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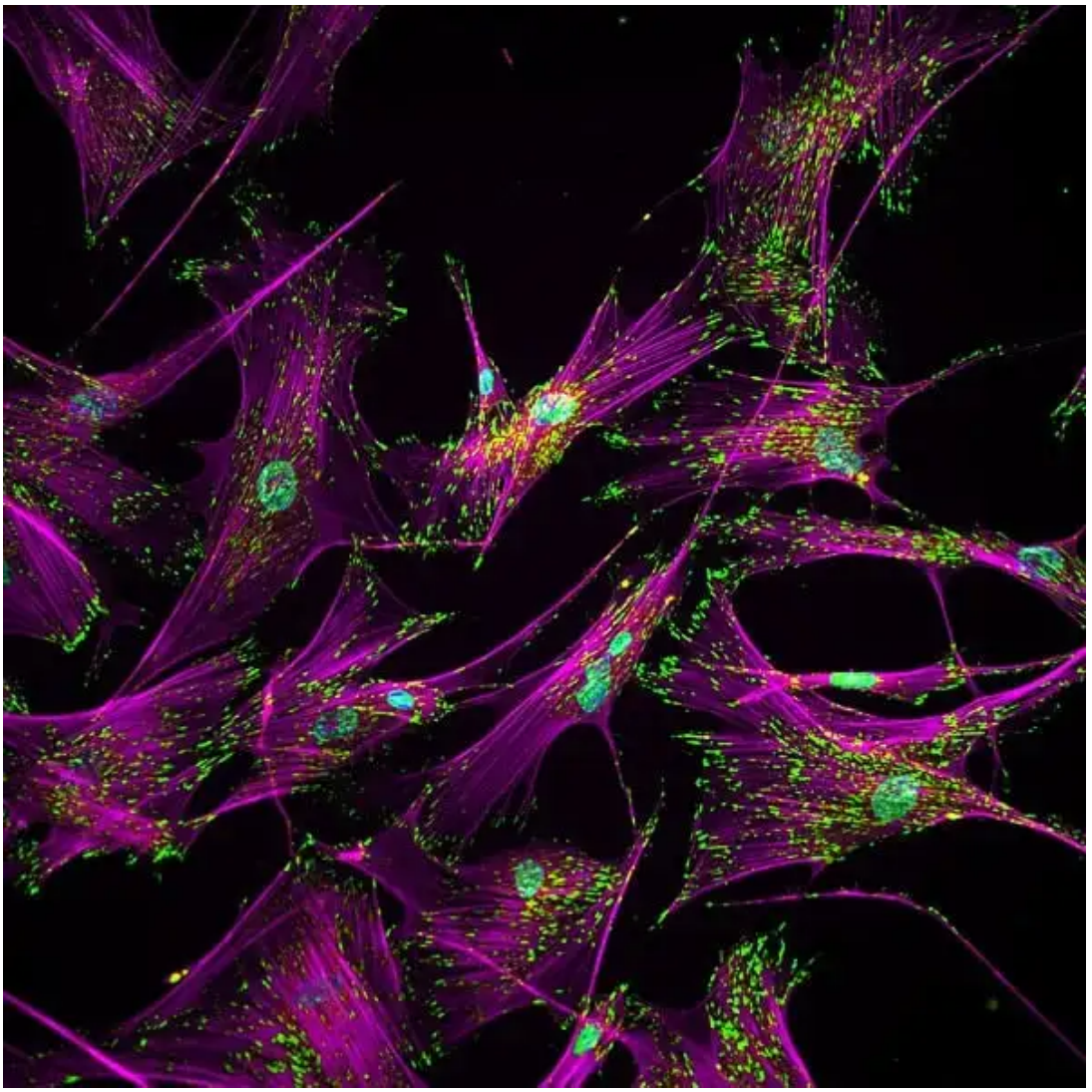
Onco-this-Week

November 3, 2018(https://sciwri.club/archives/date/2018/11/03)



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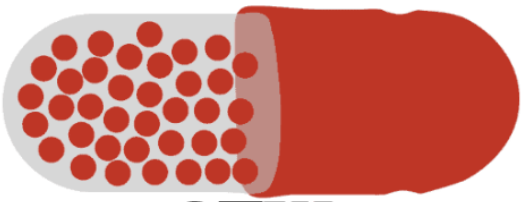
The Current Edition Of Onco-This-Week By Richa Tewari Showcases FDA Approval Of Lorbrena For ALK-Positive Lung Cancer Along With The News About Venetoclax (Venclyxto®) With Rituximab Getting Approval By The European Commission For The

Treatment Of CLL Patients. In A Major Step Forward, The @US_FDA (Https://Twitter.Com/US_FDA) Confers Fast Track Designation To BET Inhibitor CP-0610 For Treatment Of Myelofibrosis. In An Impressive Progress, Urogen's Mitomycin Gel Granted Breakthrough Status For Urothelial Cancer By The FDA. The Trivia Segment Features A QnA About The CTCAE Scale Which Helps In Defining Adverse Events Observed With Treatment. We Hope You Enjoy This Information Packed Edition Of OTW And Stay Tuned For More Oncology Updates.- Abhi Dey (Https://Www.Linkedin.Com/In/Abhinavdey/)



OTW in a Capsule

HIGHLIGHTS

1. **Pembrolizumab's approval in 1L squamous NSCLC patients.** While NSCLC patients with non-squamous histology had several PD-(L)1 inhibitor options in their treatment regimens, with FDA's approval, pembrolizumab, in combination with carboplatin and either paclitaxel/nab-paclitaxel, becomes the first PD-1 inhibitor in frontline with patients metastatic squamous NSCLC. To be given regardless of PD-L1 expression, the combination succeeded to show improvement in overall survival, thus passing the ultimate test.

2. **Fast Track designation to BET inhibitor CPI-0610 in Myelofibrosis.** Patients with myelofibrosis have very limited treatment options. JAK inhibitor Ruxolitinib is the only approved therapy in this indication, and there has hardly been any progress on treatment front after its approval in late 2011. CPI-0610 is expected to fill the unmet need in patients who become refractory to Ruxolitinib given in front-line. The designation is given on the basis of preliminary results from the Ph II study, MANIFEST, which is recently expanded to include another cohort assessing CPI-0610 + ruxolitinib in JAK 1/2-inhibitor-naïve, 1L MF patients.

3. **Encouraging signs of survival and clinical benefit observed with MDNA55 in rGBM patients.** Recurrent GBM patients facing a grim diagnosis now have a hope in form of MDNA55, which showed promising response rates in a Ph II trial. In an interim analysis, MDNA55 showed much better overall survival rate at 6, 9 and 12 months than bevacizumab or lomustine. Medicenna would be hoping for the difference to emerge in final analysis also, especially when they already look forward to move into front-line settings, where patients have stronger immune systems.

DRUG APPROVALS

Lorlatinib gets accelerated approval in 2L+ ALK+ NSCLC patients based on phase II B7461001 trial (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210868s000lbl.pdf)

"The last decade has witnessed dramatic improvements in the treatment of metastatic ALK-positive non–small cell lung cancer due to earlier generation ALK biomarker-driven therapies. Yet almost all patients still relapse due to drug resistance, with a large proportion of patients developing new or worsening brain metastases," Alice T. Shaw, MD, PhD, Professor of Medicine at Harvard Medical School, and Director of the Center for Thoracic Cancers at Massachusetts General Hospital, said in a press release.

> Breaking News: FDA Approves Lorbrena for ALK-Positive Lung Cancer – Lorlatinib shrinks tumors in half of patients previously treated with older ALK inhibitors. https://t.co/Fufb8RylGQ (https://t.co/Fufb8RylGQ) #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw)
>
> — Cancer Health (@cancerhealthmag) November 2, 2018 (https://twitter.com/cancerhealthmag/status/1058507738010017792?ref_src=twsrc%5Etfw)

"In a clinical study which included patients with or without brain metastases, Lorbrena demonstrated clinical activity in patients with metastatic ALK-positive non–small cell lung cancer who had failed other ALK biomarker-driven therapies," added Shaw.

Venetoclax + Rituximab approved in EU in 2L+ CLL patients based on Ph III MURANO study results (http://hugin.info/174806/R/2223386/871323.pdf)

“There are approximately 30,000 people living with chronic lymphocytic leukaemia in Europe, an incurable blood cancer that becomes harder to treat with each relapse,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We are pleased that, thanks to this approval, Venclyxto plus MabThera will provide a new chemotherapy-free option for people with previously treated chronic lymphocytic leukaemia, helping them to live longer without their disease progressing compared to a standard-of-care therapy.”

> Venetoclax (Venclyxto®) plus rituximab granted approval by the European Commission for the treatment of CLL patients. Read more here https://t.co/WURgYhnSvQ (https://t.co/WURgYhnSvQ) pic.twitter.com/D8hHWrqEzo (https://t.co/D8hHWrqEzo)
>
> — Lymphoma Hub (@lymphomahub) November 3, 2018 (https://twitter.com/lymphomahub/status/1058701083168727041?ref_src=twsrc%5Etfw)

Pembrolizumab + chemotherapy combination approved in 1L squamous mNSCLC patients based on Ph III KEYNOTE-407 data (https://www.mrknewsroom.com/news-release/oncology/fda-approves-mercks-keytruda-pembrolizumab-combination-carboplatin-and-either-)

“Today’s approval expands our current lung cancer indications to include combination treatment in patients with squamous cell carcinoma, a type of lung cancer that is particularly difficult to treat,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. “Approval by the FDA has the potential to mean that KEYTRUDA can be used to improve survival for more patients with this debilitating disease.”

> FDA approves pembrolizumab in combination with chemotherapy for first-line treatment of metastatic squamous NSCLC https://t.co/6sTu62p3Gp (https://t.co/6sTu62p3Gp) pic.twitter.com/yBqiJu3vMR (https://t.co/yBqiJu3vMR)
>
> — Anthony M Magliocco MD (@MaglioccoTony) October 31, 2018 (https://twitter.com/MaglioccoTony/status/1057628007022632961?ref_src=twsrc%5Etfw)

“The results that support this approval from the KEYNOTE-407 trial demonstrate the potential of KEYTRUDA in combination with chemotherapy in patients with squamous non-small cell lung cancer, regardless of PD-L1 expression,” said Dr. Balazs Halmos, director of the multidisciplinary thoracic oncology program at the Montefiore Einstein Center for Cancer Care and director of clinical cancer genomics at the Albert Einstein College of Medicine. “With this important approval, more patients will have the opportunity to benefit from immunotherapy.”

SPECIAL STATUSES

Fast Track designation to BET inhibitor CPI-0610 in Myelofibrosis based on Ph II MANIFEST trial data (http://ir.constellationpharma.com/news-releases/news-release-details/constellation-pharmaceuticals-receives-fda-fast-track)

“We believe there is an opportunity to improve the standard of care for MF patients with agents that modify the underlying disease,” said Adrian Senderowicz, Senior Vice President and Chief Medical Officer of Constellation Pharmaceuticals. “This Fast Track designation highlights CPI-0610’s potential to address a significant unmet need. Based on promising early data and our progress with site initiation and patient enrollment, we continue to expect to determine proof of concept in mid-2019.”

> Congratulations to our #LLSTAP (https://twitter.com/hashtag/LLSTAP?src=hash&ref_src=twsrc%5Etfw) partner @CPI_epigenetics (https://twitter.com/CPI_epigenetics?ref_src=twsrc%5Etfw)! CPI-0610 developed in partnership with @LLSResearch (https://twitter.com/LLSResearch?ref_src=twsrc%5Etfw) just received FDA Fast Track Designation for treatment of Myelofibrosis! https://t.co/9bH4KKSxPE (https://t.co/9bH4KKSxPE)
>
> — Leukemia & Lymphoma Society Research (@LLSResearch) November 2, 2018 (https://twitter.com/LLSResearch/status/1058448567994593281?ref_src=twsrc%5Etfw)

BTD granted to mitomycin gel formulation, UGN-101, for low-grade upper tract urothelial cancer based on data from Ph III OLYMPUS trial (http://investors.urogen.com/phoenix.zhtml?c=254372&p=irol-newsArticle&ID=2374119)

"We are very excited about receiving the Breakthrough Therapy Designation for UGN-101 and the potential to deliver this far less invasive, organ-sparing therapy option to patients," said Ron Bentsur, Chief Executive Officer of UroGen. "We look forward to working with the FDA as we prepare to initiate a rolling submission of the UGN-101 New Drug Application (NDA) later this year, with the potential to become the first drug ever approved as frontline treatment of LG UTUC."

> Mitomycin Gel Granted Breakthrough Status for Urothelial Cancer https://t.co/8bXYoPbDFG (https://t.co/8bXYoPbDFG)
>
> — Amer. Urol. Assn. (@AmerUrological) November 2, 2018 (https://twitter.com/AmerUrological/status/1058297881126412289?ref_src=twsrc%5Etfw)

"UGN-101 was developed to provide an effective alternative to current treatment options, that avoids the risks of surgery, anesthesia, and the deleterious effects of kidney removal," said Mark Schoenberg, M.D., Chief Medical Officer of UroGen. "The Breakthrough Therapy Designation confirms that UGN-101 represents a novel and effective approach to treat this devastating disease, and we look forward to close collaboration with the FDA as we bring this potentially transformative therapy to patients with LG UTUC as quickly as possible."

TRIAL RESULTS

CD47 inhibitor 5F9 data from Ph Ib trial in NHL patients published (https://ir.fortyseveninc.com/news-releases/news-release-details/forty-seven-inc-announces-publication-new-england-journal)

"While newer therapies have shown robust activity in r/r NHL, there remains an unmet need for new medicines that are both well-tolerated and able to induce clinically meaningful responses in patients who need urgent treatment," said Sonali Smith, M.D, Elwood V. Jensen Professor in Medicine, Director of the Lymphoma Program at the University of Chicago Medicine, and senior author of the manuscript. "The publication of these Phase 1b data in the NEJM underscores the potential of CD47 inhibition as a novel approach to treating cancer, and reinforces the strong therapeutic potential of 5F9 as a safe and efficacious option for patients with r/r NHL. I look forward to continuing to evaluate 5F9 in combination with rituximab in patients with diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) in the Phase 2 portion of this clinical trial."

> Forty Seven publishes Ph1b data from Ph1b/2 #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) of 5F9 + rituximab vs relapsed/refractory NHL
>
> Anti-CD47 #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) showed signs of clinical efficacy; was safe & well-toleratedhttps://t.co/O05Vug8LaX (https://t.co/O05Vug8LaX)#oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) @NEJM (https://twitter.com/NEJM?ref_src=twsrc%5Etfw) @theNCI (https://twitter.com/theNCI?ref_src=twsrc%5Etfw) pic.twitter.com/RP5uDifINZ (https://t.co/RP5uDifINZ)
>
> — DDNews Online (@DDNewsOnline) November 1, 2018 (https://twitter.com/DDNewsOnline/status/1058109456603537410?ref_src=twsrc%5Etfw)

Venetoclax – obinutuzumab combination improves PFS in Ph III CLL14 trial in 1L therapy in CLL patients (https://news.abbvie.com/news/press-releases/abbvie-announces-positive-results-from-cll14-phase-3-trial-evaluating-venetoclax-combination-as-first-line-therapy-with-fixed-duration-treatment-in-patients-with-chronic-lymphocytic-leukemia.htm)

"Patients with chronic lymphocytic leukemia generally face a lifetime of continuous treatment to keep their disease from recurring or relapsing. The positive results from the CLL14 trial further demonstrate the potential of venetoclax as a treatment with a fixed duration for patients with chronic lymphocytic leukemia, and may serve as the basis to expand into first-line treatment," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. "We look forward to sharing full results from the CLL14 trial, and to advancing other clinical development programs in our pipeline that have the potential to continue transforming the standards of care for patients with blood cancers."

> Research shows 3 novel agents approved for chronic lymphocytic leukemia (#CLL (https://twitter.com/hashtag/CLL?src=hash&ref_src=twsrc%5Etfw)), ibrutinib, venetoclax, and obinutuzumab, can be safely combined at standard doses to create an active, chemotherapy-free triplet regimen for relapsed or refractory disease.https://t.co/BO1leX5yy5 (https://t.co/BO1leX5yy5)
>
> — CLL Ireland (@CllIreland) October 13, 2018 (https://twitter.com/CllIreland/status/1051226187811512322?ref_src=twsrc%5Etfw)

Encouraging signs of survival and clinical benefit observed at low doses of MDNA55 in Ph IIb trial in rGBM patients (https://ir.medicenna.com/2018-10-31-Medicenna-Provides-Positive-Interim-Update-From-Phase-2b-Trial-of-MDNA55-in-Recurrent-Glioblastoma)

"The data presented today are very encouraging particularly in patients with rGBM, who face a grim diagnosis," said Dr. Fahar Merchant, Ph.D, President and CEO of Medicenna. "While these are interim data, the ability to demonstrate a substantial survival benefit in this advanced and difficult to treat patient population is extremely rare. If the final data are consistent with these results, MDNA55 could offer new hope to GBM patients and their families. We have completed 75% of the recruitment to date, expect to be fully enrolled by early 2019, report top line data in mid-2019 followed by an End of Phase 2 (EOP2) meeting with the USFDA. Medicenna is also exploring MDNA55 for use in newly diagnosed GBM as these patients typically present with much stronger immune systems and may stand to derive an even greater benefit," concluded Dr. Merchant.

Medicenna Provides Positive Interim Update From Phase 2b Trial of MDNA55 in Recurrent Glioblastoma #gbm (https://twitter.com/hashtag/gbm?src=hash&ref_src=twsrc%5Etfw) #mdna55 (https://twitter.com/hashtag/mdna55?src=hash&ref_src=twsrc%5Etfw) #braincancer (https://twitter.com/hashtag/braincancer?src=hash&ref_src=twsrc%5Etfw)https://t.co/h8J1KeuDxo (https://t.co/h8J1KeuDxo)

— Medicenna (@Medicenna1) October 31, 2018 (https://twitter.com/Medicenna1/status/1057600539268182016?ref_src=twsrc%5Etfw)

Positive topline results observed in Ph III MAIA trial of Daratumumab in 1L Multiple Myeloma patients (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-positive-topline-results-phase-iii-maia-study)

"We are highly encouraged by this data as this is the fifth randomized study showing a profound benefit when adding daratumumab to standard of care treatments in multiple myeloma, and the second showing efficacy for patients with newly diagnosed multiple myeloma who are not eligible for ASCT. As such this data increases our hope that daratumumab may one day help even more patients at the outset of treatment of this disease," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Genmab Announces Positive Topline Results in Phase III MAIA Study of Daratumumab in Front Line Multiple Myeloma https://t.co/pZAJBcFLsy (https://t.co/pZAJBcFLsy) pic.twitter.com/uFDqydyDLE (https://t.co/uFDqydyDLE)

— Hematopoiesis News (@Hema_News) November 2, 2018 (https://twitter.com/Hema_News/status/1058412225336086529?ref_src=twsrc%5Etfw)

Ph III E2112 trial of entinostat + exemestane failed to show significant PFS in HR+ HER2neg breast cancer patients; registrational trial of Entinostat + Pembrolizumab in PD-(L)1 Refractory NSCLC patients announced (http://www.syndax.com/wp-content/uploads/2018/10/E2112_NSCLC-Reg-PR_FINAL.pdf)

"While the PFS analysis did not show a statistically significant benefit, E2112 was primarily designed to determine whether the combination of entinostat and exemestane could improve OS based on the compelling OS results obtained in the Phase 2b ENCORE 301 trial," said Briggs W. Morrison, M.D., Chief Executive Officer of Syndax. "It was Phase 2b OS results that led to the FDA granting Breakthrough Therapy Designation for this indication and we remain confident in the opportunity for a positive OS trial."

E2112: randomized phase iii trial of #endocrine (https://twitter.com/hashtag/endocrine?src=hash&ref_src=twsrc%5Etfw) therapy plus entinostat/placebo in patients with #hormone (https://twitter.com/hashtag/hormone?src=hash&ref_src=twsrc%5Etfw) receptor-positive advanced #BreastCancer (https://twitter.com/hashtag/BreastCancer?src=hash&ref_src=twsrc%5Etfw)https://t.co/JFZDL5cDc2 (https://t.co/JFZDL5cDc2) pic.twitter.com/aysszggT7R (https://t.co/aysszggT7R)

— Nature Partner Jnls (@Nature_NPJ) April 12, 2018 (https://twitter.com/Nature_NPJ/status/984506437215838208?ref_src=twsrc%5Etfw)

"Patients whose disease has progressed despite treatment with PD-1 antagonists represent a very substantial unmet medical need, and efforts to identify novel biomarkers with clinical utility represent one of the most exciting areas of ongoing research," said Michael L. Meyers, M.D., Ph.D., Chief Medical Officer of Syndax. "The

proposed trial, which could both validate the use of classical monocytes as a selection criterion and establish the benefits of a new regimen over current standard of care, provides the opportunity for a significant advance for these patients."

TRIAL STATUSES

Trial initiated of CV301 + Durvalumab in mCRC and metastatic pancreatic cancer patients (http://www.bavarian-nordic.com/investor/news/news.aspx?news=5533)

> Bavarian Nordic Announces Initiation of Clinical Trial Evaluating the Combination Therapy of CV301 and Durvalumab in Metastatic Colorectal and Pancreatic Cancers: Investigatorled study has commenced dosingÂImmunotherapy candidate CV301 is now being... https://t.co/x4GEqQEpg9 (https://t.co/x4GEqQEpg9)
>
> — Pancreatic Cancer (@PancreaticC_Bio) November 2, 2018 (https://twitter.com/PancreaticC_Bio/status/1058361349519007744?ref_src=twsrc%5Etfw)

"We are excited to continue demonstrating CV301's potential in multiple cancers and combinations, particularly in a treatment setting in which checkpoint inhibition alone has yet to show significant benefit. The combination of a targeted cancer vaccine with a checkpoint inhibitor could result in a novel approach to fighting colorectal and pancreatic cancers, which are among the most difficult-to-treat malignancies to date," said Paul Chaplin, President and Chief Executive Officer of Bavarian Nordic.

OTW Trivia

Q: What is CTCAE scale?

A: The NCI Common Terminology Criteria for Adverse Events (CTCAE) is a criterion which is used to define Adverse Event (AE). A severity scale or grading is gives for each adverse event.

Q: What are different grades of AEs defined as per CTCAE?

A: The different grades referring to the severity of the AEs are defined from Grades 1 through 5. Each grade will have unique clinical descriptions of severity for each AE, and may change from indication to indication, but will follow a general guideline as below:

- **Grade 1:** Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not required
- **Grade 2:** Moderate; local, minimal or non-invasive intervention required; affecting age-appropriate daily activities
- **Grade 3:** Severe but not immediately life-threatening; hospitalization or prolongation of hospitalization required; disabling; impacting self care and daily activities
- **Grade 4:** Life-threatening events; intervention required urgently
- **Grade 5:** Death related to AE

Q: How it is different from RECIST guidelines?

A: RECIST guidelines are used to define tumor response to a drug; whereas CTCAE descriptive terminology is only for defining adverse events observed with treatment.

Q: Are CTCAE guidelines revised or updated regularly?

A: Yes, CTCAE guidelines have been revised over years and the most recent version is CTCAE 5.0, published in Nov, 2017.

Reference: https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm (https://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm)

About the Author:


(https://i0.wp.com/www.sciwri.club/wp-content/uploads/2018/03/RT.jpg)

Richa (https://www.linkedin.com/in/richatewari/) earned her PhD at the National Brain Research Centre, India. For her thesis, she worked on the dreaded Glioblastoma multiforme. That was her first in-depth exposure to academic research in cancer biology. After her PhD, she expanded her research experience by working in the field of immunology at UCLA, USA. After her return to India, Richa switched to a corporate setting but continued her engagement with the cancer field. She is currently loving her work, which affords her the opportunity to continue developing her knowledge in the biomedical field of cancer. Outside of work, she enjoys watching, identifying and photographing birds.

Editor and Blog Design:


(https://i1.wp.com/www.sciwri.club/wp-content/uploads/2016/06/Self2015.jpg)

Abhi Dey (https://www.linkedin.com/in/abhinavdey/)

Abhi graduated from the Molecular Biophysics Unit of IISc (Bangalore, India) in 2011. As a Biomedical Scientist, he has worked with all three life-forms in his 13-year research career, viz., particulate, unicellular and multicellular. He is currently an Assistant Scientist at Emory University (Atlanta, GA) studying mechanisms of tumor recurrence in kids with brain tumors. As a postdoctoral fellow, he was the recipient of two Young Investigator Awards from Alex Lemonade Stand Foundation (Philadelphia, PA) and Rockland Immunochemicals. His current research has been funded by Northwestern Mutual Foundation (Milwaukee, WI), CURE Childhood Cancer Foundation (Atlanta, GA) and American Association for Cancer Research (AACR). When he is not on the bench you will find him spending time with his family or exploring the world through traveling and blogging.

Image Sources: Wikipedia and Twitter

Cover image: (CellImageLibrary)Immunofluorescence image of human IMR90 lung fibroblasts stained for vinculin (green) and filamentous actin (magenta). Nuclei are stained blue. This image of untreated fibroblasts comes from a study of the changes in adhesion that accompany treatment to induce stem cells and can be used in hiPSC purification. See also Singh et al. 2013 Nat Meth 10:438-444. The image appeared in the May 2013 issue of the NIGMS Biomedical Beat which features noteworthy NIGMS-supported research.– Source (http://cellimagelibrary.org/images/44701)

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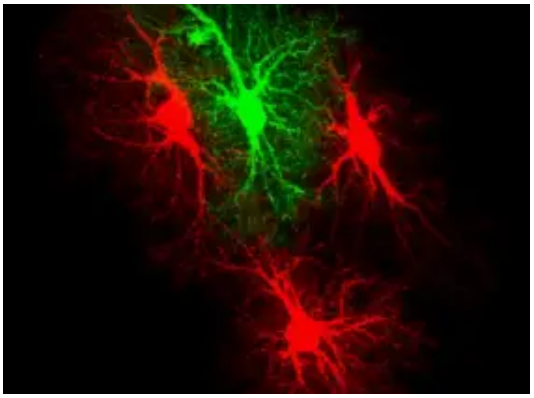

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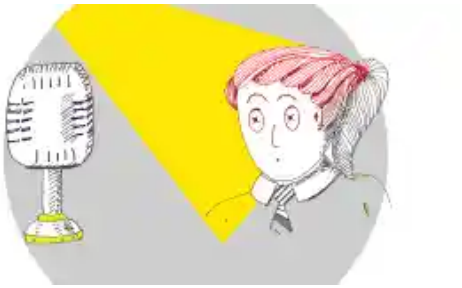

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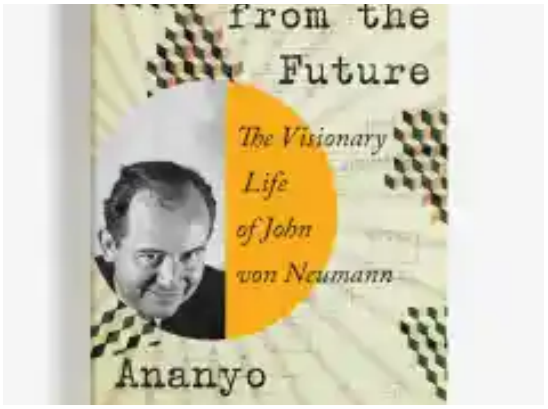

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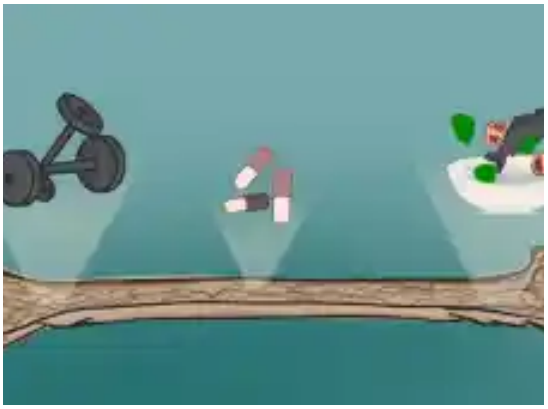

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