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| The OCE Owl |

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| July 2023 |

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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) 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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| Upcoming Public FDA Oncology Events**June 27, 2023, 11 am-3 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.eyJidWxsZXRpbl9saW5rX2lkIjoxMDAsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvbmV3cy1ldmVudHMvZmRhLW1lZXRpbmdzLWNvbmZlcmVuY2VzLWFuZC13b3Jrc2hvcHMvZmRhLXdvcmtzaG9wLTh0aC1hbm51YWwtY2xpbmljYWwtb3V0Y29tZS1hc3Nlc3NtZW50LWNhbmNlci1jbGluaWNhbC10cmlhbHMtd29ya3Nob3AtMDYyNzIwMjM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDYyMC43ODQ4MjM4MSJ9.BEtIUN3zIYFnWp6R2eZ9AVrt7VAepBTSSPxJxCaIhS8/s/1256231544/br/206112872186-l).**July 18, 2023, 8 am-5 pm ET:** [FDA-AACR-ASA Workshop: Overall Survival in Oncology Clinical Trials](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDEsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmFhY3Iub3JnL3Byb2Zlc3Npb25hbHMvcG9saWN5LWFuZC1hZHZvY2FjeS9yZWd1bGF0b3J5LXNjaWVuY2UtYW5kLXBvbGljeS9ldmVudHMvZmRhLWFhY3ItYXNhLXdvcmtzaG9wLW92ZXJhbGwtc3Vydml2YWwtaW4tb25jb2xvZ3ktY2xpbmljYWwtdHJpYWxzLz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.V6OjKV0HCABeREaVZ05dhjPWMZWDtt3teWQC73l6jag/s/1256231544/br/206112872186-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.eyJidWxsZXRpbl9saW5rX2lkIjoxMDIsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL29jZS1tZWV0aW5ncy1hbmQtd29ya3Nob3BzP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA2MjAuNzg0ODIzODEifQ.kInMhbCKuTalg748btpCAgnVe-6TMbEfuIBWGIn5e2E/s/1256231544/br/206112872186-l)Project Socrates: Educational Opportunities

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| Socrates SquareOCE 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.eyJidWxsZXRpbl9saW5rX2lkIjoxMDMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3Qtc29jcmF0ZXM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDYyMC43ODQ4MjM4MSJ9.C8Ss8ZaBCEIo--qOVqnpNQuT0-kfNTsIixItblBry-8/s/1256231544/br/206112872186-l) website for more information![**Project Livin’ Label**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDQsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3QtbGl2aW4tbGFiZWw_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDYyMC43ODQ4MjM4MSJ9.fn83iUuIo7R47bT-QiLHP21rXHYo4fNJ3qhgQaGFLXI/s/1256231544/br/206112872186-l) Episode 9 is now available! Listen to the “behind the scenes” discussions of the development and backstory of [**neoadjuvant nivolumab**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDUsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmFhY3Iub3JnL3Byb2Zlc3Npb25hbHMvcG9saWN5LWFuZC1hZHZvY2FjeS9yZWd1bGF0b3J5LXNjaWVuY2UtYW5kLXBvbGljeS9yZWd1bGF0b3J5LXNjaWVuY2UtYW5kLXBvbGljeS1lZHVjYXRpb25hbC1hY3Rpdml0aWVzL3Byb2plY3QtbGl2aW4tbGFiZWwvP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA2MjAuNzg0ODIzODEifQ.8ppy97bO923B1s6h0--yv1iDnWf9y0r4dxMDd9GWxFg/s/1256231544/br/206112872186-l) in lung cancer. You can also find the other episodes online with free CME credit offered by AACR for each!The [**FDA-ASCO Hematology/Oncology Fellows Workshop**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDYsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vYXNjby5zbWFwcGx5Lm9yZy9wcm9nL09jdG9iZXJGZWxsb3dzRGF5Lz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.uNsfcA4jyJdlpSYCcrkXG-8JUjBG5mg0lDoOEGXNP7Y/s/1256231544/br/206112872186-l) continues in its 9th year. This day-long hybrid workshop will discuss clinical trial design, endpoints, eligibility criteria, expedited pathways, expanded access, and much more! **Applications will be accepted July 5 – July 26, 2023**.The[**FDA-AACR Oncology Educational Fellowship**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDcsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmFhY3Iub3JnL3Byb2Zlc3Npb25hbHMvcG9saWN5LWFuZC1hZHZvY2FjeS9yZWd1bGF0b3J5LXNjaWVuY2UtYW5kLXBvbGljeS9mZGEtYWFjci1vbmNvbG9neS1lZHVjYXRpb25hbC1mZWxsb3dzaGlwLz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.SlASYBjQnr1PZVEQLSC60w-FVvaKJ7cN37lx_3xAXqM/s/1256231544/br/206112872186-l) 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**.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**!**Recent 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!**June 15, 2023:** [**Columvi (glofitamab-gxbm)**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDgsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvZHJ1Zy1hcHByb3ZhbHMtYW5kLWRhdGFiYXNlcy9mZGEtZ3JhbnRzLWFjY2VsZXJhdGVkLWFwcHJvdmFsLWdsb2ZpdGFtYWItZ3hibS1zZWxlY3RlZC1yZWxhcHNlZC1vci1yZWZyYWN0b3J5LWxhcmdlLWItY2VsbD91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.0skTV0upqCsmGh0EdN94F5OBBYdsYGQGChJT_bJ5kQI/s/1256231544/br/206112872186-l) for relapsed or refractory diffuse large B-cell lymphoma, not otherwise specificized or large B-cell lymphoma arising from follicular lymphoma – accelerated approval.**May 31, 2023:** [**Olaparib with abiraterone and prednisone (or prednisolone)**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDksInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvZHJ1Zy1hcHByb3ZhbHMtYW5kLWRhdGFiYXNlcy9mZGEtYXBwcm92ZXMtb2xhcGFyaWItYWJpcmF0ZXJvbmUtYW5kLXByZWRuaXNvbmUtb3ItcHJlZG5pc29sb25lLWJyY2EtbXV0YXRlZC1tZXRhc3RhdGljLWNhc3RyYXRpb24_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDYyMC43ODQ4MjM4MSJ9.bcISA49iRQq7TeK4_csxZpQRZHYmu198cehWTayt2_8/s/1256231544/br/206112872186-l) for BRCA-mutated metastatic castration-resistant prostate cancer – regular approval.**May 18, 2023:** [**Epcoritamab-bysp**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTAsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvZHJ1Zy1hcHByb3ZhbHMtYW5kLWRhdGFiYXNlcy9mZGEtZ3JhbnRzLWFjY2VsZXJhdGVkLWFwcHJvdmFsLWVwY29yaXRhbWFiLWJ5c3AtcmVsYXBzZWQtb3ItcmVmcmFjdG9yeS1kaWZmdXNlLWxhcmdlLWItY2VsbD91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.lhVhFenjOhEfMcdxhzNZWBuZ-ezK3fwMzk8wvML_SKw/s/1256231544/br/206112872186-l) for relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma – accelerated approval.**April 19, 2023:** [**Polatuzumab vedotin-piqq**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTEsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL2ZkYS1hcHByb3Zlcy1wb2xhdHV6dW1hYi12ZWRvdGluLXBpaXEtcHJldmlvdXNseS11bnRyZWF0ZWQtZGlmZnVzZS1sYXJnZS1iLWNlbGwtbHltcGhvbWEtbm90P3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA2MjAuNzg0ODIzODEifQ.TrzFiZ9BJe1iYyQwMb-qbNoguazAo9N3HZ35rh-T90Y/s/1256231544/br/206112872186-l) for previously untreated diffuse large B-cell lymphoma, not otherwise specified, and high-grade B-cell lymphoma – regular 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.eyJidWxsZXRpbl9saW5rX2lkIjoxMTIsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL2hvdy1kby1pLXVzZS1wcmVzY3JpcHRpb24tZHJ1Zy1sYWJlbGluZz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.QZj_S2DcQeb3eFlpi6-qJ8VTOUwwTcx97b4oiTNHvwU/s/1256231544/br/206112872186-l) and find a full list of [**FDA oncology approvals**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL29uY29sb2d5LWNhbmNlci1oZW1hdG9sb2dpYy1tYWxpZ25hbmNpZXMtYXBwcm92YWwtbm90aWZpY2F0aW9ucz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwNjIwLjc4NDgyMzgxIn0.AXSOiH1OqkL9vfe5fMoiBvwzUHiPFz4n_uYWAcpDJ4g/s/1256231544/br/206112872186-l) online! OCE Spotlight – Get to Know Us! |

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| Kim |  | **Nina Kim** is a medical oncologist and a clinical reviewer on the acute leukemia, MDS, and CML team. She has a research interest in clinical trial endpoints and drug development for MDS. In her spare time, she enjoys spending time with her husband and 5-month-old son, exploring DC, and watching Formula 1. |

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| **Brian Heiss** is a medical oncologist, GU oncology clinical reviewer, and member of FDA’s dosage optimization initiative, Project Optimus. He has research interests in post marketing dosage optimization and prostate cancer intermediate endpoints. In his spare time, he gardens, bikes the trails in and around DC, and supports the Washington Capitals and Nationals. |  | Brian |

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| Interested in learning more about OCE?Read our **FDA** [**Oncology Center of Excellence**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTUsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29jZS1hbm51YWwtcmVwb3J0cy8yMDIyLW9jZS1hbm51YWwtcmVwb3J0P3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA2MjAuNzg0ODIzODEifQ.zfshFlCvoIEmiTtsL5ToN1XeivfgX4lWAf__EVM9L94/s/1256231544/br/206112872186-l) [**(OCE) Annual Report**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTYsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29jZS1hbm51YWwtcmVwb3J0cy8yMDIyLW9jZS1hbm51YWwtcmVwb3J0P3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA2MjAuNzg0ODIzODEifQ.PudqMBa2MVnElnD4edJdqf14sWG7_U_DPOlbaYNeBxs/s/1256231544/br/206112872186-l)follow us on Twitter **@FDAOncology**, or send us an email at**FDAOncology@fda.hhs.gov** |

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