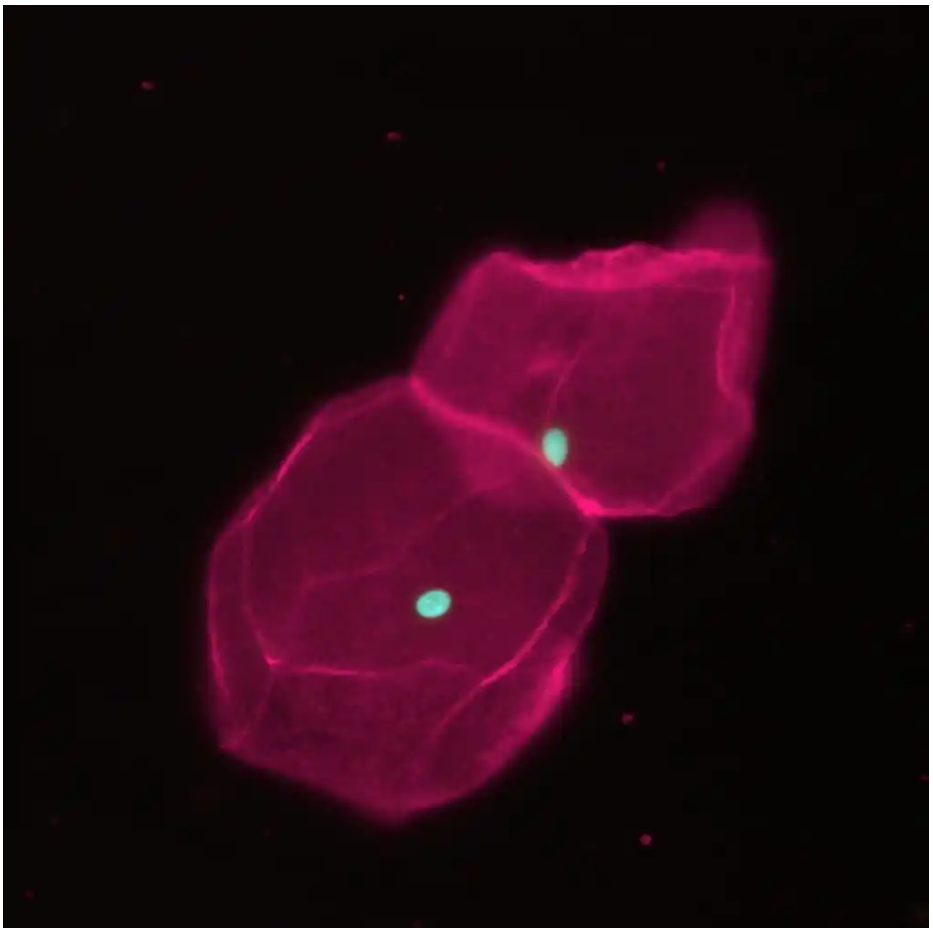
Archives (https://sciwri.club/archives/category/archives)

Onco-this-Week

April 21, 2019(https://sciwri.club/archives/date/2019/04/21)



SHARE THIS

This Edition Of Onco-This-Week Is Sponsored By

North America Immigration Law Group (Https://Goo.Gl/VLv3K1) & Nano-Tag Biotechnologies (Https://Goo.Gl/XM63s6)

HIGHLIGHTS

1. **Approval of Erdafitinib in Bladder cancer:** With this approval, Erdafitinib scores two 'firsts' – not only it becomes the first FGFR inhibitor to be approved by FDA, it also marks the approval of first targeted therapy in metastatic bladder cancer; an area otherwise saturated with immunotherapy. With FGFR mutations affecting almost 20% recurrent or refractory bladder cancer patients, the approval brings new hopes. The accelerated approval would be changed to full approval, based on the findings in a confirmatory trial.

2. **Discontinuation of Ph II ATLAS trial of Rucaparib in recurrent metastatic bladder cancer:** Clovis shares slide after the company decided to discontinue Ph II ATLAS trial. There were two things to note, though: the decision to discontinue the trial was not taken because of any safety concerns. Clovis does not hang the curtains of Rucaparib program though: the company plans to bring back combination trial in 2H 2019, in a pre-selected enriched population.

3. **Fast track designation to INT230-6 in heavily pre-treated mTNBC patients**: TNBC is one therapeutic area that is characterized by a huge unmet need; owing to the absence of targetable molecules like HER2 or HR (ER/PR). The fast track designation granted to this immune-based approach thus brings hope for the heavily pre-treated patients. All the eyes would be on Ph II trial, which the company plans to initiate this year.

DRUG APPROVALS

Erdafitinib approved in FGFR2/3+ locally advanced or metastatic bladder cancer patients who progressed on platinum-containing chemotherapy (https://www.janssen.com/balversa-erdafitinib-receives-us-fda-approval-treatment-patients-locally-advanced-or-metastatic)

> FDA approves first targeted therapy for metastatic bladder cancer: https://t.co/5uhFxwXWrM (https://t.co/5uhFxwXWrM) #erdafitinib (https://twitter.com/hashtag/erdafitinib?src=hash&ref_src=twsrc%5Etfw) #bladdercancer (https://twitter.com/hashtag/bladdercancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/thAuqEzJRf (https://t.co/thAuqEzJRf)
>
> — National Cancer Institute (@theNCI) April 12, 2019 (https://twitter.com/theNCI/status/1117610824865669 14?ref_src=twsrc%5Etfw)

"I've spent my career specializing in the care of patients with metastatic urothelial carcinoma and understand the need for new treatments for this disease," said Arlene O. Siefker-Radtke, M.D., professor of Genitourinary Medical Oncology, The University of Texas MD Anderson Cancer Center, and lead study investigator. "BALVERSA is an important new therapy for this small subset of patients with urothelial carcinoma who, up until now, had limited treatment options."

SPECIAL STATUSES

Fast track designation granted to next-gen anthracycline drug, Annamycin, in R/R AML patients (https://ir.moleculin.com/press-releases/detail/129/moleculin-receives-fda-approval-of-fast-track-designation)

> FDA Fast Tracks @moleculinbio (https://twitter.com/moleculinbio?ref_src=twsrc%5Etfw)'s #annamycin (https://twitter.com/hashtag/annamycin?src=hash&ref_src=twsrc%5Etfw) vs relapsed/refractory #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw)
>
> Yesterday, company reported non-cardiotoxic #anthracycline (https://twitter.com/hashtag/anthracycline?src=hash&ref_src=twsrc%5Etfw) improved survival in mice w/ lung-metastasized #TNBC (https://twitter.com/hashtag/TNBC?src=hash&ref_src=twsrc%5Etfw)https://t.co/AcvipTQHg3 (https://t.co/AcvipTQHg3)#oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #tumor (https://twitter.com/hashtag/tumor?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) @LythamIR (https://twitter.com/LythamIR?ref_src=twsrc%5Etfw) pic.twitter.com/iWczDWUqjU (https://t.co/iWczDWUqjU)
>
> — DDNews Online (@DDNewsOnline) April 18, 2019 (https://twitter.com/DDNewsOnline/status/1118944787246325760?ref_src=twsrc%5Etfw)

"We are thrilled that Annamycin has been granted Fast Track Designation," commented Walter Klemp, Moleculin's Chairman and CEO. "Not only does this make us eligible for accelerated approval and priority review, but it serves as an important validation of the significant unmet need we are trying to address. Currently, Annamycin is in separate Phase I/II trials in the U.S. and Europe for the treatment of AML and the Company has recently announced positive

interim top line data."

Fast track designation granted to INT230-6 in 3L+ mTNBC patients (https://intensitytherapeutics.com/intensity-therapeutics-receives-fast-track-designation-from-u-s-fda-for-development-of-int230-6-as-treatment-for-relapsed-or-metastatic-triple-negative-breast-cancer/)

> I'd urge you to listen to this interview. #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw)
>
> Intensity Therapeutics using their Diffuse RX INT230-6 platform to kill tumours and allow the body to create it's own immune response.https://t.co/Sj43cy9fqE (https://t.co/Sj43cy9fqE)
>
> Held within the @ffwdinnovations (https://twitter.com/ffwdinnovations?ref_src=twsrc%5Etfw) portfolio.
>
> — Matador © (@Tat_TvamAsi) March 31, 2019 (https://twitter.com/Tat_TvamAsi/status/1112325200215834624?ref_src=twsrc%5Etfw)

"We are extremely pleased to receive this Fast Track designation, which validates the potential of INT230-6 to treat patients with relapsed or metastatic triple negative breast cancer as a single agent," said Lewis H. Bender, President and Chief Executive Officer of Intensity Therapeutics. "Finding improved therapies for this disease is a critical unmet medical need, and we look forward to working closely with the FDA this year to initiate a Phase 2 clinical study for this indication."

Fast Track designation granted to p53 reactivator APR-246 in p53 mutant MDS patients (https://www.aprea.com/news/aprea-therapeutics-receives-fda-fast-track-designation-and-orphan-drug-designation-for-apr-246-for-the-treatment-of-myelodysplastic-syndromes-mds/)

> The FDA granted fast track designation to APR-246 for the treatment of patients with myelodysplastic syndrome who have TP53 mutations. https://t.co/z12UzTT49U (https://t.co/z12UzTT49U) pic.twitter.com/d8X9z1k1Ic (https://t.co/d8X9z1k1Ic)
>
> — MDS Foundation, Inc. (@MDSFoundation) April 19, 2019 (https://twitter.com/MDSFoundation/status/1119171312113598464?ref_src=twsrc%5Etfw)

"The granting of Fast Track designation and Orphan Drug Designation by FDA for APR-246 in TP53 mutated MDS underscores the significant unmet medical need in this disease," said Christian S. Schade, President and Chief Executive Officer of Aprea. "With our Phase 3 clinical study in MDS underway, we look forward to continuing our productive dialogue with FDA and bringing APR-246 to patients as soon as possible."

TRIAL STATUSES

Ph I trial of bacterial minicell-based oncolytic immunotherapy VAX014 to be initiated in NMIBC patients (https://www.businesswire.com/news/home/20190418005162/en/)

> SDBN Feed: Vaxiion Therapeutics Initiates Phase 1 Clinical Trial of VAX014 for the Treatment of Non-Muscle Invasive Bladder Cancer in the United States – https://t.co/LNpYGoPXzQ (https://t.co/LNpYGoPXzQ) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) #news (https://twitter.com/hashtag/news?src=hash&ref_src=twsrc%5Etfw)
>
> — SDBN (@sdbn) April 18, 2019 (https://twitter.com/sdbn/status/1118873431968309248?ref_src=twsrc%5Etfw)

"Advancing our first product candidate into clinical trials is a major milestone, signifying Vaxiion's transition to a clinical stage company," said Vaxiion President, Matthew Giacalone. "We are now one step closer to achieving our ultimate goal of filling the unmet needs existing in the gaps of the current non-muscle invasive bladder cancer treatment algorithm."

First patient dosed in Ph I/IIa trial of mesothelin-targeting T cell engager HPN536 in ovarian and other solid tumors (https://ir.harpoontx.com/news-releases/news-release-details/harpoon-therapeutics-doses-first-patient-mesothelin-targeting-t)

> #Harpoon (https://twitter.com/hashtag/Harpoon?src=hash&ref_src=twsrc%5Etfw) Therapeutics has initiated a phase 1/2a study of #HPN536 (https://twitter.com/hashtag/HPN536?src=hash&ref_src=twsrc%5Etfw) in patients with advanced cancers associated with mesothelin expression who have failed standard therapy. #Beacon (https://twitter.com/hashtag/Beacon?src=hash&ref_src=twsrc%5Etfw) #Bispecific (https://twitter.com/hashtag/Bispecific?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/GgQc2NFMOa (https://t.co/GgQc2NFMOa)
>
> — Beacon Intelligence (@BeaconIntel) March 19, 2019 (https://twitter.com/BeaconIntel/status/1108005208787955714?ref_src=twsrc%5Etfw)

“We are pleased with the rapid progress of our clinical programs, based on our proprietary TriTAC platform, with patient dosing now underway for our second product candidate, HPN536, that targets mesothelin,” said Natalie Sacks, M.D., Chief Medical Officer of Harpoon Therapeutics. “The dose escalation portion of the trial will focus on patients with ovarian cancer, where mesothelin is over expressed in a high percentage of patients. HPN536 is a targeted, off the shelf immunotherapy that has been optimized for delivery to solid tumors and designed to provide a novel way to engage a patient’s own immune cells to fight cancer for patients who have limited treatment options.”

Ph II ATLAS trial of Rucaparib in recurrent metastatic bladder cancer discontinued post IDMC review (http://www.pharmafile.com/news/521270/clovis-oncology-discontinue-phase-2-bladder-cancer-trial)

> #AACR19 (https://twitter.com/hashtag/AACR19?src=hash&ref_src=twsrc%5Etfw) – A Phase II clinical trial of the PARP inhibitor rucaparib has demonstrated clinical responses in a subgroup of patients with #pancreaticcancer (https://twitter.com/hashtag/pancreaticcancer?src=hash&ref_src=twsrc%5Etfw). Click the image for the full news story: https://t.co/xlymySvscT (https://t.co/xlymySvscT)
>
> — Oncology Central (@OncologyCentral) April 18, 2019 (https://twitter.com/OncologyCentral/status/1118786241116262400?ref_src=twsrc%5Etfw)

The decision to discontinue Ph II ATLAS trial was based on decisions taken post analysis from an independent data monitoring committee. The review of preliminary data from 62 patients found the treatment “may not provide a meaningful clinical benefit.” Clovis maintained that the decision was not based on any safety concern.

COLLABORATIONS

Ph I/II trial to evaluate anti-CEACAM1 mAB CM-24 + Nivolumab in NSCLC patients (https://www.nasdaq.com/press-release/famewave-announces-clinical-collaboration-with-bristol-myers-squibb-for-the-planned-phase-12-trial-20190412-00252)

> $KTOV (https://twitter.com/search?q=%24KTOV&src=ctag&ref_src=twsrc%5Etfw) FameWave Announces Clinical Collaboration with Bristol Myers Squibb for the Planned Phase 1/2 Trial in Non-Small Cell Lung Cancer to Evaluate Immuno-Oncology Candidate CM-24 in Combination with Nivolumab (Opdivo®)https://t.co/ChvGEYOr6O (https://t.co/ChvGEYOr6O)
>
> — Stock News Now (@StockNewsNow) April 12, 2019 (https://twitter.com/StockNewsNow/status/1116727781939748870?ref_src=twsrc%5Etfw)

“FameWave’s collaboration with Bristol-Myers Squibb, a global leader in immuno-oncology, is a crucial step to begin evaluation of CM-24 in combination with a PD-1 inhibitor,” said Dr. Michael Schickler, chief executive officer of FameWave. “We look forward to evaluating CM-24 in NSCLC since we believe it has a great potential as a novel immune checkpoint to be used in combination therapies for a variety of hard-to-treat cancers.”

COMPANION Dx

Approval expanded for PD-L1 IHC 22C3 pharmDx assay; to be used for 1L NSCLC patients suitable for Pembrolizumab too (https://www.agilent.com/about/newsroom/presrel/2019/16apr-ca19009.html)

> The FDA has expanded the approval of the PD-L1 IHC 22C3 pharmDX assay, allowing the test to be used as a companion diagnostic to identify more patients with stage III or metastatic NSCLC who can undergo first-line treatment with pembrolizumab #lcsm (https://twitter.com/hashtag/lcsm?src=hash&ref_src=twsrc%5Etfw) https://t.co/UJFcVyo8KK (https://t.co/UJFcVyo8KK)
>
> — OncLive.com (@OncLive) April 17, 2019 (https://twitter.com/OncLive/status/1118662942965358592?ref_src=twsrc%5Etfw)

“Anti-PD-1 therapies are a promising treatment class for many cancer types, and PD-L1 testing provides key information to physicians managing stage III or metastatic NSCLC patients,” said Sam Raha, president of Agilent’s Diagnostics and Genomics Group. “The updated FDA approval of PD-L1 IHC 22C3 pharmDx broadens the scope of patients that can be identified for first-line treatment with KEYTRUDA and offers new hope to the many patients diagnosed with stage III or metastatic NSCLC. By expanding the use of PD-L1 IHC 22C3 pharmDx, Agilent strives to continue our legacy of pioneering companion diagnostics to support the launch of landmark therapies.”

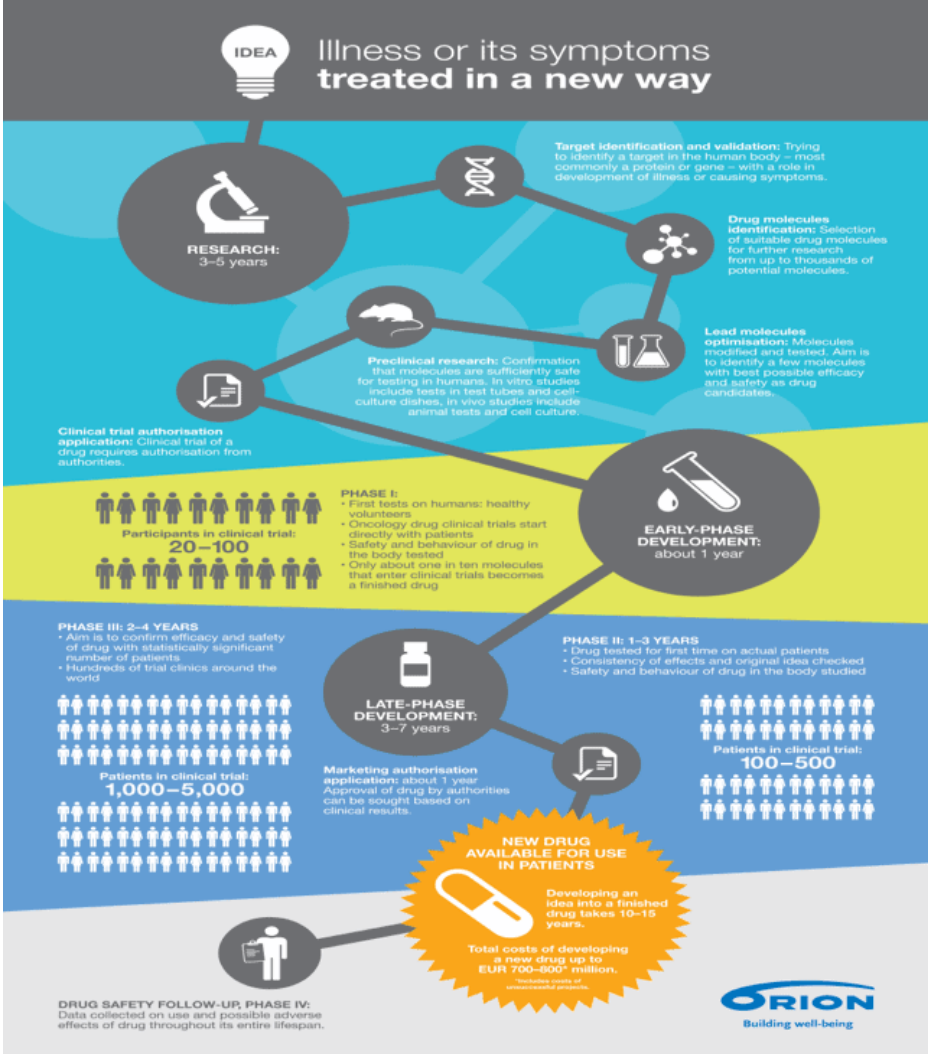
CONFERENCE COVERAGE

> ASCO Announces Top Studies to Be Presented at 2019 Annual Meeting | @ASCO (https://twitter.com/ASCO?ref_src=twsrc%5Etfw) #ASCO19 (https://twitter.com/hashtag/ASCO19?src=hash&ref_src=twsrc%5Etfw) https://t.co/kK8TQrYiVj (https://t.co/kK8TQrYiVj)
>
> — Dr Sunil Verma (@cancermd) April 18, 2019 (https://twitter.com/cancermd/status/1118859416550248448?ref_src=twsrc%5Etfw)

1. ASCO 2019: TLR9 agonist SD-101 + Pembrolizumab data from Ph Ib/II trial in PD-(L)1 naive or ref melanoma, SCCHN patients to be presented (http://investors.dynavax.com/news-releases/news-release-details/dynavax-present-data-toll-receptor-9-agonist-sd-101-asco-annual)
2. ASCO 2019: Top studies to be presented at ASCO (including 5-yr survival data of Pembro in mNSCLC patients in KEYNOTE-001 trial) (https://www.asco.org/about-asco/press-center/news-releases/asco-announces-top-studies-be-presented-2019-annual-meeting)
3. ASCO 2019: Updates from STING agonist ADU-S100 and anti-APRIL antibody BION-1301 to be presented (http://investors.aduro.com/news-releases/news-release-details/aduro-biotech-abstracts-accepted-presentation-2019-american)
4. ASCO 2019: Updates from CASSIOPEIA, MAIA, COLUMBA, CASTOR, POLLUX, CEPHEUS, SGNTV-001, innovaTV 208, COMPLEMENT 1 and PERSEUS trials to be presented (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-data-be-presented-2019-asco-annual-meeting)
5. ASCO 2019: PV10 updates from Ph I and Ib trials in mNET and cutaneous melanoma patients to be presented (https://www.provectusbio.com/news/press-releases/provectus-pr-20190417-1)
6. ELCC 2019: mOS NR at 20-month follow-up with Atezolizumab with Bev and Chemo in 1L non-sq and 2L EGFR/ALK+ mNSCLC in Ph III IMpower150 trial (https://www.onclive.com/conference-coverage/elcc-2019/atezolizumab-regimen-improves-os-after-tki-failure-in-egfr-positive-nsclc)
7. ELCC 2019: Updated Entrectinib data in overall and CNS positive cohorts from Ph I ALKA-372-001, STARTRK-1 and Ph II STARTRK-2 trials presented (https://www.onclive.com/conference-coverage/elcc-2019/entrectinib-data-highlighted-as-fda-weighs-approval-for-ros1-nsclc?eKey=cnRld2FyaUBzbWFydGFuYWx5c3QuY29t&utm_medium=email&utm_campaign=ONCSS%20Conference%20Coverage%20360%20ELCC%20
8. ELCC 2019: 77% ORR with Osimertinib in 1L EGFR+ NSCLC patients in Ph I AURA trial; supports Ph III FLAURA trial results and approval (https://www.onclive.com/conference-coverage/elcc-2019/update-further-supports-osimertinib-in-frontline-egfr-positive-nsclc?eKey=cnRld2FyaUBzbWFydGFuYWx5c3QuY29t&utm_medium=email&utm_campaign=ONCSS%20Conference%20Coverage%20360%20ELCC%20
9. ESMO GI 2019: Update on allogeneic and autologous NKG2D-based CAR-T candidates in refractory mCRC patients to be presented (https://www.celyad.com/en/news/celyad-to-present-update-on-allogeneic-and-autologous-nkg2d-based-car-t-candidates-in-refractory-mcrc-at-esmo-21st-world-gi-congress)

OTW Trivia

Drug Development Timeline: From Bench to Bedside



(Source: https://www.orion.fi/en/rd/drug-development/)
(https://www.orion.fi/en/rd/drug-development/)HIGHLIGHTS)

About the Author:


(https://io.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:

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. Currently, he is a Lead Scientist at MicroCures Inc. Previously, he served as 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 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: "Fluorescent micrograph of epithelial cells from the bladder wall. The cells were isolated immediately after collection of a urine specimen and are not fixed. The image was taken using a standard epi-fluorescent microscope." Source (http://www.cellimagelibrary.org/images/40968)

group is to build a NETWORK among scientists, engineers and entrepreneurs).

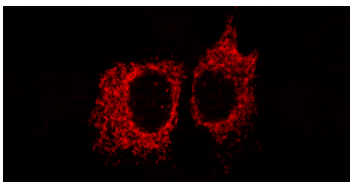
Disclaimer

The authors and editors for Onco-this-week declare no financial benefits or remuneration from the sponsors. The sponsorships support the non-profit organization PhD Career Support Group (PhD CSG). The research conducted by authors and editors is a voluntary effort to popularize science for the public on behalf of PhD CSG. The sponsors do not have any influence on the nature or kind of the news/analysis reported in Onco-this-Week. The views and opinions expressed in this article are those of the authors and do not necessarily reflect the official policy or position of Club SciWri or PhD CSG. Examples of analysis performed within this article are only examples. They should not be utilized in real-world analytic products as they are based only on very limited and dated open source information. Assumptions made within the analysis are not reflective of the position of anyone volunteering or working for Club SciWri or PhD CSG. This blog is strictly for news and information. It does not provide medical advice, diagnosis or treatment. This content is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of your physician or another qualified health provider with any questions you may have regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of something you have read on this website.

SHARE THIS

TAGS

RELATED ARTICLES



(https://sciwri.club/archives/6596)

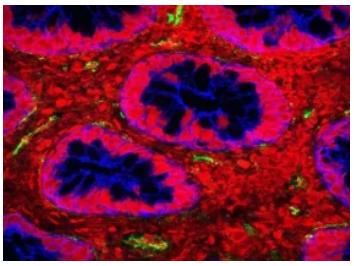
Onco-this-Week (ASCO2018 Special Bulletin) (https://sciwri.club/archives/6596)

(https://sciwri.club/archives/1655)

CSG LinkedIN Discussions (https://sciwri.club/archives/1655)

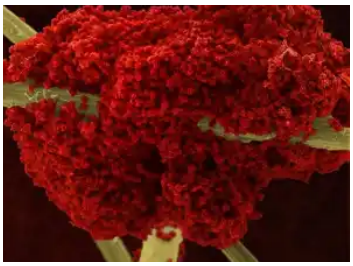
(https://sciwri.club/archives/2139)

Pooja: When a film maker becomes a science communicator (https://sciwri.club/archives/2139)



(https://sciwri.club/archives/8818)

Onco-this-Week (https://sciwri.club/archives/8818)



(https://sciwri.club/archives/8484)

Medness Plus (https://sciwri.club/archives/8484)

(https://sciwri.club/archives/4479)

Why do we follow norms? (https://sciwri.club/archives/4479)

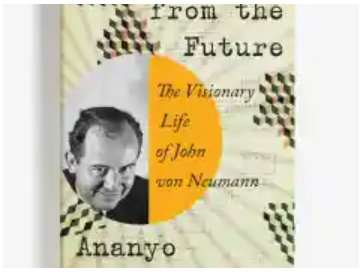
LATEST FROM CLUB SCIWRI

(https://sciwri.club/archives/13304)

There and back again: Angela Andersen's journey as a scientist-turned-science editor helping others to succeed (https://sciwri.club/archives/13304)

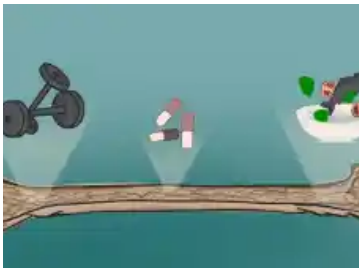
(https://sciwri.club/archives/13267)

A Chat with Science Writer Philip Ball (https://sciwri.club/archives/13267)



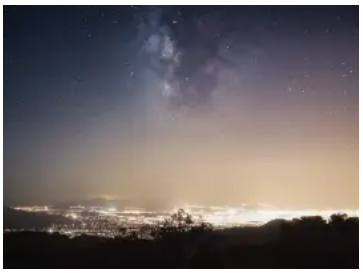
(https://sciwri.club/archives/13232)

Exploring 'The Man From The Future': A Conversation with Ananyo Bhattacharya (https://sciwri.club/archives/13232)



(https://sciwri.club/archives/13186)

The Hidden Life of Bones (https://sciwri.club/archives/13186)



(https://sciwri.club/archives/13160)

Bright lights, big problems: Exploring light pollution's impact on our eyes (https://sciwri.club/archives/13160)

(https://sciwri.club/archives/13113)

Redefining the meaning of "checking the right boxes"—achieving science equity. (https://sciwri.club/archives/13113)

Support Club SciWri

DONATE (HTTPS://WWW.PAYPAL.COM/DONATE/?CMD=_S-XCLICK&HOSTED_BUTTON_ID=KLALD3KMHZFR2)

(https://www.facebook.com/sciwri.club) (https://twitter.com/ClubSciWri) (https://www.instagram.com/clubsciwri/) (https://www.linkedin.com/company/club-sciwri)

Help scientists make science accessible for all