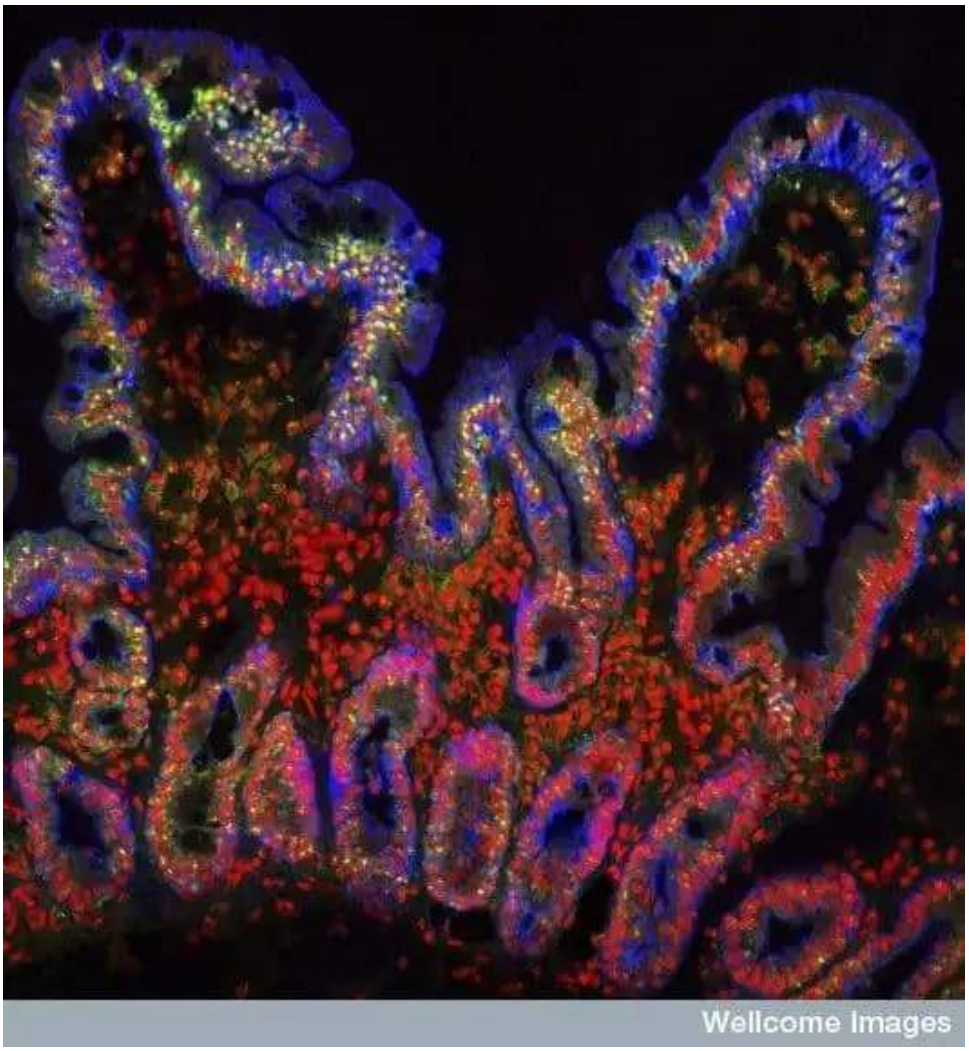
Archives (https://sciwri.club/archives/category/archives)

Onco-this-Week

January 20, 2019(https://sciwri.club/archives/date/2019/01/20)



SHARE THIS

OTW in a Capsule

HIGHLIGHTS

1. **Cabozantinib's FDA approval in Sorafenib-refractory HCC patients**: Sorafenib is considered the backbone of frontline treatment in HCC patients, even when it is associated with significant side effects but the greater unmet need is in patients who become refractory on Sorafenib. It would be interesting to see if Cabozantinib fills this unmet need, and also how it fares compared to the other options like Regorafenib and Nivolumab.
2. **Pembrolizumab's responses in PD-L1+ 2L esophageal/GEJ carcinoma patients**: Pembrolizumab continues to shine! Ph III KEYNOTE-181 trial results showed that Pembrolizumab significantly increased OS in this patient population and thus became the first PD-1 inhibitor to demonstrate a survival benefit. However, the benefit was limited to PD-L1 positive patients, and was not extended to patients with squamous cell histology and in the entire intention-to-treat (ITT) study population. Not daunted by this, Merck plans to submit approval application for Pembrolizumab as a monotherapy in earlier patient sub-group.
3. **Less responsiveness of melanoma patients with V600K mutations to BRAFi ± MEKi than ones with V600E:** There were always clinicopathologic differences in the two subgroups, harbouring V600E or V600K. The differences got validated in a latest study where patients with V600K were shown to be less responsive to melanoma treatment's backbone: BRAF inhibitor and MEK inhibitor combination. However, all is not lost for this group as there are indications of immunotherapy working efficiently for them. It would be good to see clinical trials designed to validate the hypothesis on patient level so that patients derive maximum benefit by choosing best personalized therapy from available options.

(https://goo.gl/XM63s6)

DRUG APPROVALS

Apalutamide approved in EU in high risk nmCRPC patients based on Ph III SPARTAN trial data (https://pipelinereview.com/index.php/2019011770333/Small-Molecules/Janssen-announces-European-Commission-approval-of-ERLEADA-apalutamide-for-non-metastatic-castration-resistant-prostate-cancer-patients-who-are-at-high-risk-of-developing.html)

> New Drug: Apalutamide for prostate cancer. https://t.co/fc4PWnKGLW (https://t.co/fc4PWnKGLW) pic.twitter.com/RkCs6sEceQ (https://t.co/RkCs6sEceQ)
>
> — AustralianPrescriber (@AustPrescriber) January 18, 2019 (https://twitter.com/AustPrescriber/status/1086088304779497474?ref_src=twsrc%5Etfw)

"Today's approval of apalutamide is a significant milestone and we are pleased that we can now offer patients with high-risk non-metastatic castration-resistant prostate cancer a new treatment option," said Dr Ivo Winiger-Candolfi M.D., Janssen Oncology Solid Tumor Therapy Area Lead, Europe, Middle East and Africa, Cilag GmbH International. "Bringing medicines to patients at earlier stages of disease is vital, and the approval of apalutamide could mark a step change in how we treat prostate cancer in the future. Crucially, treating patients at this stage could delay the cancer from spreading, a key part of our commitment to patients living with this disease and to their families."

Nivolumab/Ipilimumab combo approved in EU in 1L intermediate- and poor-risk RCC patients based on Ph III CheckMate-214 data (https://news.bms.com/press-release/corporatefinancial-news/european-commission-approves-opdivo-nivolumab-plus-low-dose-ye)

> Phase 3 Nivolumab + Ipilimumab provides significantly higher overall survival and objective response rates than does sunitinib in previously untreated advanced clear-cell renal-cell carcinoma https://t.co/BIoOopeMrM (https://t.co/BIoOopeMrM) @NEJM (https://twitter.com/NEJM?ref_src=twsrc%5Etfw). pic.twitter.com/UP3wrWOGZb (https://t.co/UP3wrWOGZb)
>
> — Cancer Cell (@Cancer_Cell) March 22, 2018 (https://twitter.com/Cancer_Cell/status/976623468576944129?ref_src=twsrc%5Etfw)

"Currently, less than 50% of patients with metastatic renal cell carcinoma survive beyond two years, and there is almost no complete remission observed, which underscores the need for new treatments for this disease," said Bernard Escudier, MD, ex-Chairman of the Genitourinary Oncology Committee, Institut Gustave Roussy. "Today's approval offers patients in the European Union a first-line treatment option that has demonstrated a complete response rate of almost 10% and a significant improvement in overall survival with fewer Grade 3 and 4 adverse reactions compared to sunitinib."

Cabozantinib approved by FDA in Sorafenib-refractory HCC pts based on significant OS benefit in Ph III pivotal CELESTIAL trial (http://ir.exelixis.com/phoenix.zhtml?c=120923&p=irol-newsArticle&ID=2383313)

> Cabozantinib Wins OK for Advanced Liver Cancer https://t.co/fAyJHtXVN1 (https://t.co/fAyJHtXVN1) pic.twitter.com/7m8jUM20Tn (https://t.co/7m8jUM20Tn)
>
> — Med. Tech. Network (@MedTechNetwork) January 18, 2019 (https://twitter.com/MedTechNetwork/status/1086393692284317697?ref_src=twsrc%5Etfw)

"This new indication for CABOMETYX is an important treatment advance for patients with this aggressive form of liver cancer, a community in need of new therapeutic options," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "This approval is an important milestone as we continue to explore how CABOMETYX may benefit people with difficult-to-treat-cancers beyond renal cell carcinoma. We would like to thank the patients and clinicians who participated in CELESTIAL and to acknowledge the team at the FDA for their continued collaboration during the review of our application."

REGULATORY NEWS

Immunomedics receives CRL from FDA for BLA seeking accelerated approval of sacituzumab govitecan in heavily pre-treated TNBC patients (https://www.nasdaq.com/press-release/immunomedics-receives-complete-response-letter-from-fda-for-sacituzumab-govitecan-biologics-licens-20190117-01231)

> The drug, sacituzumab govitecan, which is produced by Immunomedics, was designated a "breakthrough therapy" by the FDA "based on preliminary evidence that it demonstrates substantial improvement over existing therapies for a life threatening disease." https://t.co/xU6NQeYRTg (https://t.co/xU6NQeYRTg)
>
> — ABC News Health (@ABCNewsHealth) January 18, 2019 (https://twitter.com/ABCNewsHealth/status/1086382074259521536?ref_src=twsrc%5Etfw)

“We believe in sacituzumab govitecan’s potential to be a viable treatment option for these patients,” said Michael Pehl, President and Chief Executive Officer of Immunomedics. “The issues related to approvability in the CRL were exclusively focused on Chemistry, Manufacturing and Control matters and no new clinical or preclinical data need to be generated. We are going to request a meeting with the FDA as soon as possible to gain a full understanding of the Agency’s requirements and timelines for approval and we will work closely with the FDA with the goal of bringing this important medicine to patients as soon as possible.”

sBLA accepted for Atezolizumab + chemotherapy (Abraxane and carboplatin) in 1L non-sq EGFR/ALK WT mNSCLC patients based on Ph III IMpower130 results; PDUFA: Sep 2019 (http://hugin.info/174806/R/2231584/877344.pdf)

> A supplemental biologics license application has been accepted by the FDA for frontline atezolizumab triplet regimen in metastatic nonsquamous non–small cell lung cancer: https://t.co/URsXJJAxTt (https://t.co/URsXJJAxTt) #LungCancer (https://twitter.com/hashtag/LungCancer?src=hash&ref_src=twsrc%5Etfw) #lcsm (https://twitter.com/hashtag/lcsm?src=hash&ref_src=twsrc%5Etfw) #nsclc (https://twitter.com/hashtag/nsclc?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/Opl7tpAoQB (https://t.co/Opl7tpAoQB)
>
> — Targeted Oncology (@TargetedOnc) January 18, 2019 (https://twitter.com/TargetedOnc/status/1086337731112898562?ref_src=twsrc%5Etfw)

“We look forward to working with the FDA in order to bring this Tecentriq-based combination to people with non-squamous non-small cell lung cancer as soon as possible,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “Lung cancer is a challenging disease to treat, and this review takes us one step closer towards offering a new treatment option that has shown a clinically meaningful survival benefit in the treatment of this type of disease.”

Patent protection to use of Tedopi® in the treatment of brain metastasis until 2034 in Japan (https://ose-immuno.com/wp-content/uploads/2019/01/EN_190115_Patent_Tedopi.pdf)

> The Japanese Patent Office has granted a patent for use of Tedopi, a combination of 10 neoepitopes aimed at stimulating T-lymphocytes, in patients with brain metastasis following promising results seen in NSCLC patients. Read more here: BitLyURL #ImmunoOncology (https://twitter.com/hashtag/ImmunoOncology?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/cJeAELiuD5 (https://t.co/cJeAELiuD5)
>
> — OSE_IMMUNO (@OSEIMMUNO) January 15, 2019 (https://twitter.com/OSEIMMUNO/status/1085220285073317890?ref_src=twsrc%5Etfw)

“This new patent family, first granted in Japan, is an important step toward further strengthening and expanding our Tedopi® immuno-oncology portfolio. The product’s use to the treatment of brain metastasis originating from cancers in HLA-A2 positive patients demonstrates the product’s therapeutic potential. Tedopi® is currently undergoing Phase 3 testing in NSCLC patients following checkpoint inhibitor failure, a patient population with no currently approved therapeutic option, representing an important potential market. In addition, Tedopi® is being evaluated in combination with Opdivo®, an anti-PD-1 checkpoint inhibitor, in a Phase 2 trial in pancreatic cancer. Tedopi® is positioned as a leading asset in multiple oncology indications requiring for novel therapeutic

approaches and in patient populations for which a significant medical need exists," said Alexis Peyroles, chief executive officer of OSE Immunotherapeutics.

BTK inhibitor Zanubrutinib gets breakthrough therapy designation in 2L MCL patients (http://phx.corporate-ir.net/phoenix.zhtml?c=254246&p=irol-newsArticle&id=2383285)

> FDA Grants Zanubrutinib Breakthrough Designation for Mantle Cell Lymphoma https://t.co/sngeuJIZUx (https://t.co/sngeuJIZUx) via @OncLive (https://twitter.com/OncLive?ref_src=twsrc%5Etfw) @MassiveBio (https://twitter.com/MassiveBio?ref_src=twsrc%5Etfw) is committed to ensuring patients know all of the latest advances in treatment options #clinicaltrials (https://twitter.com/hashtag/clinicaltrials?src=hash&ref_src=twsrc%5Etfw) #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) #massivebio (https://twitter.com/hashtag/massivebio?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/9WRSLPqR63 (https://t.co/9WRSLPqR63)
>
> — Massive Bio (@MassiveBio) January 17, 2019 (https://twitter.com/MassiveBio/status/1086037432431198211?ref_src=twsrc%5Etfw)

"We are very excited to receive the Breakthrough Therapy designation from the FDA," said Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "Zanubrutinib has been designed to maximize BTK occupancy and minimize off-target effects. We believe that the Breakthrough Therapy designation underscores the potential of zanubrutinib as a meaningful treatment for patients with MCL who have received at least one prior therapy. More than 1,300 patients worldwide have been treated with zanubrutinib, and it's being developed in a broad clinical program that currently includes seven Phase 3 or pivotal trials conducted globally or in China."

IND filed with China NMPA for TROP2-targeting batansine ADC, BAT8003, in TROP2+ve cancers (https://www.bio-thera.com/EN/ShowNews.asp?id=51)

> Bio-Thera Solutions Files IND for Phase 1 Clinical Trial with BAT8003 (Trop2-ADC) as Treatment for Trop2 Positive Cancers https://t.co/fHzfYcAeMT (https://t.co/fHzfYcAeMT) pic.twitter.com/KeeEjzY1zQ (https://t.co/KeeEjzY1zQ)
>
> — Latest News from Business Wire (@NewsFromBW) December 27, 2018 (https://twitter.com/NewsFromBW/status/1078278256065884161?ref_src=twsrc%5Etfw)

"The filing of this IND for our novel Trop2-ADC is a significant achievement for Bio-Thera Solutions", said Dr. Shengfeng Li, CEO, Bio-Thera Solutions. "Pending NMPA acceptance of the IND, we will begin the dose escalation portion of this Phase I trial early in 2019 and anticipate reporting on the early safety assessment and determination of a maximum tolerated dose in mid-year 2019.

TRIAL RESULTS

FAILED TRIAL: Ph III ANNOUNCE trial of PDGFR inhibitor Olaratumab + Doxorubicin in mSTS patients failed to meet primary endpoint of OS improvement (https://investor.lilly.com/news-releases/news-release-details/lilly-reports-results-phase-3-soft-tissue-sarcoma-study)

> Olaratumab Falls Short in Phase III Soft Tissue Sarcoma Trial https://t.co/FdC8z9F5jr (https://t.co/FdC8z9F5jr) pic.twitter.com/AzQmF9Y16v (https://t.co/AzQmF9Y16v)
>
> — ImmunotherapyPapers (@Immunotx_papers) January 18, 2019 (https://twitter.com/Immunotx_papers/status/1086340730476322816?ref_src=twsrc%5Etfw)

"Lilly was surprised and disappointed that LARTRUVO did not improve survival for patients with advanced soft tissue sarcoma in this study," said Anne White, president, Lilly Oncology. "Lilly is committed to helping people who have soft tissue sarcoma and we will carefully study the detailed data in an effort to better understand the different results between the two trials. We are thankful for the patients and physicians who have participated in the ANNOUNCE study."

FAILED TRIAL: Ph II trial of pan-HER inhibitor Varlitinib in 1L gastric cancer failed to meet primary endpoint of significant reductions in tumour size after 12 weeks of treatment (http://aslanpharma.com/app/uploads/2019/01/Press-Release_Varlitinib-GC-Update-ENG.pdf)

> Frontline varlitinib added to mFOLFOX6 was not found to significantly reduce tumor size after 12 weeks of therapy compared with mFOLFOX6 alone in patients with HER1/HER2 co-expressing advanced or metastatic gastric cancer https://t.co/37wheyGkpq (https://t.co/37wheyGkpq)
>
> — OncLive.com (@OncLive) January 16, 2019 (https://twitter.com/OncLive/status/1085537327416512512?ref_src=twsrc%5Etfw)

Dr Mark McHale, Chief Operating Officer, ASLAN Pharmaceuticals, said:"First-line gastric cancer is a very challenging indication to treat and the majority of patients present with advanced disease at initial diagnosis. To date, no targeted therapies have been approved to treat gastric cancer with low HER-family expression. Whilst we are disappointed by the study findings, we are encouraged by the positive safety data and remain confident that varlitinib's potent pan-HER inhibition has the potential to yield benefits in biliary tract cancer where HER family expression is known to be high. We look forward to presenting the upcoming data in first-line biliary tract cancer at ASCO GI later this week and delivering topline data from our pivotal TreeTopp study in second-line biliary tract cancer which is expected in the second half of 2019."

Early tumor shrinkage observed in Ph I/IIa ISO-CC-005 trial of folate-based therapy, arfolitixorin, in 1L mCRC patients (isofolmedical.com/report-early-tumor-shrinkage/)

> Arfolitixorin linked to tumour shrinkage in colorectal cancer https://t.co/I5DUCkwYpv (https://t.co/I5DUCkwYpv) pic.twitter.com/9NZQJNLfJV (https://t.co/9NZQJNLfJV)
>
> — Euro Pharma Review (@PharmaReview) January 18, 2019 (https://twitter.com/PharmaReview/status/1086226752559550466?ref_src=twsrc%5Etfw)

Karin Ganlöv, M.D., chief medical officer of Isofol, commented, "Analysis of data from the extension arm of this phase 1/2a study are very promising when compared to historical control treatments such as mFolfox and Folfiri. These data further support the hypothesis that arfolitixorin in combination with 5-FU with either irinotecan or oxaliplatin provides clinical benefit even after eight weeks treatment with a good toxicity profile. We are excited

to continue to explore this hypothesis with our ongoing AGENT pivotal Phase 3 study."

Melanoma patients with V600K less responsive to BRAFi ± MEKi than ones with V600E; may benefit more from anti-PD-1 immunotherapy (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1266)

> If oncologist Alexander Menzies had to have cancer, he would choose melanoma. Here's why. #medical (https://twitter.com/hashtag/medical?src=hash&ref_src=twsrc%5Etfw) #healthcare (https://twitter.com/hashtag/healthcare?src=hash&ref_src=twsrc%5Etfw) https://t.co/Fc405dUhrB (https://t.co/Fc405dUhrB)
>
> — Financial Review (@FinancialReview) January 18, 2019 (https://twitter.com/FinancialReview/status/1086352526021218304?ref_src=twsrc%5Etfw)

"The clinicopathic differences previously observed in V600E and V600K BRAF-mutant melanoma can now be explained by their biology," said Alexander Menzies, MD, PhD, medical oncologist and associate professor at Melanoma Institute Australia, The University of Sydney, and Royal North Shore and Mater Hospitals. "These genotypes should be considered as distinct clinical entities with differing responses to treatments, and they should be managed differently."

TRIAL STATUSES

First patient dosed in Ph III ORIENT-16 trial of PD-1 inhibitor Sintilimab in 1L advanced gastric cancer/ GEJ patients (http://innoventbio.com/en/#/news/127)

> Innovent Biologcs testing potential of sintilimab in combination with chemotherapy in ORIENT-16, a phase III trial, on gastric cancer patients https://t.co/jyGc8Pomi8 (https://t.co/jyGc8Pomi8) pic.twitter.com/hQfIMNjjLE (https://t.co/hQfIMNjjLE)
>
> — Pharmacutical Daily (@PharmacDaily) January 17, 2019 (https://twitter.com/PharmacDaily/status/1085806920856784896?ref_src=twsrc%5Etfw)

"Over the past decade, the treatment of various malignant tumors has progressed rapidly. From traditional chemotherapy to targeted molecular therapy and immunotherapy, the prognosis of cancer patients has been improved remarkably. However, breakthroughs in the treatment of gastric cancer have been few. With the exception of trastuzumab in first-line use for HER-2 positive patients, several phase III clinical trials have failed successively. Based on the efficacy signals and the safety profile from previous trials, we hope to validate the therapeutic potential of sintilimab in combination with chemotherapy in ORIENT-16, a phase III trial," said Dr. Jianming Xu, a professor from the Chinese PLA General Hospital.

First patient dosed on Ph I/II trial of KRAS G12C Inhibitor, MRTX849, in KRAS G12C-positive advanced solid tumors (http://ir.mirati.com/news-releases/news-release-details/mirati-therapeutics-announces-dosing-first-patient-phase-12)

$MRTX (https://twitter.com/search?q=%24MRTX&src=ctag&ref_src=twsrc%5Etfw) Mirati's MRTX849 in Ph1/2 trial in #KRAS (https://twitter.com/hashtag/KRAS?src=hash&ref_src=twsrc%5Etfw) G12C+ve tumours (NSCLC, CRC and others). #lcsm (https://twitter.com/hashtag/lcsm?src=hash&ref_src=twsrc%5Etfw) #crcsm (https://twitter.com/hashtag/crcsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/ZDXnKVMDGa (https://t.co/ZDXnKVMDGa)

— Anand Prabu (@anandprabu) January 9, 2019 (https://twitter.com/anandprabu/status/1083041033921941504?ref_src=twsrc%5Etfw)

"Today we have achieved an important milestone in the battle against cancers driven by KRAS mutations, one of the most common and difficult to treat patient populations. MRTX849 has been designed to specifically target KRAS G12C mutations, which are thought to be responsible for at least 14% of non-small cell lung adenocarcinoma, 4% of colorectal cancer, and subsets of other types of cancers," said Charles Baum, M.D., Ph.D., President and Chief Executive Officer of Mirati. "In preclinical studies MRTX849 potently and specifically bound to KRAS G12C and produced durable tumor regressions in patient-derived cancer models implanted in mice. Our Phase 1/2 clinical trial is designed to rapidly advance MRTX849 towards registration and approval."

First patient dosed in Ph Ia/Ib trial of ADCT-601 in advanced solid tumors (https://adctherapeutics.com/)

#ADC (https://twitter.com/hashtag/ADC?src=hash&ref_src=twsrc%5Etfw) Therapeutics starts testing antibody drug conjugate ADCT-601 on patients with selected advanced solid #tumors (https://twitter.com/hashtag/tumors?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) https://t.co/Owi3SY9ggo (https://t.co/Owi3SY9ggo) pic.twitter.com/1eBgV08f38 (https://t.co/1eBgV08f38)

— Pharmacutical Daily (@PharmacDaily) January 16, 2019 (https://twitter.com/PharmacDaily/status/1085453854009905152?ref_src=twsrc%5Etfw)

Jay Feingold, MD, PhD, Chief Medical Officer and Senior Vice President of Clinical Development at ADC Therapeutics, said, "AXL is a novel and ideal target for an ADC approach, as it is overexpressed in many solid tumor types. We look forward to exploring the effect of ADCT-601 on patients with selected advanced solid tumors who have failed or are intolerant to any established therapy. With five ADCs in eight ongoing clinical trials for multiple indications, we believe our highly targeted therapies have the potential to meaningfully improve outcomes for patients with solid tumors and hematological cancers."

First patient dosed in expanded Ph II trial of HS-110 + Pembrolizumab in advanced NSCLC patients in 1L maintenance settings (https://www.heatbio.com/news-media/news-releases/detail/623/update-heat-biologics-doses-first-patient-in-new-cohort-of)

Daniel Morgensztern, MD, Associate Professor of Medicine and Director of Thoracic Oncology, Washington University School of Medicine and lead investigator for this trial, commented, "Results from the ongoing Phase 2, multicenter clinical trial combining HS-110 with Bristol-Myers Squibb's checkpoint inhibitor nivolumab (Opdivo®), suggest that HS-110 may enhance the efficacy of checkpoint inhibitors in patients with advanced lung cancer. Expanding this trial to include Merck's anti-PD-1 checkpoint inhibitor pembrolizumab (KEYTRUDA®) is an important next step in evaluating the broad potential of this platform technology."

Pivotal Ph III trial of HER2-targeting exatecan ADC [Fam-] Trastuzumab Deruxtecan (DS-8201) initiated in HER2-low metastatic Breast Cancer (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006963.html)

"DESTINY-Breast04 has been initiated based on preliminary phase 1 study results to determine whether [fam-] trastuzumab deruxtecan could serve as a targeted therapy option for patients with HER2 low metastatic breast cancer that progresses after standard chemotherapy, regardless of HR status," said Gilles Gallant, BPharm, PhD, Vice President, DS-8201 Global Team Leader, Oncology Research and Development, Daiichi Sankyo. "HER2 targeting agents have improved survival rates for HER2 positive breast cancer, but none have been approved in HER2 low expressing tumors. DESTINY-Breast04, our third phase 3 breast cancer trial with [fam-] trastuzumab deruxtecan, has potential to define a new patient population for HER2 targeted treatment."

Dx ASSAYS

Roche and PhoenixMD to develop Dx assay for RSK2 pathway in TNBC and other cancers (https://www.prnewswire.com/news-releases/phoenix-molecular-designs-announces-collaboration-to-develop-diagnostic-for-triple-negative-breast-cancer-300779097.html?tc=eml_cleartime&fbclid=IwARodSpd6wQ4JtUZONdMpiN9_zOyBGIRku8MVjCHFoDlc6N_-ItLGoH5bu6A)

> PhoenixMD & @Roche (https://twitter.com/Roche?ref_src=twsrc%5Etfw) to develop #CompanionDiagnostic (https://twitter.com/hashtag/CompanionDiagnostic?src=hash&ref_src=twsrc%5Etfw) for PMD-026 vs triple-negative #BreastCancer (https://twitter.com/hashtag/BreastCancer?src=hash&ref_src=twsrc%5Etfw)
>
> PhoenixMD to refine #CDx (https://twitter.com/hashtag/CDx?src=hash&ref_src=twsrc%5Etfw) for patient stratification in upcoming #clinicaltrials (https://twitter.com/hashtag/clinicaltrials?src=hash&ref_src=twsrc%5Etfw) of RSK2 inhibitorhttps://t.co/7SoMroujKl (https://t.co/7SoMroujKl)#oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #diagnostic (https://twitter.com/hashtag/diagnostic?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/QI2fzVj11w (https://t.co/QI2fzVj11w)
>
> — DDNews Online (@DDNewsOnline) January 16, 2019 (https://twitter.com/DDNewsOnline/status/1085627750906421248?ref_src=twsrc%5Etfw)

"By working together, PhoenixMD and Roche are at the forefront of innovation in TNBC, the most deadly breast cancer type with no approved therapies. Creating our diagnostic assay and identifying disease biomarkers, such as RSK2 for TNBC, will dramatically reduce the development time needed to create targeted drugs and will improve a drug's chance of advancing through clinical trials," said Dr. Sandra E. Dunn, CEO of PhoenixMD. "The top-line data generated from our CDx is encouraging, and we look forward to applying these learnings to identify TNBC patients that may benefit from PMD-026 in our upcoming Phase I/Ib study."

Medicare coverage approved to clonoSEQ® Assay for MRD testing in MM and ALL patients at multiple timepoints throughout treatment and remission (http://www.adaptivebiotech.com/adaptive-biotechnologies-announces-medicare-coverage-of-the-clonoseq-assay-for-mrd-testing-in-patients-with-multiple-myeloma-and-acute-lymphoblastic-leukemia-at-multiple-timepoints-throughout-treatmen/)

> MRD testing using the @AdaptiveBiotech (https://twitter.com/AdaptiveBiotech?ref_src=twsrc%5Etfw) clonoSEQ assay is now covered by Medicare for #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw) patients! #mmsm (https://twitter.com/hashtag/mmsm?src=hash&ref_src=twsrc%5Etfw)https://t.co/kHyaufPYX4 (https://t.co/kHyaufPYX4)
>
> — Multiple Myeloma RF (@theMMRF) January 18, 2019 (https://twitter.com/theMMRF/status/1086361566482710528?ref_src=twsrc%5Etfw)

"This is great news for patients. The establishment of favorable Medicare coverage for clonoSEQ soon after FDA authorization further demonstrates the clinical relevance of MRD assessment and underscores the benefit that this test delivers in the management of myeloma and ALL patients," said Charles Sang, senior vice president, Adaptive Diagnostics. "clonoSEQ is a highly sensitive and standardized MRD test that enables more cost-effective care by assessing the effectiveness of therapy, monitoring remission and identifying relapse in lymphoid blood cancers, serving as a critical tool to help clinicians decide if a patient should initiate, pause or discontinue a potentially costly treatment regimen."

COLLABORATIONS & LICENSING DEALS

NBTS and GCAR collaborate to launch GBM AGILE trial in GBM patients (http://globenewswire.com/news-release/2019/01/16/1700875/0/en/National-Brain-Tumor-Society-Invests-in-GBM-AGILE-the-World-s-First-Global-Adaptive-Trial-for-Glioblastoma-Brain-Cancer.html?ev=1)

> We are so proud of the partnership with the Global Coalition for Adaptive Research on the #GBMAgile (https://twitter.com/hashtag/GBMAgile?src=hash&ref_src=twsrc%5Etfw) project. Check out https://t.co/rNUw9dhoBV (https://t.co/rNUw9dhoBV) to learn more about this adaptive, revolutionary #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw)! #BTSM (https://twitter.com/hashtag/BTSM?src=hash&ref_src=twsrc%5Etfw) #braintumor (https://twitter.com/hashtag/braintumor?src=hash&ref_src=twsrc%5Etfw) #glioblastoma (https://twitter.com/hashtag/glioblastoma?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/eoUfbugyWu (https://t.co/eoUfbugyWu)
>
> — National Brain Tumor Society (@NBTStweets) January 18, 2019 (https://twitter.com/NBTStweets/status/1086303711125737474?ref_src=twsrc%5Etfw)

"The past decade of scientific advances has moved glioblastoma research to a pivotal point which calls for a platform like GBM AGILE to get potentially breakthrough medicines to patients – who can't afford to wait – faster than standard clinical trial designs," said David Arons, Chief Executive Officer, National Brain Tumor Society. "GBM AGILE is a 'game-changer' for neuro-oncology and is an opportunity for NBTS to collaborate with multiple stakeholders in the brain tumor field to revolutionize the future for patients. This trial also represents the spirit of the NBTS Defeat GBM Research Collaborative program, which was specifically designed to accelerate precision medicine research and take more 'shots on goal' by supporting opportunities to find treatments and a cure for the most deadly and aggressive type of brain tumor, glioblastoma."

Aileron Therapeutics and Pfizer to evaluate p53 mimetic ALRN-6924 + CDK4/6 inhibitor Palbociclib in MDM2-amplified cancers in Ph Ib trial (https://investors.aileronrx.com/news-releases/news-release-details/aileron-enters-clinical-trial-collaboration-pfizer-evaluate-alrn)

> Aileron Therapeutics shares are trading up 7.8% after the company announced a partnership with Pfizer to research the effectiveness of the combination of Pfizer's palbociclib with Aileron's ALRN-6924 in treating cancer. $ALRN (https://twitter.com/search?q=%24ALRN&src=ctag&ref_src=twsrc%5Etfw) https://t.co/hnxdqepeE1 (https://t.co/hnxdqepeE1) @benzinga (https://twitter.com/Benzinga?ref_src=twsrc%5Etfw)
>
> — Trades Haven (@TradesHaven) November 27, 2018 (https://twitter.com/TradesHaven/status/1067433386044665857?ref_src=twsrc%5Etfw)

"We are excited about this combination trial with Pfizer's palbociclib," stated Manuel Aivado, MD, PhD, President and Chief Executive Officer of Aileron. "The combination of ALRN-6924 and palbociclib demonstrated enhanced antitumor activity and meaningfully delayed tumor growth in animal models over single agents alone. We believe the combination of these two drugs represents a complementary attack on the proliferation of cancer cells that may benefit patients with a variety of different cancers."

MD Anderson Cancer Center and Dragonfly Therapeutics to take TriNKETs™ into clinical trials in 2019 (https://www.mdanderson.org/newsroom/immunotherapy-clinical-trials-collaboration-with-dragonfly-therapeutics.h00-159299889.html)

> Dragonfly Therapeutics has budgeted $10M to begin its first clinical trials to be conducted in collaboration with the MD Anderson Cancer Center in Houston. #clinicaltrials (https://twitter.com/hashtag/clinicaltrials?src=hash&ref_src=twsrc%5Etfw) #CancerResearch (https://twitter.com/hashtag/CancerResearch?src=hash&ref_src=twsrc%5Etfw) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw)https://t.co/ndaqTMvYDv (https://t.co/ndaqTMvYDv)
>
> — Novateur Ventures (@NovateurBio) January 18, 2019 (https://twitter.com/NovateurBio/status/1086404116006334464?ref_src=twsrc%5Etfw)

"We will be studying the possibility of offering novel therapeutics that can directly kill cancer, recruit immune cells and provide a potentially different safety window than existing immuno-oncology options," said John Heymach, M.D., Ph.D., chair of Thoracic Head & Neck Medical Oncology at MD Anderson. "We are hopeful that these agents could provide a new treatment option for our patients."

"MD Anderson has demonstrated expertise in advancing breakthrough treatment options to patients in thoughtfully designed, innovative clinical trials," said Bill Haney, co-founder and CEO of Dragonfly Therapeutics. "We're excited to work with their clinicians to bring our first oncology drug candidates to patients."

Cipla to market Bio-Thera Solutions' BAT1706 (bevacizumab biosimilar) in select emerging markets (https://www.businesswire.com/news/home/20190114005291/en/)

> Cipla Signs an Exclusive License Agreement with Bio-Thera for its BAT1706 (bevacizumab, biosimilar) @Cipla_Global (https://twitter.com/Cipla_Global?ref_src=twsrc%5Etfw) @Biothera (https://twitter.com/Biothera?ref_src=twsrc%5Etfw) https://t.co/mS4KolK08a (https://t.co/mS4KolK08a) pic.twitter.com/mi98X8tDPV (https://t.co/mi98X8tDPV)
>
> — PharmaShots (@Pharmashot) January 15, 2019 (https://twitter.com/Pharmashot/status/1085158641378959360?ref_src=twsrc%5Etfw)

"Bio-Thera is pleased to partner with Cipla to commercialize our lead biosimilar program in select emerging markets", said Dr. Shengfeng Li, CEO of Bio-Thera. "This partnership is an important first step towards making BAT1706, our bevacizumab biosimilar product, availability globally to help increase patient access to this important cancer therapeutic at affordable prices."

"This agreement is in keeping with Cipla's stated intention to build a strong pipeline of biosimilars through partnerships. We are committed to working towards ensuring patients receive access to life-saving drugs. Through this partnership, Cipla will leverage its strengths in marketing to take this key oncology biosimilar to patients in need." said Umang Vohra, MD & Global CEO of Cipla Limited

RESULTS ALERT: ASCO GI 2019

> The GI Symposium begins today! Follow @ASCO (https://twitter.com/ASCO?ref_src=twsrc%5Etfw) Featured Voices and join the discussion using #GI19 (https://twitter.com/hashtag/GI19?src=hash&ref_src=twsrc%5Etfw) https://t.co/1KrbTRqw03 (https://t.co/1KrbTRqw03) @CathyEngMD (https://twitter.com/CathyEngMD?ref_src=twsrc%5Etfw) @ShaalanBeg (https://twitter.com/ShaalanBeg?ref_src=twsrc%5Etfw) @ColonCancerDoc (https://twitter.com/ColonCancerDoc?ref_src=twsrc%5Etfw) @TGeorgeMD (https://twitter.com/TGeorgeMD?ref_src=twsrc%5Etfw) pic.twitter.com/lZTuwOA8NY (https://t.co/lZTuwOA8NY)
>
> — CancerDotNet (@CancerDotNet) January 17, 2019 (https://twitter.com/CancerDotNet/status/1085985292497113088?ref_src=twsrc%5Etfw)

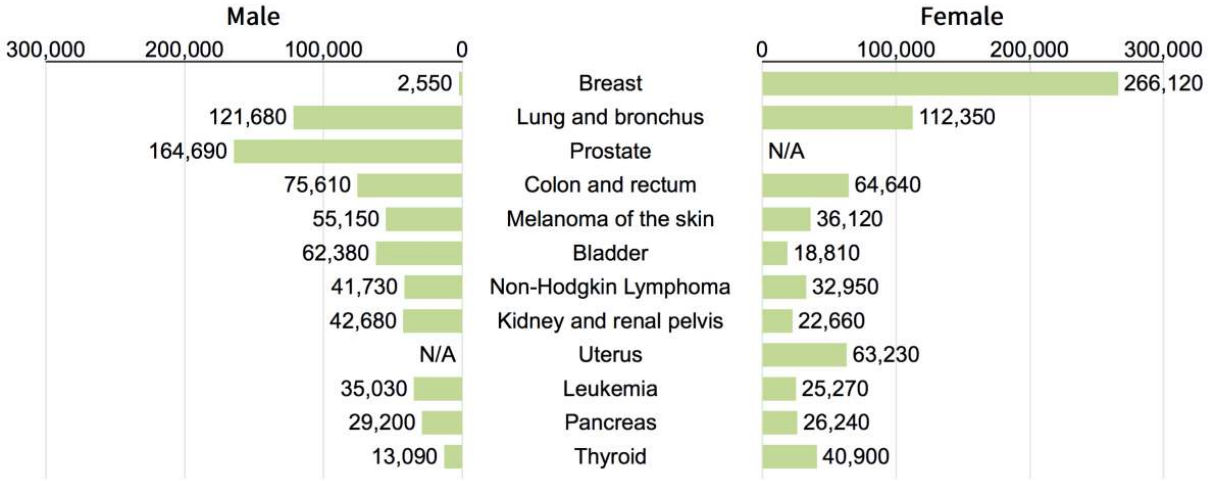
1. Pembrolizumab reduces risk of death by 31% in PD-L1+ 2L esophageal/GEJ carcinoma pts in Ph III KEYNOTE-181 trial (https://www.mrknewsroom.com/news-release/oncology/mercks-keytruda-pembrolizumab-reduced-risk-death-31-percent-compared-chemother)
2. Five noteworthy studies in the treatment and management of liver, esophageal, colorectal, and colon cancers (https://www.asco.org/about-asco/press-center/news-releases/2019-symposium-highlight-notable-research-advances)
3. Updated data from Ph II trial of HER2 inhibitor Margetuximab + Pembrolizumab in gastric cancer patients to be presented (http://ir.macrogenics.com/news-releases/news-release-details/updated-clinical-data-combination-margetuximab-and-pembrolizumab)
4. Plan for Ph III AVENGER 500 trial of altered metabolism directed (AMD) drug devimistat (CPI-613) + mFOLFIRINOX in 1L pancreatic cancer patients to be presented (https://markets.businessinsider.com/news/stocks/rafael-pharmaceuticals-to-present-plan-for-phase-3-trial-avenger-500-of-devimistat-cpi-613-in-combination-with-modified-folfirinox-as-a-first-line-treatment-for-metastatic-pancreatic-cancer-at-1027876163)
5. Bayer to highlight new research (https://www.bayer.us/en/newsroom/press-releases/article/?id=123270)
6. Positive Varlitinib + chemotherapy data in 1L BTC patients from Ph Ib/II trial to be presented (http://aslanpharma.com/app/uploads/2019/01/190115-Press-Release_ASCO-GI-Data-ENG.pdf)
7. Post-hoc analyses data from Ph III REFLECT trial of Lenvatinib in HCC patients to be presented (https://

www.eisai.com/news/2019/news201903.html)

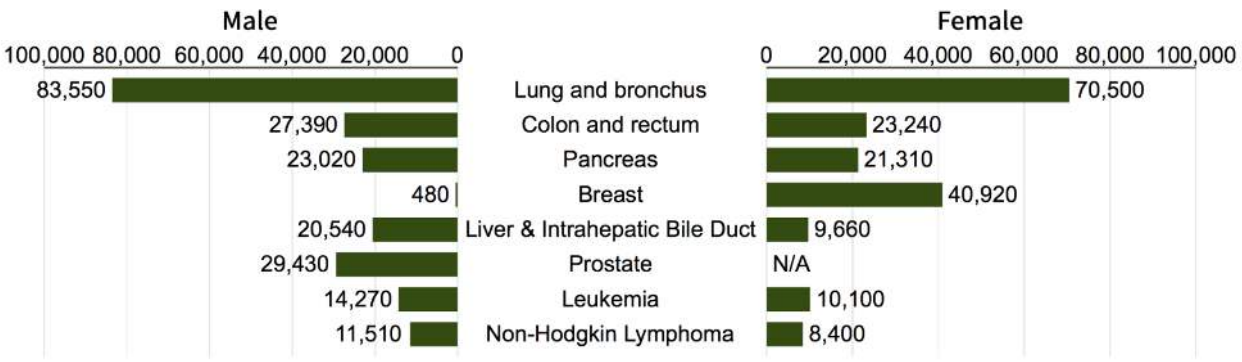
8. Encorafenib + Binimetinib + Cetuximab combination yields mOS of 15.3 months in BRAF mutated 2L-3L mCRC patients in Ph III BEACON CRC trial (http://investor.arraybiopharma.com/news-releases/news-release-details/array-biopharma-announces-153-months-median-overall-survival)
9. Ph III TAGS trial data of LONSURF® (trifluridine/tipiracil) in metastatic gastric cancer patients to be presented (https://www.taihooncology.com/us/newsroom/press-releases/2019-01-17-LON-PM-US-1152-TOI-Servier-Present-Data-ASCO-GI)
10. Data from Ph III INT-11 trial of CXCL12 inhibitor Tipifarnib in pancreatic cancer patients to be presented (http://ir.kuraoncology.com/news-releases/news-release-details/kura-oncology-reports-clinical-activity-tipifarnib-subsets)
11. Data from safety lead-in to Ph III FIGHT trial of FGFR2b inhibitor Bemarituzumab presented (http://investor.fiveprime.com/news-releases/news-release-details/five-prime-therapeutics-presents-data-safety-lead-phase-3-fight)
12. Metabolic-based cancer therapy, SM-88, improves survival in Ph II trial of advanced Pancreatic Cancer patients (https://ir.tymeinc.com/investors/news-releases/press-release-details/2019/TYMEs-Novel-Metabolic-Based-Cancer-Therapy-SM-88-Improves-Survival-in-Phase-II-Study-of-Patients-with-Advanced-Pancreatic-Cancer/default.aspx)

OTW Trivia

Top 12 most common cancer sites (by gender):



Eight deadliest cancer sites (by gender)



(Source: https://seer.cancer.gov/statfacts/html/common.html (https://seer.cancer.gov/statfacts/html/common.html))

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. 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: "Confocal image of villi from the human small intestine. The finger-like shape increases the surface area of the intestine, improving the efficiency of food absorption. The intestinal crypts (enzyme secreting glands) can be seen below the villi. The green stain highlights the nucleoli of the rapidly growing epithelial layer of both the villi and the crypts. All the nuclei are stained red and the epithelial cell membranes appear blue." Source (http://cellimagelibrary.org/images/38903)

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.

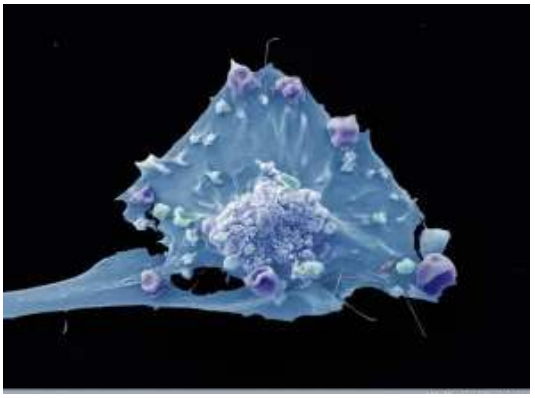
SHARE THIS

The contents of Club SciWri are the copyright of Ph.D. Career Support Group for STEM PhDs (A US Non-Profit 501(c)3, PhDCSG is an initiative of the alumni of the Indian Institute of Science, Bangalore. The primary aim of this group is to build a NETWORK among scientists, engineers, and entrepreneurs).

This work by Club SciWri (https://sciwri.club/wp-admin/www.sciwri.club) *is licensed under a Creative Commons Attribution-NonCommercial 4.0 International License* (http://creativecommons.org/licenses/by-nc/4.0/).

TAGS

RELATED ARTICLES



(https://sciwri.club/archives/7239)

Onco-this-Week (https://sciwri.club/archives/7239)

(https://sciwri.club/archives/7885)

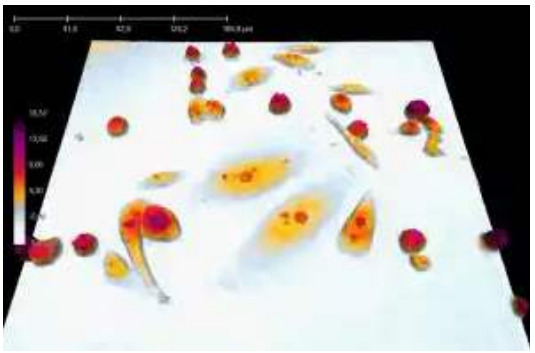
Onco-This-Week (https://sciwri.club/archives/7885)

(https://sciwri.club/archives/617)

Homeopathy Part V: The candy man can!* (https://sciwri.club/archives/617)

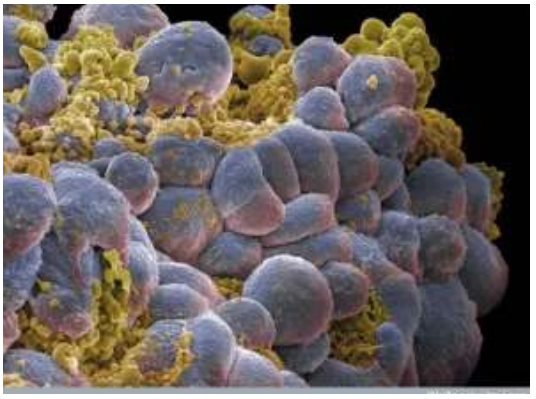
(https://sciwri.club/archives/8893)

Medness Plus (https://sciwri.club/archives/8893)



(https://sciwri.club/archives/8669)

Onco-this-Week (https://sciwri.club/archives/8669)



(https://sciwri.club/archives/8850)

Onco-this-Week (https://sciwri.club/archives/8850)

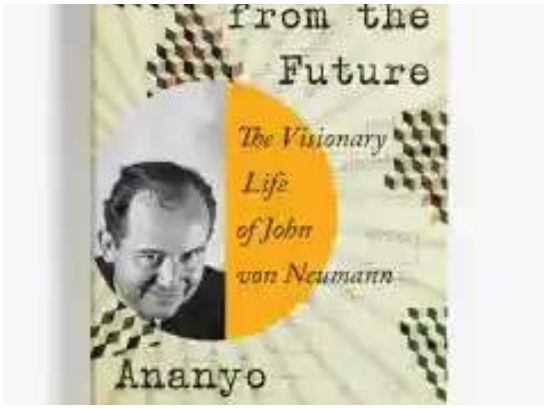
LATEST FROM CLUB SCIWRI

(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)

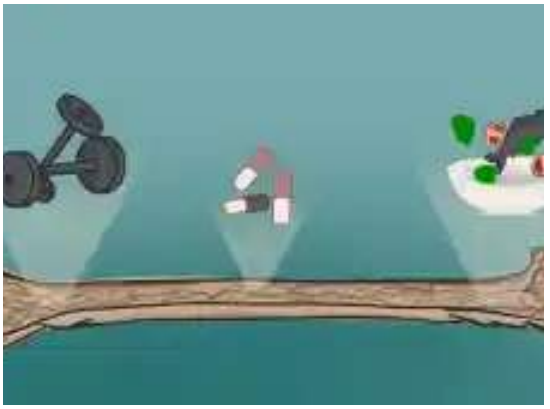
(https://sciwri.club/archives/13267)

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

Help scientists make science accessible for all

DONATE (HTTPS://WWW.PAYPAL.COM/DONATE/?CMD=_S-XCLICK&HOSTED_BUTTON_ID=KL4LD3KHW2FR2)

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