Meet-the-Expert Webinar: Careers In Government

Monday, December 7, 2020
2:00-3:00 p.m. ET
Webinar Agenda

2:00-2:10 p.m. ET Overview: Welcome and Introductions
2:10-2:25 p.m. ET Presentation – Jennifer Gao, MD
2:25-2:40 p.m. ET Presentation – Kathryn Lurain, MD, MPH
2:40-2:55 p.m. ET Question and Answer Session
2:55-3:00 p.m. ET Closing Remarks
How to Submit Questions

• Click the “Q&A” icon located on at the bottom of your Zoom control panel
• Type your question in the Q&A box, then click “Send”
• Questions will be answered in the Question & Answer session at the end of the webinar (as time permits)
Webinar Faculty

Chris Langsdorf – Thermo Fisher Scientific

Jennifer Gao, MD – Food and Drug Administration

Kathryn Lurain, MD, MPH – National Cancer Institute
Oncology 2025
A Vision For the Future

Jennifer J. Gao, MD
Associate Director for Education
Oncology Center of Excellence

December 7, 2020
FDA Mission

The Food and Drug Administration is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

Drug and biologics must be proven safe and effective to FDA’s satisfaction before companies can market them in interstate commerce.

FDA does not take into account cost or payment issues.

FDA does not regulate “practice of medicine”.
Oncology Center of Excellence

CDER

Center for Drug Evaluation and Research

CBER

Center for Biologics Evaluation and Research

CDRH

Center for Devices and Radiological Health

REGULATORY REVIEW

REGULATORY SCIENCE

EDUCATION

STAKEHOLDER ENGAGEMENT

REGULATORY POLICY
Office of Oncologic Diseases: Clinical Divisions

- Division of Oncology 1
- Division of Oncology 2
- Division of Oncology 3
- Division of Hematologic Malignancies 1
- Division of Hematologic Malignancies 2

Oncology center of excellence
Drug Development Lifecycle

- IND: Investigational New Drug Application
- NDA: New Drug Application
- BLA: Biologic Licensing Application
- FAERS: FDA Adverse Event Reporting System
Striking the Balance

Flexible, Efficient, Interactive

“Too Cautious!
Stifling Innovation!
Reduce regulatory burden!”

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Reduce regulatory burden!”

Consistent, Thorough, Independent
2019 Oncology Approvals

- Total: 49
- NMEs/Original BLAs: 11
- Supplements (additional indications or patient populations): 27
- Premarket Approval Applications (PMA): 4
- Biosimilars: 3
- PMA Modifications: 4
OCE Projects
PROJEC1
SOCRATES
Interagency Oncology Task Force Fellowship

- Eligibility: apply through the NCI IOTF program
- Duration: 1-2 years
- Clinical track: up to 2 fellows per year
Project Renewal

FDA mission: promote and protect public health

Project Renewal: accurate and up-to-date information to inform prescribing decisions

Establish repeatable, objective, scientific process  Engage and collaborate with oncology community  Educate on regulatory policy & product label
FDA takes first action under new international collaboration with Australia and Canada designed to provide a framework for concurrent review of cancer therapies.

Project Orbis

- Global collaboration
- Launched Oct 2004
- September 17, 2019: first action under Project Orbis with TGA (Australia) and HC (Canada)
- Utilization of RTOR and AAid programs
Project Community
Project Silver

Improving the evidence base for treating older adults with cancer

- Regulatory policy
- Advocacy and outreach
- Global engagement
- Research and publications
Project Patient Voice

- Pilot
- Publicly available website
- Describes patient reported, longitudinal, symptomatic adverse events
- Data collected from cancer clinical trials for approved drugs
- Sponsors voluntarily provide existing PRO data (i.e. submitted with NDA/BLA) for consideration

All Patients Who Completed the Questionnaire Described Their Experience of NAUSEA During the First 24 Weeks of Treatment:

Figure 1 shows the proportion of patients reporting the frequency of NAUSEA at each time point. For example, at week 3, 30% of patients taking drug reported nausea (ranging from rarely to almost constantly). The range of patients who reported having any amount of nausea during the first 24 weeks while taking drug was between 17% - 50%.

Figure 1. Patient-Reported Nausea During the First 24 Weeks on Treatment
Project Equity

- Develop policy/guidance
- Increase enrollment in oncology clinical trials
  - Generate evidence throughout life cycle of drug (i.e., pre- and post-approval)
- Foster internal and external research & policy collaborations
- Integrate diverse perspectives in regulatory activities
- Integrate across all OCE programs
Project Facilitate

Assisting healthcare providers with requests for access to investigational oncology products

DO YOU NEED HELP SUBMITTING A SINGLE PATIENT IND EXPANDED ACCESS (EA) REQUEST (ALSO KNOWN AS COMPASSIONATE USE) FOR A PATIENT WITH CANCER?

...FDA’s Oncology Center of Excellence (OCE) can help:

- Locate IRB resources
- Find an EA contact for a drug/biotech company
- Complete Form FDA 3926

Phone: (240) 402-0004
Email: OncProjectFacilitate@fda.hhs.gov

Patients: Talk to your healthcare provider to discuss whether expanded access is an appropriate option.
Academics and Publications
One Pill.
One Life.
One Career.

One pill can transform a life.
One life can transform many.
One career can transform that pill,
that life, that many.

Transformative Careers. FDA Oncology.

Further information regarding careers at FDA Oncology:
futureofthemeonc@fda.hhs.gov
Careers at the National Cancer Institute

Why I love working at the Disneyland of Clinical Research

Kathryn Lurain, MD, MPH
Assistant Research Physician
HIV and AIDS Malignancy Branch

December 7, 2020
The NIH Bethesda Campus

President Roosevelt on October 31, 1940
The NCI Intramural Research Program

National Cancer Institute

Extramural
• Grants
• Programs
• Centers

Intramural

Intramural Research Program (IRP)

CCR

DCEG

NATIONAL CANCER INSTITUTE
Center for Cancer Research

@NCIResearchCtr
Who is CCR?

- 23 Basic Science Laboratories
- 18 Clinical Research Branches
- 6 Goal/Theme-Oriented Programs

238 Principal Investigators in Bethesda and Frederick

- ~300 staff scientists/staff clinicians
- ~500 technical lab staff
- ~900 postdoctoral/clinical fellows
- ~250 postbaccalaureate/predoctoral students
- ~500 summer students
Our MISSION
To improve the lives of cancer patients by solving important, challenging and neglected problems in cancer research, prevention and patient care

Our VISION
To create the cancer medicines of tomorrow
The NCI Intramural Clinical Research Program

- NIH is the largest clinical research center in the world
- The NIH clinical center is not a regular hospital
  - Dedicated to patient-intensive clinical research and developing new approaches for prevention, diagnosis and treatment of cancer
- Opportunity for **bench-to-bedside** and **bedside-to-bench research**
- Clinical training for next generations of scientists
CCR Training for Young Clinicians & Scientists at Many Levels

- Undergraduate Scholarship Program
- Summer Internship Program (SIP)
- Postbac Programs
- GPP Programs
- Postdoc Programs
- GME Programs/ Clinical Fellows
- Clinical Electives Program
- Medical Research Scholars Program
- PhD or MD/DDS Degree
- Postdoctoral Training
- Transition to Junior Faculty

Age 17
High School
College (Undergrad)
Gap Years
Graduate, Medical or Dental School
Postdoctoral Training
Transition to Junior Faculty
Examples of Groundbreaking CCR Research

- Combination chemotherapy
- Anti-retroviral therapies
- Discovery of TGFβ
- HPV vaccine development
  - Early gene therapy
  - Pioneering immunotherapy
  - Development of immunotoxins
- Molecular classification of lymphoma and renal cancer
  - Epigenetics and chromatin biology
  - Basic Immunology
  - Imaging technology (SKY, UroNav)
  - Laser capture microdissection
  - Discovery and use of KGF (Kepivance)
# CCR Drug Approvals

<table>
<thead>
<tr>
<th>Status</th>
<th>Drug Name</th>
<th>Drug Type</th>
<th>Target</th>
<th>Investigator/s</th>
<th>Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approved for marketing</td>
<td>Avelumab</td>
<td>Anti PD-L1 Antibody</td>
<td>Merkel Cell Carcinoma</td>
<td>Gulley/Schlom</td>
<td>March 2017</td>
</tr>
<tr>
<td>Approved for marketing</td>
<td>Yescarta</td>
<td>CD19 CAR T</td>
<td>B-Cell Lymphoma</td>
<td>Kochenderfer/Rosenberg</td>
<td>October 2017</td>
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<tr>
<td>Approved for marketing</td>
<td>Lumoxiti</td>
<td>Anti CD22-toxin</td>
<td>Hairy Cell Leukemia</td>
<td>Pastan/Kreitman</td>
<td>September 2018</td>
</tr>
<tr>
<td>Approved for marketing</td>
<td>Selumetinib</td>
<td>MEK inhibitor</td>
<td>NF1</td>
<td>Widemann/Gross</td>
<td>April 2020</td>
</tr>
<tr>
<td>Approved for marketing</td>
<td>Pomalidomide</td>
<td>Immunomodulator</td>
<td>Kaposi Sarcoma</td>
<td>Yarchoan</td>
<td>May 2020</td>
</tr>
<tr>
<td>Breakthrough Therapy</td>
<td>LN-145</td>
<td>TIL therapy</td>
<td>Advanced cervical cancer</td>
<td>Surgery Branch</td>
<td>May 2019</td>
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<tr>
<td>Breakthrough Therapy</td>
<td>CD22</td>
<td>CD22 CAR T</td>
<td>B-cell Acute Lymphoblastic Leukemia</td>
<td>Shah</td>
<td>August 2019</td>
</tr>
<tr>
<td>Breakthrough Therapy</td>
<td>MK-6482</td>
<td>Hypoxia-inducible factor-2 alpha inhibitor</td>
<td>von Hippel-Lindau disease-associated renal cell carcinoma</td>
<td>Linehan/Srinivasan</td>
<td>July 2020</td>
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<tr>
<td>Orphan Drug</td>
<td>Zotiraciclib</td>
<td>Kinase inhibitor</td>
<td>Glioma</td>
<td>Wu</td>
<td>December 2019</td>
</tr>
</tbody>
</table>
The story of pomalidomide in Kaposi sarcoma
The story of pomalidomide in Kaposi sarcoma

Activity of Thalidomide in AIDS-Related Kaposi’s Sarcoma


Pomalidomide plus low-dose dexamethasone in myeloma refractory to both bortezomib and lenalidomide: comparison of 2 dosing strategies in dual-refractory disease

Martha Q. Lacy,1 Jacob B. Allred,2 Morie A. Gertz,1 Suzanne R. Hayman,1 Kristen Detweiler Short,1 Francis Buadi,1 Angela Dispenzieri,1 Shaji Kumar,1 Philip R. Greipp,1 John A. Lust,1 Stephen J. Russell,1 David Dingli,1 Steven Zelenrust,1 Rafael Fonseca,3 P. Leif Bergsagel,3 Vivek Roy,4 A. Keith Stewart,3 Kristina Laumann,2 Sumithra J. Mandrekar,2 Craig Reeder,3 S. Vincent Rajkumar,1 and Joseph R. Mikhail3
The story of pomalidomide in Kaposi sarcoma

Pomalidomide for Kaposi Sarcoma in People With or Without HIV

The safety and scientific validity of this study is the responsibility of the study sponsor and investigators. Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our disclaimer for details.

Sponsor:
National Cancer Institute (NCI)

Information provided by (Responsible Party):
National Institutes of Health Clinical Center (CC) / National Cancer Institute (NCI)
The story of pomalidomide in Kaposi sarcoma

Restoration of immune surface molecules in Kaposi sarcoma-associated herpes virus infected cells by lenalidomide and pomalidomide

David A. Davis¹,*, Suraj Mishra¹,*, Holda A. Anagho¹, Ashley I. Aisabor¹, Prabha Shrestha¹, Victoria Wang¹, Yuki Takamatsu¹, Kenji Maeda¹, Hiroaki Mitsuya¹, Jerome B. Zeldis² and Robert Yarchoan¹

Pomalidomide increases immune surface marker expression and immune recognition of oncovirus-infected cells


ONCOIMMUNOLOGY
2019, VOL. 8, NO. 2, e1546544 (16 pages)
https://doi.org/10.1080/2162402X.2018.1546544

ORIGINAL RESEARCH
OPEN ACCESS
Check for updates

NIH
NATIONAL CANCER INSTITUTE
Center for Cancer Research
The story of pomalidomide in Kaposi sarcoma

Pomalidomide combined with chemotherapy...

Novel combination immunotherapy approaches...

Immunomodulatory agents for new virus-driven cancers...

**NCI Protocol #:** 10363  
**Local Protocol #:** pending  
**ClinicalTrials.gov Identifier:** TBD

**TITLE:** A Phase I Study of pomalidomide and nivolumab in patients with virus-associated malignancies with or without HIV

**Coordinating Center:** NCICCR / NCI Center for Cancer Research  
**Principal Investigator:** Kathryn Lurain, MD, MPH  
HIV and AIDS Malignancy Branch  
National Cancer Institute

**SARCOMA**

A phase I trial of pomalidomide in combination with liposomal doxorubicin in patients with Kaposi sarcoma with or without other KSHV-associated diseases.

Ramya Ramaswami, Kathryn Anne Lurain, Anaida Widell, Priscilla Hermon Goncalves, Irene Ekwedie, William Douglas Figg, Cody J. Peer, Ralph Mangusun, Jomy George, Seth M. Steinberg, Vikram Khetani, Denise Whitby, Thomas S. Uldrick, Robert Yarchooan
The story of pomalidomide in Kaposi sarcoma

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Center for Cancer Research

@NCIResearchCt
The NCI Intramural Research Program
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The Society for Immunotherapy of Cancer (SITC) Cancer Immunotherapy Winter School is a comprehensive cancer immunotherapy education program, led by experts in the field. Participants will improve their understanding of the core principles of tumor immunology and cancer immunotherapy and examine developing areas in the field.

Attendees are able to tailor their learning experience as the program offers both clinical- and research-focused tracks. In addition to deepening their understanding of integral facets of the field of cancer immunotherapy, attendees will expand their professional network, developing new relationships with faculty and other thought leaders in this intimate setting.

Register for the Virtual Program at: https://www.sitcancer.org/education/winter-school
Career Connections Online Job Board

The Career Connections Online Job Board gives job seekers the key information on talent seekers and the job openings they need to make the next step in their career, including:

• Search jobs by location
• Set personal notifications and preferences
• Learn more about talent seekers
• Directly apply for open positions

Questions/Comments: connectED@sitcancer.org