancer investigators

BASIC SCIENCE

Reaffirm our commitment to basic science to drive novel approaches and technologies

BIG DATA

Increase data aggregation and interpretation to speed our work across the cancer enterprise

CLINICAL TRIALS

Fully realize the power of clinical trials through innovative design, administration, and analyses



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CANCER
INSTITUTE**

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