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| The OCE Owl |

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| June 2023 |

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| ****Greetings from FDA Oncology****This newsletter provides a summary of FDA Oncology Center of Excellence (OCE) upcoming public events, educational opportunities, and recent oncology product approvals. The events are free and everyone is welcome to attend – we hope to see many of you there!  |

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| Upcoming Public FDA Oncology Events**Thursday, June 15, 2023, 2:30-4:00 PM ET:** [*Conversation on Cancer: National Black Family Cancer Awareness Week – Engaging the Generations public panel discussion*](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDAsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvbmV3cy1ldmVudHMvZmRhLW1lZXRpbmdzLWNvbmZlcmVuY2VzLWFuZC13b3Jrc2hvcHMvanVuZS0xNS0yMDIzLWNvbnZlcnNhdGlvbnMtY2FuY2VyLW5hdGlvbmFsLWJsYWNrLWZhbWlseS1jYW5jZXItYXdhcmVuZXNzLXdlZWstZW5nYWdpbmctZ2VuZXJhdGlvbnM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDUyNC43NzIyNjk5MSJ9.pTzpsYOurqbRbgDzONdXTx00299JIT26TAJKtBwdrIM/s/1256231544/br/203655531446-l);[Registration](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDEsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LnN1cnZleW1vbmtleS5jb20vci9YU0ZGQjIzP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA1MjQuNzcyMjY5OTEifQ.ughgFdeS53sy0r39ooghF3YrTTD7T0d4lgbHl43IWyg/s/1256231544/br/203655531446-l)**Tuesday, June 27, 2023, 11:00-3:00 PM ET:** [*FDA Oncology Center of Excellence Presents 8th Annual Clinical Outcome Assessment in Cancer Clinical Trials Workshop – Overall Side Effect Impact: A Core Oncology Patient-Reported Outcome*](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDIsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvbmV3cy1ldmVudHMvZmRhLW1lZXRpbmdzLWNvbmZlcmVuY2VzLWFuZC13b3Jrc2hvcHMvZmRhLXdvcmtzaG9wLTh0aC1hbm51YWwtY2xpbmljYWwtb3V0Y29tZS1hc3Nlc3NtZW50LWNhbmNlci1jbGluaWNhbC10cmlhbHMtd29ya3Nob3AtMDYyNzIwMjM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDUyNC43NzIyNjk5MSJ9.erNTbnLiY8F1InxrGQ6pPRp-_n1UcFaNIPfggPUwUqg/s/1256231544/br/203655531446-l); [Registration](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vZmRhLnpvb21nb3YuY29tL3dlYmluYXIvcmVnaXN0ZXIvV05fcGdTdG5MZlhUcjJQYUlMYkZlbnItQT91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNTI0Ljc3MjI2OTkxIn0.PRDhWkENBkQ223sgwzDvmSO7SKFyXTQQ4AAosM1T_So/s/1256231544/br/203655531446-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.eyJidWxsZXRpbl9saW5rX2lkIjoxMDQsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL29jZS1tZWV0aW5ncy1hbmQtd29ya3Nob3BzP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA1MjQuNzcyMjY5OTEifQ.QNBVaNfg2U-MWv0OG0W4mJ1mkH0Qkk1ai5gH08Kem2M/s/1256231544/br/203655531446-l) Project Socrates: Educational Opportunities

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| Socrates SquareOCE has several free educational programs for hematology oncology fellows, junior faculty, basic and translational scientists, or anyone interested in learning more about regulatory science and drug development. This includes workshops, fellowships, and webinars. Check out our[Project](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDUsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3Qtc29jcmF0ZXM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDUyNC43NzIyNjk5MSJ9.CaLFRoSSdqF6GuBUELKndpU0LJqDPWPbgp2KdsSgh44/s/1256231544/br/203655531446-l) [S](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDYsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3Qtc29jcmF0ZXM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDUyNC43NzIyNjk5MSJ9.I8B8ZiBnp8ZdKYBVhkkiLaEQF5o0EDPdP2ZurAjqYi8/s/1256231544/br/203655531446-l)[ocrates](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDcsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3Qtc29jcmF0ZXM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDUyNC43NzIyNjk5MSJ9.LxVo7h58KxWvxDrFh3xTu0-JEGiPTrybeJD0yfTEOPM/s/1256231544/br/203655531446-l) webpage for more information!**Dr. George Demetri** will be featured as OCE’s next ICONS in Oncology  Distinguished Lecture Series Speaker, June 12, 2023,10:30-12:00 PM, ET. If you are interested in watching, email Projectsocrates@fda.hhs.gov**.**The **FDA-AACR Oncology Educational Fellowship** is a year-long fellowship  held once a month, primarily over Zoom, consisting of a mix of didactics and  case-based small group discussions. The fellowship ends with a mock ODAC held at FDA White Oak. Applications will be accepted June 1 - August 14, 2023: [Program Overview &  Application](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDgsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmFhY3Iub3JnL3Byb2Zlc3Npb25hbHMvcG9saWN5LWFuZC1hZHZvY2FjeS9yZWd1bGF0b3J5LXNjaWVuY2UtYW5kLXBvbGljeS9mZGEtYWFjci1vbmNvbG9neS1lZHVjYXRpb25hbC1mZWxsb3dzaGlwLz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNTI0Ljc3MjI2OTkxIn0.wbrsvasD1WaWDpIYDuoxk_eJUF97GM78yR6MTO8qkKc/s/1256231544/br/203655531446-l)The **FDA-ASH Workshop on Regulatory Science in Hematology i**s a two-day workshop for current hematology/oncology fellows, physicians, and researchers to learn about drug development and regulatory medicine. Applications will be accepted until June 16, 2023.  [Program Overview & Application.](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDksInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmhlbWF0b2xvZ3kub3JnL2Fkdm9jYWN5L2dldC1pbnZvbHZlZC9hc2gtZmRhLWNvbGxhYm9yYXRpb24_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDUyNC43NzIyNjk5MSJ9.xy5xpSk6bW9cQbSHD7oKcUPwf5UZf8irNU20hfZpVPg/s/1256231544/br/203655531446-l)For hematology/oncology fellowship program directors interested in having FDA Oncology speak to your fellows, email us at Projectsocrates@fda.hhs.govRecent FDA Oncology ApprovalsWe 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!**April 19, 2023:** [Polatuzumab vedotin-piqq](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTAsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2ZkYS1hcHByb3Zlcy1wb2xhdHV6dW1hYi12ZWRvdGluLXBpaXEtcHJldmlvdXNseS11bnRyZWF0ZWQtZGlmZnVzZS1sYXJnZS1iLWNlbGwtbHltcGhvbWEtbm90P3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA1MjQuNzcyMjY5OTEifQ.EoSE0U-05gr6CtuQ3yY9Rg26IUWGGlnyXhZSM9A_hUk/s/1256231544/br/203655531446-l) for previously untreated diffuse large B-cell lymphoma, not otherwise specified, and high-grade  B-cell lymphoma – regular approval.**April 17, 2023:** [Omidubicel](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTEsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2ZkYS1hcHByb3Zlcy1vbWlkdWJpY2VsLXJlZHVjZS10aW1lLW5ldXRyb3BoaWwtcmVjb3ZlcnktYW5kLWluZmVjdGlvbi1wYXRpZW50cy1oZW1hdG9sb2dpYz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNTI0Ljc3MjI2OTkxIn0.FjOWXlbPM56mHSlUPIOOioFEBCnV737clSXDsXk46pg/s/1256231544/br/203655531446-l) to reduce time to neutrophil recovery and infection in patients with hematologic malignancies – regular approval.**April 3, 2023:** [Enfortumab vedotin-ejfv](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTIsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2ZkYS1ncmFudHMtYWNjZWxlcmF0ZWQtYXBwcm92YWwtZW5mb3J0dW1hYi12ZWRvdGluLWVqZnYtcGVtYnJvbGl6dW1hYi1sb2NhbGx5LWFkdmFuY2VkLW9yLW1ldGFzdGF0aWM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDUyNC43NzIyNjk5MSJ9.hwuOovNIDEA-FkAExuxoZkEL7SNGiZh1_cIG1_6lwq4/s/1256231544/br/203655531446-l) with pembrolizumab for locally advanced or metastatic urothelial carcinoma – accelerated approval.**March 22, 2023:** [Retifanlimab-dlwr](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2ZkYS1ncmFudHMtYWNjZWxlcmF0ZWQtYXBwcm92YWwtcmV0aWZhbmxpbWFiLWRsd3ItbWV0YXN0YXRpYy1vci1yZWN1cnJlbnQtbG9jYWxseS1hZHZhbmNlZC1tZXJrZWw_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDUyNC43NzIyNjk5MSJ9.rELLUFGJvePezTKVXElNyIXF7CrfHzWNYf7oQEz5wfw/s/1256231544/br/203655531446-l) for metastatic or recurrent locally advanced Merkel cell carcinoma – accelerated approval.**Interested in learning more?**Tune into our FDA Oncology Podcast. You can also take a look at this website [How to Use Product Labeling](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTQsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL2hvdy1kby1pLXVzZS1wcmVzY3JpcHRpb24tZHJ1Zy1sYWJlbGluZz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNTI0Ljc3MjI2OTkxIn0.gfMk54wwFS7DUVxcdpKg9rmcC1TWggARn4m66t5csZc/s/1256231544/br/203655531446-l) and find a full list of [FDA oncology approvals](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTUsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL29uY29sb2d5LWNhbmNlci1oZW1hdG9sb2dpYy1tYWxpZ25hbmNpZXMtYXBwcm92YWwtbm90aWZpY2F0aW9ucz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNTI0Ljc3MjI2OTkxIn0.fHVcRc59J53GQ6Kk2MsbP5znRQFYcd1pgQxMqOLJRXA/s/1256231544/br/203655531446-l) online! OCE Spotlight – Get to Know Us! |

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| Jenny Gao Square |  | **Jennifer Gao** is a medical oncologist and the Associate Director for Education at the FDA OCE. She has a clinical interest in breast cancer. In her spare time, she enjoys spending time with her family, including 2 young boys who enjoy golf, piano, soccer, and launching model rockets.   |

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| **Timil Patel** is a medical oncologist and a clinical reviewer on the GI and melanoma team. He has a research interest in pragmatic and decentralized trials. In his spare time, heenjoys watching his hometown sport teams (Chicago Bears and Bulls!) and taking his kids to all the awesome D.C. museums.  |  | Timil |

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| Interested in learning more about OCE?Read our **FDA** [**Oncology Center of Excellence**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTcsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29jZS1hbm51YWwtcmVwb3J0cy8yMDIyLW9jZS1hbm51YWwtcmVwb3J0P3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA1MjQuNzcyMjY5OTEifQ.4zDg0aTTL7F-mFvF5zqRCXD5MsE8hYbEEVvcs2nm5Y4/s/1256231544/br/203655531446-l) [**(OCE) Annual Report**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTgsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29jZS1hbm51YWwtcmVwb3J0cy8yMDIyLW9jZS1hbm51YWwtcmVwb3J0P3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA1MjQuNzcyMjY5OTEifQ.eWk-rM37TZJhUQwpPe38Tjn6lQS69333_u63VMQsI60/s/1256231544/br/203655531446-l)follow us on Twitter **@FDAOncology**, or send us an email at**FDAOncology@fda.hhs.gov****.**   |

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