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| |  |  |  | | --- | --- | --- | | |  |  | | --- | --- | | |  | | --- | | **Greetings from FDA Oncology****Ever wonder who works in oncology at the FDA? Or what happens behind the scenes?** We are a diverse group of over 100 oncologists and are excited to introduce ourselves, explain what we do, and engage with you!    This newsletter provides a summary of FDA [Oncology Center of Excellence (OCE)](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDAsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL2ZkYS1vcmdhbml6YXRpb24vb25jb2xvZ3ktY2VudGVyLWV4Y2VsbGVuY2U_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDgyMy44MTUzNzY2MSJ9.jrTO55dpkYkY4r-jx-nXhPxl9-hNbRKU7i9s8ZdahNk/s/1256231544/br/224676891584-l) upcoming public events, educational opportunities, and recent oncology product approvals. Events are free and everyone is welcome to attend — we hope to see you there!    Please share this newsletter with your hematology/oncology fellows, faculty, staff, and anyone interested in learning more about what we do at the OCE! | | | |

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Meeting & Registration Information](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvbmV3cy1ldmVudHMvZmRhLW1lZXRpbmdzLWNvbmZlcmVuY2VzLWFuZC13b3Jrc2hvcHMvc2Vjb25kLWFubnVhbC1mZGEtYXNjby13b3Jrc2hvcC1nZXR0aW5nLWRvc2FnZS1yaWdodC1zZXB0ZW1iZXItNi03LTIwMjMtMDkwNjIwMjM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDgyMy44MTUzNzY2MSJ9.SeMZqr8AI_D_bD91eDUZtUbsLzngyx6LfPrXIAIw9lg/s/1256231544/br/224676891584-l).  **Watch on YouTube:** [Conversation on Cancer: National Black Family Cancer Awareness Week – Engaging the Generations public panel discussion.](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDQsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LnlvdXR1YmUuY29tL3dhdGNoP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSZ2PVBLMXpvUlg3TWhBIiwiYnVsbGV0aW5faWQiOiIyMDIzMDgyMy44MTUzNzY2MSJ9.CR8WpvcJYU19N0uNX-OY-nC3dZ7mIN9zJYrNlhP3M_0/s/1256231544/br/224676891584-l)  **Watch on YouTube**: [Conversations on Cancer: Cancer Misinformation:Truth or Consequences](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDUsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LnlvdXR1YmUuY29tL3dhdGNoP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSZ2PWlUYnN4SjVPTkxZIiwiYnVsbGV0aW5faWQiOiIyMDIzMDgyMy44MTUzNzY2MSJ9.XzYj1vLf6DvpNgzo5kiQXABCohKb4jh0Y8-HlOQ_zyc/s/1256231544/br/224676891584-l)  For a full list of our past and upcoming meetings and workshops, check out this website: [OCE Meetings and Workshops.](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDYsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL29jZS1tZWV0aW5ncy1hbmQtd29ya3Nob3BzP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA4MjMuODE1Mzc2NjEifQ.JCUfUYTTUsRIx0KOaJQ2HXzpdB_EcT0vTuMH3RenurE/s/1256231544/br/224676891584-l) Project Socrates: Educational Opportunities  |  | | --- | | OCE has many free educational programs for hematology/oncology fellows, junior faculty, basic and translational scientists, and anyone interested in learning more about regulatory science and drug development. This includes workshops, fellowships, and webinars. Check out our [**Project Socrates**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDcsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3Qtc29jcmF0ZXM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDgyMy44MTUzNzY2MSJ9.TirZK3EgJu3mjgmD1FV_mC8pJMHyQEwhJzRyMztxeVA/s/1256231544/br/224676891584-l) website for more information!  [**Project Livin’ Label Episodes 9 and 10**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDgsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3QtbGl2aW4tbGFiZWw_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDgyMy44MTUzNzY2MSJ9.NPIILprvlGHkP4ipyMIzptP-l7m0gJ8pkVD9cXDn7hA/s/1256231544/br/224676891584-l) are now available! Listen to the “behind the scenes” discussions of the development and backstory of neoadjuvant nivolumab in lung cancer and ivosidenib for newly diagnosed acute myeloid leukemia. You can also find the other episodes online with free CME credit offered by AACR for each!  **Oncology fellowship program directors:** if you are interested in having FDA Oncology speak to your fellows, reach out to us at [**projectsocrates@fda.hhs.gov**](mailto:projectsocrates@fda.hhs.gov)**!** Recent FDA Oncology Approvals We recently approved these oncology products – take a look at the product labeling to learn about indications, dosage and administration, adverse reactions, trial design, efficacy results, and much more!  **August 14, 2023:** [Melphalan/Hepatic Delivery System](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDksInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL29uY29sb2d5LWNhbmNlci1oZW1hdG9sb2dpYy1tYWxpZ25hbmNpZXMtYXBwcm92YWwtbm90aWZpY2F0aW9ucz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwODIzLjgxNTM3NjYxIn0.GZIkt3mClak6O1MLB9_tyJKBd5B7uozXJcFaY9-UQn4/s/1256231544/br/224676891584-l) as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph node, subcutaneous tissue, or long that is amenable to resection or radiation. Regular Approval.  **August 14, 2023:** [Elranatamab-bcmm](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTAsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2ZkYS1ncmFudHMtYWNjZWxlcmF0ZWQtYXBwcm92YWwtZWxyYW5hdGFtYWItYmNtbS1tdWx0aXBsZS1teWVsb21hP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA4MjMuODE1Mzc2NjEifQ.eoWZHrDRHxk5j8_gx4Hfc-5a3-5S98lUV9BbnKfkmW4/s/1256231544/br/224676891584-l) for adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy. Accelerated Approval.  **August 11, 2023:** [Niraparib](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTEsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2ZkYS1hcHByb3Zlcy1uaXJhcGFyaWItYW5kLWFiaXJhdGVyb25lLWFjZXRhdGUtcGx1cy1wcmVkbmlzb25lLWJyY2EtbXV0YXRlZC1tZXRhc3RhdGljLWNhc3RyYXRpb24_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDgyMy44MTUzNzY2MSJ9.q_7gfRk8fB2EuitlMrirlRcTLVTn4PSsC6ZLFiCg0-Q/s/1256231544/br/224676891584-l) and abiraterone with prednisone for adult patients with deleterious or suspected deleterious BRCA-mutated castration-resistant prostate cancer. Regular Approval.  **August 9, 2023**: [Talquetamab-tgvs](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTIsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2ZkYS1ncmFudHMtYWNjZWxlcmF0ZWQtYXBwcm92YWwtdGFscXVldGFtYWItdGd2cy1yZWxhcHNlZC1vci1yZWZyYWN0b3J5LW11bHRpcGxlLW15ZWxvbWE_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDgyMy44MTUzNzY2MSJ9.iXmsJFMMpWoJWQCNLAcyV6u9auZfk7gxyjHpAw03ZSc/s/1256231544/br/224676891584-l) for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy. Accelerated Approval.  **August 8, 2023:** [Pralsetinib](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvZHJ1Zy1hcHByb3ZhbHMtYW5kLWRhdGFiYXNlcy9mZGEtYXBwcm92ZXMtcHJhbHNldGluaWItbm9uLXNtYWxsLWNlbGwtbHVuZy1jYW5jZXItcmV0LWdlbmUtZnVzaW9ucz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwODIzLjgxNTM3NjYxIn0.k0EPpBiYIlMSPUPH1cfp6P590iIiiL7RLJNeCbqom2M/s/1256231544/br/224676891584-l) for adult patients with metastatic RET-fusion-positive non-small cell lung cancer. Regular Approval.  **Interested in learning more?**Tune into our [**FDA Oncology Podcast**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTQsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2RydWctaW5mb3JtYXRpb24tc291bmRjYXN0LWNsaW5pY2FsLW9uY29sb2d5LWRpc2NvP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA4MjMuODE1Mzc2NjEifQ.kxrXmBy5SuI26JPd832DHLlhr58QPn3Vj8JhykoMvZU/s/1256231544/br/224676891584-l). You can also take a  look at this website [**How to Use Product Labeling**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTUsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL2hvdy1kby1pLXVzZS1wcmVzY3JpcHRpb24tZHJ1Zy1sYWJlbGluZz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwODIzLjgxNTM3NjYxIn0.PqobBCiEkH9ALwMit_iMPwUKBkvpKzjyXr27Dmujbrc/s/1256231544/br/224676891584-l) and find a full list of [**FDA oncology approvals**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTYsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL29uY29sb2d5LWNhbmNlci1oZW1hdG9sb2dpYy1tYWxpZ25hbmNpZXMtYXBwcm92YWwtbm90aWZpY2F0aW9ucz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwODIzLjgxNTM3NjYxIn0.-L4A9wKFzc4_4PZw6v9P4elxVm4-BTK4WRYjs6Pixbk/s/1256231544/br/224676891584-l) online! OCE Spotlight – Get to Know Us! |  |  |  |  | | --- | --- | --- | | Kelly Norsworthy |  | **Kelly Norsworthy**is a medical oncologist and hematologist and the Deputy Division Director for the Division of Hematologic Malignancies I. Her expertise is in development of novel therapeutics for myeloid malignancies. In her spare time, she enjoys spending time with her family outdoors by the water, at sporting events, and at the theater in the Annapolis, Baltimore, and DC area. |  |  | | --- | |  |  |  |  |  | | --- | --- | --- | | **Oladimeji (Ladi) Akinboro** is a medical oncologist and clinical reviewer on the thoracic/head and neck cancer team. He has research interests in clinical trial design and cancer immunotherapy. In his spare time, he enjoys hiking/camping with friends, reading history books and visiting history museums, running, and playing soccer (and cheering for FC Barcelona!). |  | Ladi | | | | |

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