What I did on my summer vacation

By Ned Sharpless
FDA Therapeutic Oncology Approvals
April thru October 2019

New (7)
• Entectinib for ROS1 NSCLC, NTRK+ tissue agnostic
• Pexidartinib for symptomatic tenosynovial giant cell tumor
• Alpelisib with fulvestrant for PIK3CA-mutated breast cancer
• Eradfitinib for FGFR+ advanced refractory bladder cancer
• Darolutamide for nonmetastatic castration resistant prostate cancer
• Selinexor for refractory myeloma
• NovoTTF-100L System (device) for mesothelioma

Supplements (13)
• Pembrolizumab in metastatic Small Cell Lung Cancer after at least one prior line of therapy
• Ramucirumab in HCC AFP+ treated with sorafenib
• Ruxolitinib for acute GVHD
• Niraparib for ovarian cancer treated with 3 or more prior chemotherapy regimens
• Olaparib for maintenance treatment of patients with deleterious germline or somatic BRCA-mutated ovarian cancer
• Avelumab with axitinib in advanced RCC
• Lenvatinib with pembrolizumab for endometrial
• Ivosidenib for AML
• Venetoclax with obinutuzumab in CLL
• Revlimid with Rituxan in Follicular Lymphoma
• Pembrolizumab in 1st line mNSCLC PDL1+
• Pembrolizumab in metastatic squamous cell carcinoma of the esophagus PD-L1 > 10

New (7) Supplements (13)
Take-aways

- The engine producing new cancer therapies and diagnostics is doing very well.
- Regulatory decisions are extremely complex and must be made with the data available.
- NCI has resources other agencies don’t and intra-governmental collaboration is critical.
### NCI Funding for Fiscal Year 2020

**Dollars in millions**

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<tr>
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<th>House</th>
<th>Senate</th>
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<tbody>
<tr>
<td><strong>Base appropriation</strong></td>
<td>$6,249</td>
<td>$6,157</td>
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<td><strong>Moonshot</strong></td>
<td>$195</td>
<td>$195</td>
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<tr>
<td><strong>Total</strong></td>
<td>$6,444</td>
<td>$6,352</td>
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<td></td>
<td>($300 increase over FY 19)</td>
<td>($208 increase over FY 19)</td>
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Both the House and Senate bills include $50M for Childhood Cancer Data Initiative (CCDI) in the Base appropriation amount.
Cancer Moonshot
Funding Authorized under 21st Century Cures Act (dollars in millions)
Cancer Moonshot Networks

• Individual network meetings November 17-19

• Collaborative meeting of 8 networks November 20 to catalyze inter-network communication and collaboration
Key Focus Areas

**BASIC SCIENCE**
Reaffirm our commitment to basic science to drive novel approaches and technologies

**WORKFORCE DEVELOPMENT**
Support the cancer research enterprise by focusing on the workforce of cancer investigators

**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
Childhood Cancer Research Presidential Initiative

- President’s FY 2020 budget proposal includes $50M.
- NCI held a stakeholder meeting in July 2019.
- Planning is underway in anticipation of funding.
NCI Cloud Resources

• Provide access to popular analysis tools and pipelines, as well as large cancer data sets without need to download

• Allow researchers to bring their own data, tools and pipelines to the Cloud Resources

• Offer workspaces for researchers to save and share their data, results, and analyses

Data

• Access and analyze over 2PB multi-omics cancer data without having to download
• Upload your own data for analysis

Compute

• Perform large scale analysis using the elastic compute power of commercial cloud platforms

Security

• dbGaP-authorized users can access controlled TCGA data
• Systems meet strict Federal security guidelines
Study quantifies impact of NCI-sponsored trials on clinical cancer care
NCI Bottom Line: A Blog About Grants & More

New blog featuring 1-2 posts per month addressing:

- budget- and funding-related milestones
- funding trends and patterns
- emerging policy or fiscal issues
- analyses of NCI’s grants portfolio

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Leadership Vacancies

Director, Division of Cancer Prevention (DCP)
Debbie Winn, Acting

Director, Division of Cancer Biology
Daniel Gallahan, Acting
Jonathan S. Wiest, Ph. D.
Director, Center for Cancer Training
Recent Leadership Appointments

Dinah Singer, Ph.D.
Deputy Director for Scientific Strategy & Development

Meg Mooney, MD, MBA
Associate Director, Cancer Therapy Evaluation Program (CTEP)

Joy Wiszneaukcas
Director, Committee Management Office

Satish Gopal, MD, MPH *(pending NIH approvals)*
Director, Center for Global Health

Oliver Bogler, Ph.D. *(pending NIH approvals)*
Director, Center for Cancer Training
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