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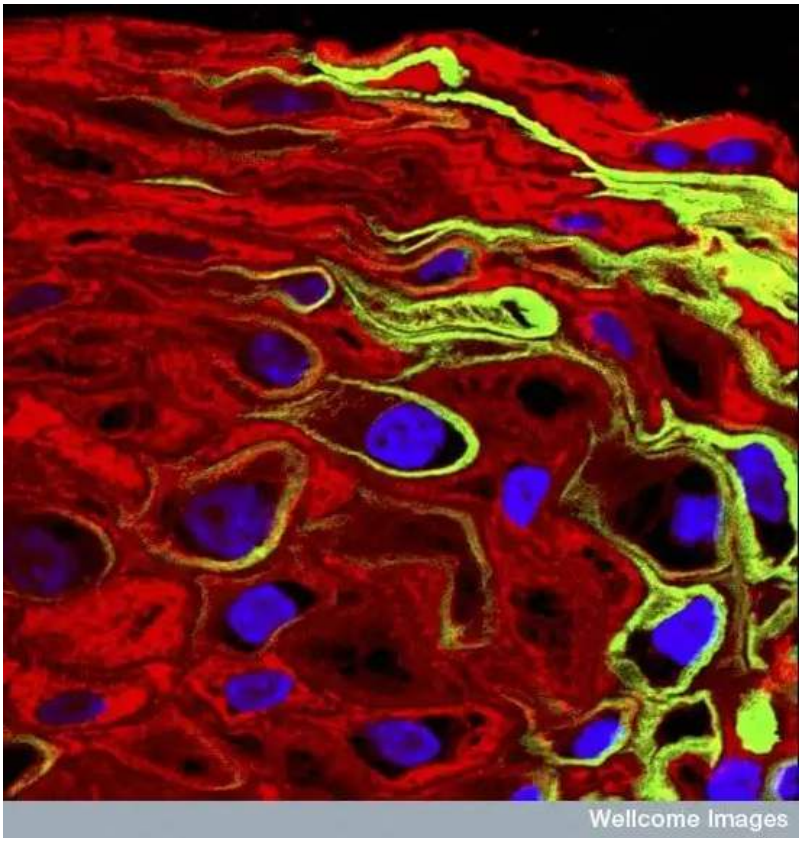
Onco-this-Week

October 28, 2018(https://sciwri.club/archives/date/2018/10/28)



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The top three news in Onco-this-Week include Cisplatin's good show in HPV-positive oropharyngeal cancer and Pembrolizumab showing a complete response rate of approximately 40% in patients with High-Risk Non-Muscle Invasive Bladder Cancer (NMIBC) unresponsive to standard of care. Our trivia section features a QnA on the RECIST guidelines for solid tumor treatments and check out how these guidelines are changing to accommodate immunotherapies. Also featured is the coverage from ESMO 2018 conference organized by European Society for Medical Oncology. – Abhi Dey

OTW in a Capsule

1. ***Cisplatin remains standard for low-risk HPV+ oropharyngeal cancer.*** In today's world, when cytotoxics have lagged behind targeted agent and immunotherapies, cisplatin came back pretty strongly in low-risk HPV+ oropharyngeal cancer. 300+ patients were randomized to get radiotherapy with either cisplatin or EGFR inhibitor, Cetuximab, which was expected to show improved or same survival rates but better toxicity profiles. However, as per the results announced in ESMO 2018 conference, Cetuximab showed worse OS and added to toxicities. So, no change of SoC here yet!
2. ***CRR of ~40% with Pembrolizumab in high-risk NMIBC patients unresponsive to BCG therapy.*** Though immunotherapies have already established themselves in metastatic bladder cancer space and more are still coming (read Nivolumab + Ipilimumab combination in heavily pre-treated mBladder Cancer patients), the early stage bladder cancer patients still had fewer options. As per results from Ph II KEYNOTE-057 trial presented in ESMO 2018, Pembrolizumab not only shows the potential to be an emerging option in this patient segment which makes up to 80% of all newly diagnosed bladder cancer cases, it also consolidates its anti-tumor activity as monotherapy in various cancers.
3. ***Missing 'sting' in MK-1454 monotherapy data.*** Merck presented preliminary data of its STING agonist, MK-1454, from Ph I trial in ESMO 2018, and it was not difficult to see why the much-awaited data failed to created a buzz in investors and clinicians. In combination arm with Pembrolizumab, there were still some PRs but the monotherapy arm fared very badly with notable absences of any CRs or PRs. Even in the combination arm, the responders are all PD-(L)1-naive patients – the unmet need in progressors thus remains unfilled.

REGULATORY NEWS

Priority review granted to LONSURF® (trifluridine/tipiracil)'s sNDA for the treatment of metastatic Gastric/ Gastroesophageal Junction (GEJ) adenocarcinoma; PDUFA Feb 2019 (https://www.taiho.co.jp/en/release/2018/20181026.html)

> Compelling data for Lonsurf in metastatic #gastriccancer (https://twitter.com/hashtag/gastriccancer?src=hash&ref_src=twsrc%5Etfw) presented at ESMO 2018 https://t.co/5wttEJIYbR (https://t.co/5wttEJIYbR) pic.twitter.com/5apFnssnB2 (https://t.co/5apFnssnB2)
>
> — StomachCancerCa (@StomachCancerCa) October 22, 2018 (https://twitter.com/StomachCancerCa/status/1054389916707291136?ref_src=twsrc%5Etfw)

The sNDA was based on data from randomized, pivotal Ph III TAGS trial evaluating LONSURF versus placebo and BSC in 2L+ metastatic gastric/gastroesophageal junction (GEJ) adenocarcinoma patients. The trial met its primary endpoint of improvement in overall survival (OS) and secondary endpoint of improvement in progression-free survival (PFS) with consistent safety and tolerability profile.

EMA adopts positive opinion for Pembrolizumab as adjuvant therapy in Melanoma based on RFS data from pivotal Ph III EORTC1325/KEYNOTE-054 trial (https://investors.merck.com/news/press-release-details/2018/European-Medicines-Agency-Adopts-Positive-Opinion-for-Mercks-KEYTRUDA-pembrolizumab-as-Adjuvant-Therapy-in-Melanoma/default.aspx)

> $MRK (https://twitter.com/search?q=%24MRK&src=ctag&ref_src=twsrc%5Etfw) EMA Adopts Positive Opinion for KEYTRUDA® as Adjuvant Therapy in Melanoma https://t.co/lsbMQ7XD8M (https://t.co/lsbMQ7XD8M)
>
> — Odi Bruckman (@odibro) October 22, 2018 (https://twitter.com/odibro/status/1054325214803320832?ref_src=twsrc%5Etfw)

"There is a growing need for innovative therapies that can help reduce the risk of recurrence following surgery in patients with stage III melanoma," said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. "Today's news reflects the collaborative efforts of Merck and EORTC to improve the way we treat melanoma earlier in the treatment paradigm. We look forward to working with European regulatory authorities to bring KEYTRUDA to these patients in the adjuvant setting."

RESULTS

Ph III ARAMIS trial of AR inhibitor Darolutamide completed in nmCRPC patients – primary endpoint met (https://www.orion.fi/en/Orion-group/media/stock-exchange-releases/2018/orion-and-bayer-have-completed-the-phase-iii-trial-of-darolutamide-in-patients-with-non-metastatic-castration-resistant-prostate-cancer---the-primary-endpoint-was-met/)

> SPARTAN vs PROSPER vs ARAMIS Darolutamide(ODM-201) significantly extended metastasis-free survival ,compared to placebo.The safety profile and tolerability has been granted Fast Track by FDA pic.twitter.com/mfFXcORmAZ (https://t.co/mfFXcORmAZ)
>
> — GUO-AEU (@GUOaeu) October 26, 2018 (https://twitter.com/GUOaeu/status/1055769988672434176?ref_src=twsrc%5Etfw)

"Prostate cancer is the second most commonly diagnosed malignancy in men in worldwide, and approximately 70 percent of patients have the non-metastatic form of the disease. While conventional hormone therapy is effective in the treatment of non-metastatic cancer, the efficacy is often eventually lost as the sole form of treatment. Additional treatment options in the early stages of the cancer that delay the time to metastases with a manageable safety profile are long awaited. They are significant for the patient's overall well-being," says Christer Nordstedt, Senior Vice President, Research and Development at Orion.

Ph III CASSIOPEIA study of Daratumumab + bortezomib + thalidomide + dexamethasone in 1L multiple myeloma patients met the primary endpoint of sCR after induction and consolidation therapy (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-positive-topline-results-phase-iii-cassiopeia)

> Genmab Announces Positive Topline Results in Phase III CASSIOPEIA Study of Daratumumab in Front Line #MultipleMyeloma (https://twitter.com/hashtag/MultipleMyeloma?src=hash&ref_src=twsrc%5Etfw) @Genmab (https://twitter.com/Genmab?ref_src=twsrc%5Etfw) https://t.co/vLBx1ntbsZ (https://t.co/vLBx1ntbsZ) pic.twitter.com/eZronEjr3R (https://t.co/eZronEjr3R)
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> — Hematopoiesis News (@Hema_News) October 27, 2018 (https://twitter.com/Hema_News/status/1056184194068635648?ref_src=twsrc%5Etfw)

"Having previously seen positive data in the ALCYONE trial, for the frontline treatment of patients ineligible for

autologous stem cell transplant, we are very pleased to see the results from the CASSIOPEIA study, which presents exciting insights into the potential of daratumumab for newly diagnosed multiple myeloma patients who received an autologous stem cell transplantation (ASCT). We also look forward to the data from the second part of the study, which will provide further data on the impact of daratumumab monotherapy as maintenance treatment," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

TRIAL STATUSES

BeiGene announces NDA acceptance in China and top-line pivotal data for BTKi Zanubrutinib in R/R CLL or SLL patients (http://ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2373150)

"Our team has made three NDA submissions in China this year, including two for zanubrutinib and one for tislelizumab, our investigational anti-PD-1 antibody. We are hopeful that these submissions, if approved, could further transform BeiGene as well as bring important new treatment options to cancer patients," commented John Oyler, co-founder, CEO and Chairman of BeiGene.

> Zanubrutinib Shows Promise in Phase 1 Trial
> "The data showed that all patients with CLL/SLL responded to treatment, including 2 complete responses, 6 partial responses, and 1 partial response with lymphocytosis..."https://t.co/G6dKyVmHEW (https://t.co/G6dKyVmHEW)
>
> — CLL Ireland (@CllIreland) October 21, 2018 (https://twitter.com/CllIreland/status/1053994577722597378?ref_src=twsrc%5Etfw)

"We are delighted that the submission for zanubrutinib in patients with relapsed/refractory CLL/SLL was accepted by the NMPA in China, and we are excited to announce the top-line pivotal data for zanubrutinib in these patients, which demonstrated a high overall response rate of 80 percent despite a relatively short follow-up. These results in China are also consistent with the data from our global studies," said Dr. Xiaobin Wu, General Manager of China and President of BeiGene, Ltd.

COLLABORATIONS

Daiichi Sankyo, Merck and Pfizer to evaluate HER2-targeting ADC DS-8201 with Avelumab and a DDRi in HER2-expressing or mutated solid tumors (https://www.bizjournals.com/prnewswire/press_releases/2018/10/25/NY50691)

> Daiichi Sankyo signs clinical trial collaboration deal with Merck and Pfizer: Daiichi Sankyo has entered into a clinical trial collaboration agreement with Merck and Pfizer to evaluate the combination of its [fam-] trastuzumab deruxtecan (DS-8201) with... https://t.co/N83w7zGYxv (https://t.co/N83w7zGYxv)
>
> — cafepharma (@cafepharma) October 26, 2018 (https://twitter.com/cafepharma/status/1055825836513710080?ref_src=twsrc%5Etfw)

"The collaboration is another milestone in our development strategy to maximize the potential of [fam-] trastuzumab deruxtecan for various HER2 expressing and mutated cancers in combination with immunotherapy and other agents with novel mechanisms of action," said Tom Held, Vice President, Head, Antibody Drug Conjugate Task Force, Oncology Research and Development, Daiichi Sankyo. "We look forward to working with Merck KGaA, Darmstadt, Germany and Pfizer to determine an appropriate combination strategy to help further improve outcomes for patients. In particular, we are enthusiastic about better understanding the potential of combining [fam-] trastuzumab deruxtecan with DNA damage response agents."

AstraZeneca strengthens and expands oncology development and commercialisation collaboration with Innate Pharma; obtains full rights to anti-NKG2A antibody monalizumab (https://www.astrazeneca.com/media-centre/press-releases/2018/astrazeneca-strengthens-and-expands-oncology-development-and-commercialisation-collaboration-with-innate-pharma23102018.html)

$IPH.PA (https://twitter.com/search?q=%24IPH.PA&src=ctag&ref_src=twsrc%5Etfw) Poster: Phase II study of monalizumab, a first-in-class NKG2A monoclonal antibody, in combination with cetuximab in previously treated recurrent or metastatic squamous cell carcinoma of the head and neck (R/M SCCHN) #ESMO18 (https://twitter.com/hashtag/ESMO18?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/9Y2DTG40g0 (https://t.co/9Y2DTG40g0)

— Tom Silver (@TomSilver39) October 20, 2018 (https://twitter.com/TomSilver39/status/1053781591212797952?ref_src=twsrc%5Etfw)

Pascal Soriot, Chief Executive Officer, said: "Our expanded collaboration with Innate Pharma enables us to further strengthen our leadership in immuno-oncology, and to explore the potential of next-generation immuno-oncology pathways, together with the world-class scientific team of Innate. Today's agreement also secures the long-term commercialisation of the recently FDA approved rare disease medicine, Lumoxiti, through dedicated focus and investment by Innate Pharma."

HIGHLIGHTS FROM ESMO 2018

Cisplatin remains standard for low-risk HPV+ oropharyngeal cancer (https://www.esmo.org/Press-Office/Press-Releases/Cetuximab-cisplatin-HPV-positive-oropharyngeal-cancer-radiotherapy-mehanna)

Positive early data of Balixafortide (CXCR4 inhibitor) combination with eribulin in heavily pretreated metastatic breast cancer (https://www.polyphor.com/news/corporate-news-details/?newsid=1728513)

Tesaro presents updates from GARNET, PRIMA and QUADRA trials (http://ir.tesarobio.com/news-releases/news-release-details/tesaro-announces-data-presentations-esmo-2018-congress-0)

Promising anti-tumor activity observed with Cabozantinib + Atzolizumab combination in 1L RCC patients in Ph Ib COSMIC-021 trial (http://ir.exelixis.com/phoenix.zhtml?c=120923&p=irol-newsArticle&ID=2372610)

Positive interim data from Ph II FIGHT-202 trial of FGFRi Pemigatinib in 2L+ Cholangiocarcinoma patients (https://investor.incyte.com/news-releases/news-release-details/incyte-announces-positive-interim-data-phase-2-trial-pemigatinib)

TLR9 agonist SD-101 + pembrolizumab combination shows a 70% ORR in advanced Melanoma patients in Ph Ib/II SYNERGY-001 trial (http://investors.dynavax.com/news-releases/news-release-details/dynavaxs-sd-101-combination-keytrudar-pembrolizumab-continues)

Kura Oncology presented update on positive Ph II trial of Tipifarnib in HRAS mutant HNSCC and preliminary results in HRAS mutant SCC (http://ir.kuraoncology.com/news-releases/news-release-details/kura-oncology-presents-update-positive-phase-2-trial-tipifarnib)

Atezolizumab + carboplatin + nab-paclitaxel improve OS and PFS significantly in 1L non-sq NSCLC patients (https://www.roche.com/media/releases/med-cor-2018-10-22.htm)

Zoledronic acid improves DFS in premenopausal HR+ early breast cancer in Ph III HOBOE-2 trial (https://www.esmo.org/Press-Office/Press-Releases/HOBOE-breast-cancer-Triptorelin-Perrone)

Ph III KEYNOTE-048 trial demonstrates Pembrolizumab significantly improved OS in the PD-L1 CPS ≥20 and ≥1 populations, non-inferior in the total population in 1L R/M HNSCC patients (https://www.esmo.org/Press-Office/Press-Releases/KEYNOTE048-head-neck-cancer-immunotherapy-Burtness)

Atezolizumab + Bevacizumab combo shows 32% ORR in unresectable or advanced HCC patients in Ph Ib trial (https://www.roche.com/investors/updates/inv-update-2018-10-21b.htm)

Extended follow up results of Ph III COMBI-AD study confirm leading BRAF/MEK inhibitor combination dabrafenib + trametinib continues to show RFS benefit (https://www.novartis.com/news/media-releases/novartis-combi-ad-study-tafinlar-mekinist-continues-demonstrate-relapse-free-survival-benefit-patients-braf-v600-mutant-stage-iii-melanoma)

Longer follow-up OS data from Ph III PALOMA-3 trial – secondary endpoint of significant OS improvement not met in HER2neg HR+ breast cancer patients (https://www.pfizer.com/news/press-release/press-release-detail/pfizer_presents_overall_survival_data_from_paloma_3_trial_of_ibrance_palbociclib_in_patients_with_hr_her2_metastatic_br

Larotrectinib delivers 81% ORR in an expanded dataset of 109 TRK fusion cancer patients across ages and tumor types (https://www.bayer.us/en/newsroom/press-releases/article/?id=123248)

Ph III ALESIA study demonstrates Alectinib significantly reduced the risk of disease worsening or death in 1L

ALK+ asian patients with mNSCLC (http://hugin.info/174806/R/2221430/869523.pdf)

Updated results for bifunctional immunotherapy M7824 (https://www.merckgroup.com/content/dam/web/corporate/non-images/press-releases/2018/oct/en/ESMO-M7824-Press-Release-Final-EN.PDF?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)

Sitravatinib's activity in CBL mutation positive NSCLC and melanoma patients in Ph Ib trial (http://ir.mirati.com/news-releases/news-release-details/mirati-therapeutics-announces-updated-data-ongoing-clinical)

Disappointing mid-stage data in Ph II trial with Sitravatinib + Nivolumab; just 16% confirmed RRs (http://ir.mirati.com/news-releases/news-release-details/mirati-therapeutics-presents-updated-positive-clinical-data)

Nivolumab + Ipilimumab combo results in significantly longer treatment-free survival in 1L RCC patients in Ph III CheckMate-214 trial (https://news.bms.com/press-release/corporatefinancial-news/opdivo-nivolumab-combination-yervoy-ipilimumab-results-signifi)

Significant OS and PFS benefit from Atezolizumab + carboplatin + nab-paclitaxel in 1L non-sqNSCLC patients in Ph III IMpower130 study (http://hugin.info/174806/R/2221173/869408.pdf)

Nivolumab + low-dose Ipilimumab demonstrated durable clinical benefit in 1L MSI-H or dMMR mCRC patients in CheckMate-142 trial (https://news.bms.com/press-release/corporatefinancial-news/opdivo-nivolumab-plus-low-dose-yervoy-ipilimumab-demonstrates-)

Nivolumab + Ipilimumab demonstrated durable four-year survival benefits in advanced melanoma patients in Ph III CheckMate-067 trial (https://news.bms.com/press-release/corporatefinancial-news/opdivo-nivolumab-combination-yervoy-ipilimumab-demonstrates-du)

New clinical findings involving STING agonist MK-1454 as monotherapy and in combination with Pembrolizumab presented (https://www.mrknewsroom.com/news-release/oncology-newsroom/first-presentation-early-data-mercks-investigational-sting-agonist-mk)

SOLO-1 Ph III trial demonstrates olaparib maintenance therapy decreases risk of disease progression or death by 70% in advanced BRCA-mutated ovarian cancer patients in 1L maintenance settings (https://www.mrknewsroom.com/news-release/oncology-newsroom/solo-1-phase-3-trial-demonstrates-lynparza-olaparib-maintenance-thera)

Pembrolizumab showed a CRR of ~40% in high-risk NMIBC patients unresponsive to BCG therapy in Ph II KEYNOTE-057 trial (https://www.mrknewsroom.com/news-release/oncology-newsroom/mercks-keytruda-pembrolizumab-showed-complete-response-rate-nearly-40)

Updated results of [Fam-] Trastuzumab deruxtecan (DS-8201) in HER2-expressing advanced CRC patients presented (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006919.html)

Entrectinib shrank tumours in people with NTRK fusion-positive solid tumours irrespective of tumour type or spread to the central nervous system (CNS) (http://hugin.info/174806/R/2221294/869467.pdf)

OS benefit confirmed with Palbociclib combo in pretreated HR+/HER2- breast cancer (https://www.esmo.org/Press-Office/Press-Releases/PALOMA3-breast-cancer-palbociclib-fulvestrant-Cristofanilli)

Alpelisib combo nearly doubles PFS in PIK3CA-mutant breast cancer in Ph III SOLAR-1 trial (https://www.esmo.org/Press-Office/Press-Releases/SOLAR-aplelisib-fulvestrant-breast-cancer-Andre)

Atezolizumab + nab-Paclitaxel improve outcomes as an initial treatment for PD-L1-positive mTNBC patients in Ph III IMpassion130 study (https://www.roche.com/media/releases/med-cor-2018-10-20.htm)

Nivolumab + Ipilimumab combination shows promising results in heavily pre-treated mBladder cancer patients (https://news.bms.com/press-release/corporatefinancial-news/opdivo-nivolumab-combination-yervoy-ipilimumab-shows-promising)

OTW Trivia

Q: What is RECIST?

A: RECIST (**R**esponse **E**valuation **C**riteria **I**n **S**olid **T**umors) guideline provides a simple and practical set of instructions to assess the activity and efficacy of new cancer treatment in solid tumors, using validated and consistent criteria to assess changes in tumor burden by clearly defining when patients are analyzed to have improved ("*responded*"), stayed the same ("*stable*") or worsened ("*progressed*") during the course of or at the end of treatment.

Q: When RECIST guidelines were first formed?

A: The original RECIST criteria were published in February 2000 by an international collaboration between European Organization for Research and Treatment of Cancer (EORTC), National Cancer Institute (NCI) of the United States and the National Cancer Institute of Canada Clinical Trials Group to provide harmonisation of tumour response assessment.

Q: Were RECIST guidelines updated over years?

A: RECIST 1.1, published in January 2009, was an update to the original RECIST criteria. Today, the majority of clinical trials evaluating efficacy of cancer treatments in solid tumors are using RECIST.

Q: What are iRECIST guidelines?

A: The iRECIST guidelines address immunotherapies, ensuring consistent trial design and interpretation of tumour progression measurements for immunomodulating drugs.

Q: Why were iRECIST guidelines needed?

A: Immunotherapies are distinctive from traditional therapeutics modalities in several aspects, like delayed responses after pseudoprogression. iRECIST guidelines describes a standard approach to solid tumour measurement and definitions for objective change in tumour size which can be used in clinical studies of immunotherapeutic drugs.

SOURCE: http://www.irrecist.com/recist/

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:


(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) Confocal micrograph of lesions in human cervical epithelium infected with human papilloma virus (HPV16). Early viral proteins (green) bind to and re-orgainse the ketatin filaments (red) towards the edge of the cell. Cell nuclei are stained with Dapi (blue).– Source (http://cellimagelibrary.org/images/38804)

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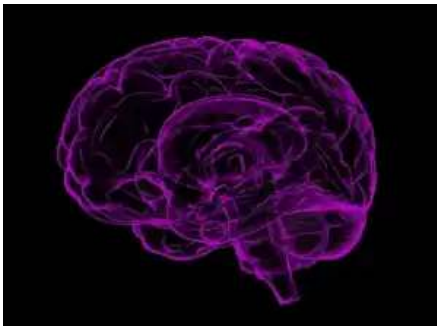

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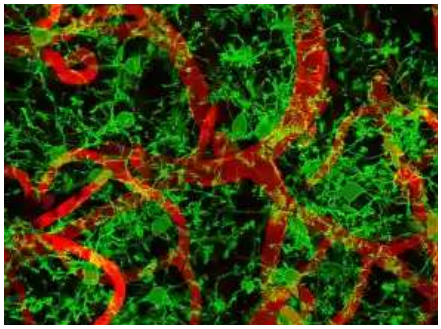

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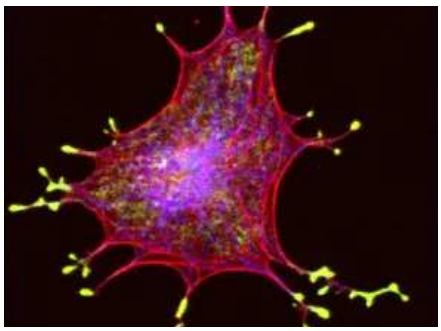

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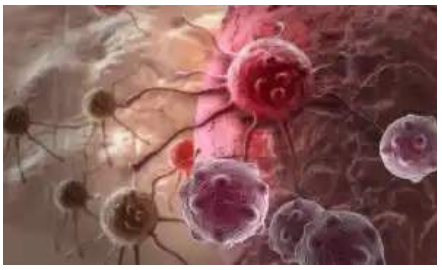

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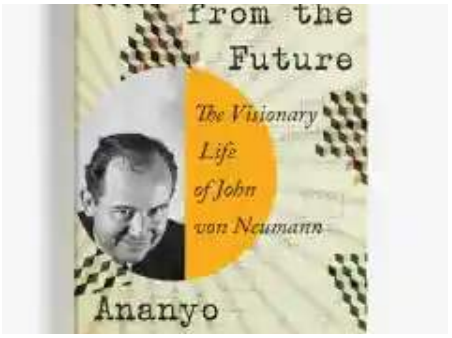

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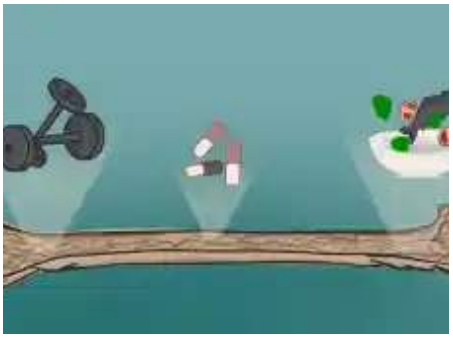

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