Oncology Center for Excellence (OCE)

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FDA
Oncology Center of Excellence (OCE)

• Established in January 2017 as a part of 21st Century CURES Act

• Mission: To achieve patient-centered regulatory decision-making through innovation and collaboration
Oncology Center of Excellence (OCE)

- Director
  - Deputy Director
  - AD Oncology Cell & Gene Therapies
  - AD Oncology Medical Devices
  - AD Oncology In Vitro Diagnostics
  - AD Pediatric Oncology
  - AD Oncology Regulatory Science & Informatics (INFORMED)
  - AD Oncology Patient Outcomes
  - AD Immuno-Oncology
  - AD Oncology Regulatory Affairs
  - AD Research Strategy & Partnerships

AD = Associate Director
OCE Initiatives

Regulatory Science

Outreach Workshops/Symposia

Education

Science-Based Regulatory Policy

Regulatory Review
OCE Regulatory Review

• Provide clinical review via Medical Oncology Review (MORE) Team

• Regulatory authority for marketing authorization remains in home Centers (CDER, CBER, CDRH)

• MORE teams required for products under expedited programs (Breakthrough, Fast Track, Regenerative Medicine, Priority Review, Accelerated Approval)

• MORE teams may be requested for any other regulatory submission at the discretion of the home Center
OCE MORE team

• Team makeup:
  – Primary clinical reviewer
  – Clinical team leader
  – Division Director (CDER)/Branch Chief (CBER)
  – OCE Director or designee

• Goal: provide both disease expertise and regulatory expertise within each MORE team

• May be made up of reviewers from multiple Centers to provide needed breadth of expertise
2017 OCE Accomplishments

– Took part in review and approvals of cancer products across the 3 centers that review drugs, biologics and devices
  • Clinical review conducted for:
    – 12 new drugs and biologics for treatment of cancer
    – 1 medical device (i.e., PMA) to diagnose or identify a patient for treatment
  • Provided subject matter and regulatory expertise on over:
    – a dozen submissions for breakthrough designation
    – 100 key development meetings

– Created cross-center forum: OCE clinical rounds include reviewers from all 3 centers (CDER, CBER and CDRH)
2017 OCE Accomplishments, cont’d

– Interaction with NIH/National Cancer Institute (NCI)/Cancer Therapy Evaluation Program (CTEP)
  • Quarterly meetings with CTEP
  • FDA Liaison to NCI’s Cooperative groups
  • Inclusion of NCI/CTEP on workshops

– Outreach with patient advocacy groups and oncology organizations
  • 9 Workshops and over 20 symposia
  • OCE approval bursts, podcasts, Twitter account, webpage
# OCE Regulatory Review: 2017 Approvals in Cancer

*Drugs in red are for “New molecular entities”*

<table>
<thead>
<tr>
<th>Cancer type</th>
<th>Drugs</th>
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<tbody>
<tr>
<td>Breast</td>
<td>abemaciclib, palbociclib, <em>ribociclib</em>, pertuzumab, neratinib</td>
</tr>
<tr>
<td>Bladder</td>
<td>pembrolizumab, avelumab, <em>durvalumab</em>, nivolumab</td>
</tr>
<tr>
<td>Gastric</td>
<td>pembrolizumab, nivolumab, regorafenib</td>
</tr>
<tr>
<td>Kidney</td>
<td>cabozantinib, sunitinib</td>
</tr>
<tr>
<td>Lung</td>
<td>alectinib, dabrafenib and trametinib, ceritinib, pembrolizumab, <em>brigatinib</em>, osimertinib</td>
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<tr>
<td>Melanoma</td>
<td>nivolumab</td>
</tr>
<tr>
<td>Merkel Cell</td>
<td>avelumab</td>
</tr>
<tr>
<td>Ovarian</td>
<td>olaparib, <em>niraparib</em></td>
</tr>
<tr>
<td>Tissue agnostic</td>
<td>pembrolizumab</td>
</tr>
<tr>
<td>Leukemia</td>
<td>gemtuzumab ozogamicin, liposome-encapsulated daunorubicin and cytarabine, <em>enasidenib</em>, <em>tisagenlecleucel</em>, inotuzumab ozogamicin, blinatumomab, midostaurin, bosutinib, dasatinib</td>
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<tr>
<td>Lymphoma</td>
<td>acalabrutinib, <em>axicabtagene ciloleucel</em>, pembrolizumab, brentuximab vedotin, copanlisib, obinutuzumab, rituximab and hyaluronidase</td>
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<tr>
<td>Multiple Myeloma</td>
<td>lenalidomide</td>
</tr>
<tr>
<td>Biosimilars</td>
<td>Ogivri (trastuzumab-dkst), Mvasi (bevacizumab-awwb)</td>
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OCE Community Outreach

– Community oncologists
– Patient groups
– Under represented groups (trial disparities project)
– Internship programs for summer high school students
OCE Regulatory Science

- New regulatory approaches to expedite oncology product development:
  - Facilitate efficient testing of novel drug combinations (e.g., master protocols in dose-finding and activity-estimating trials)
  - Streamline regulatory review processes for breakthrough products

- Methods to incorporate patients along the drug development continuum (Patient-Focused Drug Development)
  - Foster rigorous patient outcome measurement in cancer clinical trials and decision making

- Real world evidence in oncology product development
OCE Workshops

Events in 2017

• December 1, 2017: Assessment of Cardiovascular Toxicities in Immuno-Oncology Trials.

• November 28, 2017: Defining Disease Recurrence and Harmonizing Conduct in Adjuvant Bladder and Kidney Cancer Trials.

• November 13, 2017: Partners in Progress: Cancer Patient Advocates and FDA.

• November 6, 2017: FDA-ASCO Public Workshop: Geriatric Oncology Workshop.

• October 10, 2017: FDA-AACR Liquid Biopsies in Oncology Drug and Device Development Part II.

• July 20, 2017: FDA-AACR Oncology Dose Finding Workshop

• May 3-5, 2017: Accelerating Anticancer Agent Development and Validation Workshop

• April 25, 2017: FDA/C-Path Consortium Second Annual Workshop on Clinical Outcomes Assessments in Cancer Clinical Trials.

• Feb 23, 2017: FDA-ASCO: Hematology and Oncology Fellows Day Workshop
OCE: 2018 and beyond

Strengths and challenges of the current operating model:

• FDA colleagues value the oncology expertise that OCE delivers through its education and professional development programs and direct engagement with Centers on regulatory reviews

• External partners value the increased cohesiveness, responsiveness, and expertise that OCE brings

• FDA colleagues’ challenges with OCE derive from inconsistencies in review decision criteria and differing capabilities and cultures across OCE and Centers and process inefficiencies in joint reviews
OCE: 2018 and beyond

Strategic mandate in near term:

• Develop an integrated and cohesive strategic agenda for oncology policy, regulatory science research, and external engagement.

• Serve as “One FDA” voice in oncology and as a first point of contact in oncology for external partners

• Provide bespoke support to clinical oncology reviews including priority, fast-track (FT), breakthrough (BT) and accelerated approval applications and jointly selected INDs and pre-INDs
OCE: 2018 and beyond

• Mandate would be best achieved in next 2-3 years by maintaining the current construct with OCE in Office of the Commissioner
  – dedicated funding for staff and programs
  – comprised primarily of Associate Directors and RPMs

• This near-term construct as transition to potential end-state structures
Thank you!