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This newsletter provides a summary of OCE upcoming public events, educational opportunities, and recent oncology product approvals. These are all free and everyone is welcome to attend – we hope to see many of you there!   |  | | --- | |  |  Director's Message We hope you and your families had a safe, restful, and enjoyable summer.  Here at the FDA Oncology Center of Excellence (OCE) we’ve spent the summer working on your behalf to approve safe and effective cancer treatments and diagnostics.  We also spent quality time convening with oncology colleagues from around the world to share emerging science and highlight work that translates into potentially life-saving anti-cancer medical products. And now, we’re proud to announce a history-making collaboration.   |  | | --- | | On October 19, 2023, OCE’s “Conversations on Cancer” public panel discussion will be held in conjunction with the European Medicines Agency (EMA). OCE meets regularly with EMA colleagues to discuss the regulatory cancer product review process.  In May, OCE and EMA decided to expand our collaboration resulting in the first-ever co-branded “Conversation on Cancer” which will focus on breast cancer as the topic. Watch FDA Oncology social media platforms for your opportunity to register for this inaugural, international discussion during National Breast Cancer Awareness Month.  OCE is also committed to doing our part to meet Cancer Moonshot 2.0 goals. The re-ignited Cancer Moonshot aims to mobilize a national effort to prevent more than 4 million cancer deaths by 2047 and to improve the experience of people who are touched by cancer. We’re actively working with our federal government public health partners and non-government public health advocates. Even before the Cancer Moonshot was re-launched in February 2022, we established patient-centered cancer research, specifically the OCE Patient-Focused Drug Development (PFDD) program which fosters collaboration between FDA Centers and external stakeholders involved in patient outcomes research in people living with cancer.  As we prepare for the transition into autumn, OCE is excited about the new season and the work ahead!  Sincerely,  Richard Pazdur, MD • OCE Center Director |  |  | | --- | |  |  Upcoming EventsFDA-EMA present Conversations on Cancer: *****Living with Metastatic Breast Cancer***** EMA  FDA Oncology Center of Excellence (OCE) in conjunction with the European Medicines Agency (EMA) presents a Conversations on Cancer public panel discussion October 19, 2023 addressing the experience of living with metastatic breast cancer. The discussion will take place **Thursday, October 19, 2023 from 9:30 AM-11:00 AM ET / 3:30 PM-5:00 PM CEST.**  Approximately 10-30% of breast cancer patients in the world are living with advanced stage or metastatic disease. With improvements in treatments and more options for therapies, many of these patients are living for years with their cancer.  Cancer survivorship has become an issue of growing importance since the Institute of Medicine reported this to be an important public health issue in 2006, and it has continued to be highlighted through the more recent launch of the Cancer Moonshot. Though many patients living with advanced breast cancer experience some of the same stressors and long-term impacts of therapies that affect all cancer survivors, they are not routinely included in cancer survivorship programs and research.  The panel will feature speakers with a range of perspectives on breast cancer and, for the first time, will be an international collaboration with our colleagues at the EMA with the hope of highlighting the day-to-day, year-to-year experience of patients living with metastatic breast cancer.   |  |  | | --- | --- | | |  | | --- | | [**Register Here**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDEsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LnN1cnZleW1vbmtleS5jb20vci9TR0Y1RkNQP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA5MjEuODI5MjYyNzEifQ.jeOtKqy13VfYQM01FxNlnyqTwWyNpTK7VnkStSW90tU/s/1256231544/br/226374798216-l) | |  *****Two-Day Virtual Public Workshop to Enhance Clinical Study Diversity***** The FDA, in collaboration with the Clinical Trials Transformation Initiative (CTTI), is convening a public workshop to solicit input on increasing the enrollment of historically underrepresented populations in clinical studies and encouraging clinical study participation that reflects the prevalence of the disease or condition among demographic subgroups. The workshop will take place **November 29 and 30, 2023 from 10:00-2:00 ET**.  Representatives from drug sponsors, medical device sponsors, clinical research organizations, academia, patients, and other stakeholders will share their experiences and approaches for increasing enrollment and encouraging participation of historically underrepresented populations in clinical studies.  Additional information about the public workshop along with registration details will follow in advance of the workshop.   |  |  | | --- | --- | | |  | | --- | | [**Register Here**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9..8MlhP3Dk6CqR2eyiTYKkh-sVh1_Kt4FPXUxbSEyTWhw/s/1256231544/br/226374798216-l) | |  |  | | --- | |  |  ICYMI (In Case You Missed It)*****Conversations on Cancer: National Black Family Cancer Awareness Week with SU2C Celebrity Ambassador and Grey's Anatomy star Chandra Wilson!***** n  This online panel discussion kicked off the official start of [National Black Family Cancer Awareness Week](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvbmV3cy1ldmVudHMvZmRhLW1lZXRpbmdzLWNvbmZlcmVuY2VzLWFuZC13b3Jrc2hvcHMvanVuZS0xNS0yMDIzLWNvbnZlcnNhdGlvbnMtY2FuY2VyLW5hdGlvbmFsLWJsYWNrLWZhbWlseS1jYW5jZXItYXdhcmVuZXNzLXdlZWstZW5nYWdpbmctZ2VuZXJhdGlvbnM_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDkyMS44MjkyNjI3MSJ9.oS5eQLE_OuOJD2Ip9dn_STbEXwSiVV7bkSXAm6LT_LI/s/1256231544/br/226374798216-l), June 15-21, 2023, which begins annually on Thursday before the Federal Juneteenth Holiday. The mission is to increase cancer awareness, increase cancer equity, reduce morbidity and mortality, and prevent unnecessary cancer burden on families in the most vulnerable populations. The official social media moniker is #BlackFamCan. This year, Grey's Anatomy star and SU2C Ambassador Chandra Wilson joined us! See this [**clip**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDQsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8veW91dHUuYmUvc1RrVHFFc0FBSkU_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDkyMS44MjkyNjI3MSJ9.nS5Zgtswqgdg4BMjn0WY-S8xr7TwhQeu5cw0LOLM9D8/s/1256231544/br/226374798216-l) of what she had to say or watch the full discussion.   |  |  | | --- | --- | | |  | | --- | | [**Watch on YouTube**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDUsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LnlvdXR1YmUuY29tL3dhdGNoP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSZ2PVBLMXpvUlg3TWhBIiwiYnVsbGV0aW5faWQiOiIyMDIzMDkyMS44MjkyNjI3MSJ9.GwYPwh0CrGLzuGPHFa1vGyHXnih4dZLDpYi0YJZDbrw/s/1256231544/br/226374798216-l) | |  *****Conversations on Cancer: Cancer Disparities in Appalachia, July 25, 2023***** ap  Despite advances in cancer prevention and precision cancer care, not all communities have benefited, and cancer disparities persist in the Appalachia community. The Appalachian Region has a cancer mortality rate of 184 per 100,000 population (10% higher than the national rate). Central Appalachia has the highest rate at 222 per 100,000 (32% percent higher than the national rate).  This [Conversations on Cancer](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDYsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvbmV3cy1ldmVudHMvZmRhLW1lZXRpbmdzLWNvbmZlcmVuY2VzLWFuZC13b3Jrc2hvcHMvanVseS0yNS0yMDIzLWNvbnZlcnNhdGlvbnMtY2FuY2VyLWNhbmNlci1kaXNwYXJpdGllcy1hcHBhbGFjaGlhLTA3MjUyMDIzP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA5MjEuODI5MjYyNzEifQ.DIfUzfUFGDDwA6-kF7zU7k1Wf42aaKPULN6Yr9uAG3w/s/1256231544/br/226374798216-l) focused on the Appalachia community to discuss the factors contributing to the cancer disparities, but also focus on ongoing interventions and opportunities in bridging the cancer chasm in rural health inequity.   |  |  | | --- | --- | | |  | | --- | | [**Watch on YouTube**](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDcsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LnlvdXR1YmUuY29tL3dhdGNoP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSZ2PV9qQVp6QU1kV0VnIiwiYnVsbGV0aW5faWQiOiIyMDIzMDkyMS44MjkyNjI3MSJ9.yQO2Le59ty8i7oWWaNYZrkDfIy_aEKUn9dZxTQ7pey8/s/1256231544/br/226374798216-l) | |  *****Patients and Advocates at 2023 Conferences***** c  OCE is committed to attending major oncology conferences and meetings like the ones held by the American Association for Cancer Research (AACR), the American Society of Clinical Oncology (ASCO), and the Drug Information Association (DIA). We also enjoy meeting with patients and advocates, while also adding to the wealth of scientific data about cancer research. ***Will we see you there next year?***   |  | | --- | |  |  Recent Approvals Interested in learning more about recent FDA oncology drug approvals? Take a look at these recent ones! You can also watch OCE’s [Project Livin’ Label](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDgsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3QtbGl2aW4tbGFiZWw_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDkyMS44MjkyNjI3MSJ9.X7XAXildtK570329l4F9hALdz2CaShVYAO1VlkQopQE/s/1256231544/br/226374798216-l), which is an FDA-led conversation with a patient, an oncologist, a representative from the drug company, FDA oncologists, an oncology nurse, and an oncology pharmacist talking about the backstory of a recent oncology approval.   * **September 14, 2023: Temozolomide (temodar)** Indication: Adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma. Treatment of adults with refractory anaplastic astrocytoma and treatment of adults with newly diagnosed glioblastoma, concomitantly with radiotherapy and then as maintenance treatment. * **August 9, 2023, Pralsetinib (gavreto)** Indication:  Adult patients with metastatic rearranged during transfection (RET) fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA-approved test. Pralsetinib was previously granted accelerated approval for the NSCLC indication on Sept. 4, 2020 * **August 2, 2023**, **Trifluridine and Tipiracil (Lonsurf) with bevacizumab** Indication: Adult patients with metastatic colorectal cancer (mCRC) previously treated with fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapy, and if RAS wild-type, an anti-EGFR therapy. Single-agent lonsurf was previously approved for this indication in September 2015.   You can find more information about [how to use product labeling](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMDksInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL2hvdy1kby1pLXVzZS1wcmVzY3JpcHRpb24tZHJ1Zy1sYWJlbGluZz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwOTIxLjgyOTI2MjcxIn0.QQiaA6ZB4jt7Z2LNDoQCJICaXXrmy1edr1tM_Ob1as8/s/1256231544/br/226374798216-l) and the [full list of FDA oncology approvals](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTAsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvZHJ1Z3MvcmVzb3VyY2VzLWluZm9ybWF0aW9uLWFwcHJvdmVkLWRydWdzL29uY29sb2d5LWNhbmNlci1oZW1hdG9sb2dpYy1tYWxpZ25hbmNpZXMtYXBwcm92YWwtbm90aWZpY2F0aW9ucz91dG1fbWVkaXVtPWVtYWlsJnV0bV9zb3VyY2U9Z292ZGVsaXZlcnkiLCJidWxsZXRpbl9pZCI6IjIwMjMwOTIxLjgyOTI2MjcxIn0.faAHWepofJZC9yARUWcz_K0Twc8oiUKxWUd0DcSNkt4/s/1256231544/br/226374798216-l) online.   |  | | --- | |  |  Getting to Know OCE Hello, I am Vishal Bhatnagar, a medical oncologist and the OCE Associate Director for Patient Outcomes. I lead the OCE Patient Focused Drug Development program, whose main goal is to better integrate the collection, analysis, and communication of the patient experience information in cancer clinical trials.   |  | | --- | | In practical terms, this means that I encourage and advise trial sponsors on measuring how patients feel and function while taking anti-cancer drugs. This information is important to FDA, and should also be shared with patients in the broader patient community so that they know what to expect when receiving treatment for cancer.  To that end, I value the ability to work closely with patient advocates as a part of the many initiatives we have. This includes hearing from patient advocates as panelists in OCE hosted public workshops, meeting with patients at conferences, or listening to patients at in FDA listening sessions. If you’re interested in learning more about these initiatives or our program, check out [OCE's Patient-Focused Drug Development](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTEsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3BhdGllbnQtZm9jdXNlZC1kcnVnLWRldmVsb3BtZW50P3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA5MjEuODI5MjYyNzEifQ._4q-m9uHP2kT3ICeIm931J6QYG7QuzZkMR-YwjIWlOI/s/1256231544/br/226374798216-l) or reach out through [OCE-Engagement@fda.hhs.gov](mailto:OCE-Engagement@fda.hhs.gov). |  |  | | --- | |  |  Getting to Know You! This issue we are pleased to highlight Prostate Health Education Network (PHEN at [https://prostatehealthed.org](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTIsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vcHJvc3RhdGVoZWFsdGhlZC5vcmc_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDkyMS44MjkyNjI3MSJ9.xJiirs684VjyoUFBGtcoeh5Ga2mvPnJOhv_lhDB9Yvk/s/1256231544/br/226374798216-l)). PHEN’s mission is to eliminate the African American prostate cancer disparity, and increase support and resources that will lead to a cure for the disease for the benefit of all men.   |  | | --- | | PHEN was founded in 2003 by Thomas A. Farrington, a prostate cancer survivor and author of the books "Battling the Killer Within" and "Battling the Killer Within and Winning," and former Information Technology entrepreneur and business executive. Project Community asked him for his thoughts on the following:  **What are you currently working on that makes you feel excited or proud?** We at PHEN are engaged in a number of initiatives aimed at increasing prostate cancer awareness and educating the public about the importance of early detection screening, and understanding prostate cancer treatment options. We are very proud of all these initiatives. The one initiative that we are especially proud and excited about is the progress that we are making with our [Clinical Trials Rally](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTMsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vcGhlbnRyaWFscy5jb20vP3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA5MjEuODI5MjYyNzEifQ.b1HhfsKP2lWPSixe6tBDkP2diENghDXQnTWFAdw8o3A/s/1256231544/br/226374798216-l) to increase the participation of Black patients in prostate cancer clinical trials. Over the past 10 - 15 years there has been tremendous progress made with the FDA approving a number of new therapies to treat prostate cancer. However, Black patients were not participants in the clinical trials at significant enough levels to understand the full impact of these new therapies on this population. These were opportunities lost to better understand the disease for all men. With the aggressive efforts of our clinical trials rally in partnership with clinical trial sponsors, we are seeing more participation by Black patients as we shape the next generation of prostate cancer treatments. We view this as major progress towards a potential cure for the disease which is very exciting.  **What has your experience been working with the Oncology Center of Excellence, Project Community?** Members of the PHEN team have enjoyed the opportunities to work with the OCE and its Project Community. This is a very important effort that will help the public better understand FDA's role in approving cancer treatments. Reaching out to Black communities to educate about what clinical trials are, and their importance to the population with the highest cancer rates is a crucial aspect of Project Community that we are excited to see. We are committed to supporting the OCE efforts in every way that we can.  **Please share any advice you or your organization have for other advocates.** PHEN is celebrating our 20th Anniversary during 2023. Each year I become more aware of just how important advocacy is at every level. As the leader of an advocacy organization, and cancer patient and survivor, I use my organization and voice to impact policies, mobilize national efforts in the fight against cancer, and to support individuals and families. Whether as an organization, or as an individual, our voices are important as advocates and can make a profound difference at some level in the lives of many people. My advice is to understand that you can be an impact player as an advocate, so go all out because you are needed. |   • • •  Each newsletter will highlight a Project Community advocate we have had the privilege of engaging with— if you would like to nominate your organization, or for any additional information, please reach out to us at *[OCE-Engagement@fda.hhs.gov](mailto:OCE-Engagement@fda.hhs.gov" \o "Newsletter Nomination for Getting to Know You" \t "_blank)*. Use: Newsletter Nomination for Getting to Know You in the subject line.   |  | | --- | |  |  Awareness Calendar ab5   |  | | --- | |  |   **Brought to you by Project Community**  [*Project Community*](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTQsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL29uY29sb2d5LWNlbnRlci1leGNlbGxlbmNlL3Byb2plY3QtY29tbXVuaXR5P3V0bV9tZWRpdW09ZW1haWwmdXRtX3NvdXJjZT1nb3ZkZWxpdmVyeSIsImJ1bGxldGluX2lkIjoiMjAyMzA5MjEuODI5MjYyNzEifQ.zOZ_XH3JAm9_vsDhACWUmI1BnTcxo5q_gDwISZozKt8/s/1256231544/br/226374798216-l) is a public health outreach initiative established by the [*FDA Oncology Center of Excellence*](https://lnks.gd/l/eyJhbGciOiJIUzI1NiJ9.eyJidWxsZXRpbl9saW5rX2lkIjoxMTUsInVyaSI6ImJwMjpjbGljayIsInVybCI6Imh0dHBzOi8vd3d3LmZkYS5nb3YvYWJvdXQtZmRhL2ZkYS1vcmdhbml6YXRpb24vb25jb2xvZ3ktY2VudGVyLWV4Y2VsbGVuY2U_dXRtX21lZGl1bT1lbWFpbCZ1dG1fc291cmNlPWdvdmRlbGl2ZXJ5IiwiYnVsbGV0aW5faWQiOiIyMDIzMDkyMS44MjkyNjI3MSJ9.S6rIxmjx-Ybdb9ogE9u4I4O_jt0yO2G3PpGAhzxbuqQ/s/1256231544/br/226374798216-l) for patients living with cancer, survivors, advocates, families, and people living in underserved urban and rural communities who are at greater cancer risk. Our goal is to increase communication between the underserved and medical professionals in communities nationwide, to foster understanding, and awareness to reduce cancer risk and increase survival.  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