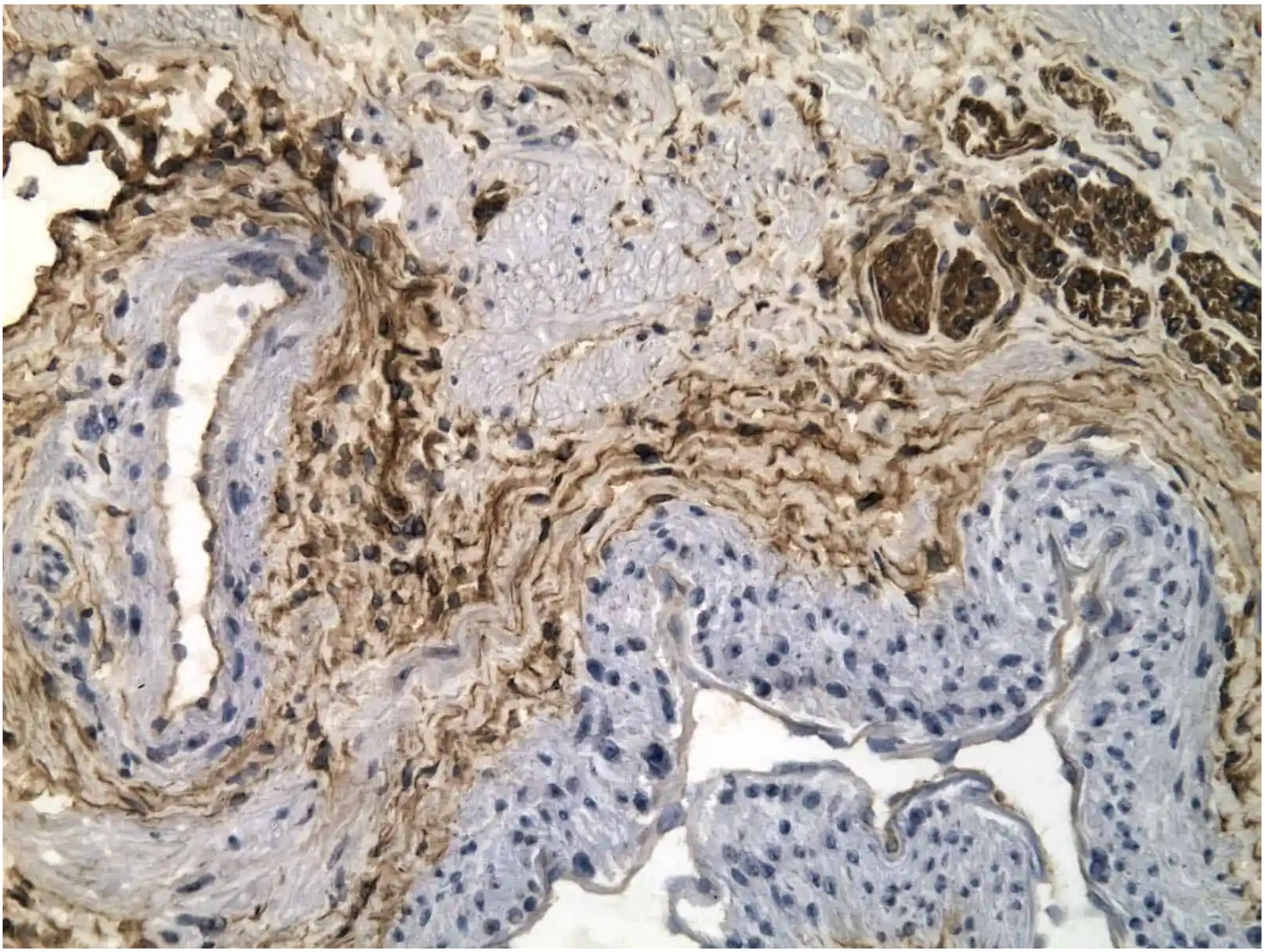
Archives (https://sciwri.club/archives/category/archives)

Onco-this-Week

July 28, 2018(https://sciwri.club/archives/date/2018/07/28)



SHARE THIS

In this edition of Onco-this-Week Richa Tewari highlights China's first PD-1 inhibitor approval (Pembrolizumab in advanced melanoma patients) and three Phase III trials meeting their primary endpoints

1.(*KEYNOTE-048 trial*: Pembrolizumab improving OS (Overall Survival) improvement in 1L (First Line) PD-L1-expressing SCCHN (Squamous Cell Carcinoma of the Head and Neck) patients,

2.ALTA-1L: Brigatinib improving PFS in ALK inhibitor-naïve, advanced NSCLC (Non-Small Cell Lung Cancer) patients, and

3. AUGMENT: Lenalidomide + rituximab improving improvement in FL (Follicular Lymphoma) and MZL (Marginal Zone Lymphoma) patients.

In the trivia section, we talk about the basics of Breakthrough Therapy Designation

The companies that we have covered this week include Merck, AstraZeneca, Innovent, Celyad, Immunicum, Takeda, Celgene, BeiGene, CBT Pharmaceuticals, Halozyme, Helix, Tolero, GSK, Adaptimmune, Immunomedics, Leap Therapeutics and Pfizer.

ONCO-THIS-WEEK TRIVIA

WHAT IS A BREAKTHROUGH THERAPY DESIGNATION?

Breakthrough Therapy Designation (BTD) is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s).

WHAT ADVANTAGES DOES BDT CONFER?

A drug that receives Breakthrough Therapy Designation is eligible for the following:

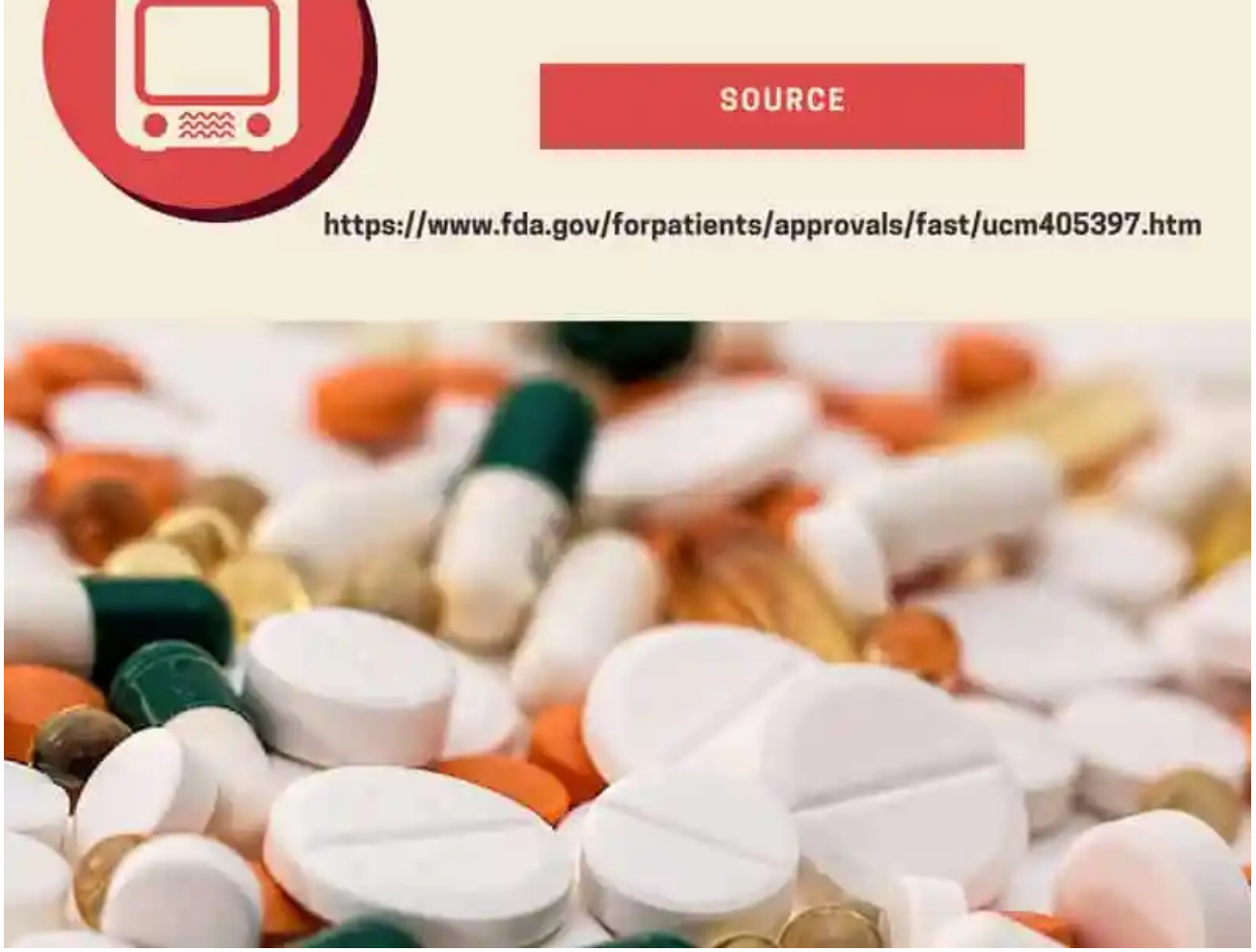
- **All Fast Track designation features**
- **Intensive guidance on an efficient drug development program, beginning as early as Phase 1**
- **Organizational commitment involving senior managers**

WHEN IS A BTD REQUEST MADE?

Ideally, a Breakthrough Therapy designation request should be received by FDA no later than the end-of-phase-2 meetings if any of the features of the designation are to be obtained. Because the primary intent of BTD is to develop evidence needed to support approval as efficiently as possible, FDA does not anticipate that BTD requests will be made after the submission of an original BLA or NDA or a supplement.

IN HOW MUCH TIME DOES FDA RESPOND TO BTD REQUESTS?

FDA will respond to BTD requests within sixty days of receipt of the request.

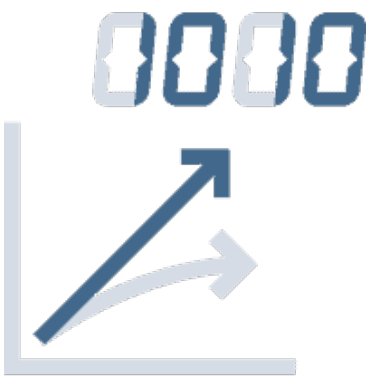


(https://io.wp.com/sciwri.club/wp-content/uploads/2018/07/Onco-this-Week-Trivia-1.jpg?ssl=1)

This edition of Onco-this-Week is Sponsored by Nano-Tag Biotechnologies (https://goo.gl/XM63s6)

NanoTag Biotechnologies

(https://goo.gl/XM63s6)



(https://i0.wp.com/sciwri.club/wp-content/uploads/2018/07/quantitative_imaging.png?ssl=1)

Note from our Sponsor: *"Our FluoTag-Q series feature high affinity monovalent binding, low steric constraints and a defined fluorophore number per molecule. This ensures a linear relation between target molecule number and fluorescence intensity."*

"NanoTag Biotechnologies is a German company founded in July 2015 by scientists with a strong background in biochemistry as well as quantitative super-resolution imaging. Situated in Göttingen, we are in constant exchange with scientists developing and applying tools for innovative cutting-edge research. The inspiring atmosphere created by leading scientists and an excellent network of entrepreneurship is an ideal breeding ground for our vision to produce thoroughly validated high-quality tools for life-sciences, biotechnology and bio-medical research. Currently, our portfolio mainly focuses on single-domain antibody-based affinity reagents ("Tags") for biochemical and fluorescence-based applications. In the near future, we are going to expand our portfolio to enzymes, affinity resins and secondary reagents for various immunoassays (IP, IF, IHC, IHC-P, WB...). Feel free to contact us (http://nano-tag.com/about-us) anytime to discuss custom projects."

DRUG APPROVALS

Pembrolizumab gets approval in China for Advanced Melanoma based on ORR data from the Ph Ib KEYNOTE-151 study (http://www.mrknewsroom.com/news-release/oncology-newsroom/keytruda-pembrolizumab-first-anti-pd-1-therapy-approved-china-advance)

"Merck is committed to bringing new treatment advances, like KEYTRUDA, to cancer patients in China," said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "The approval of KEYTRUDA in China, for this first indication, was made possible through extensive collaborative effort with the Chinese patients and investigators who participated in KEYNOTE-151, as well as the regulatory and government authorities who prioritized this filing. We appreciate their commitment to bringing forward the first anti-PD-1 therapy for advanced melanoma in China."

> Pembrolizumab Approved in China for Melanoma https://t.co/6zBn74lY8Z (https://t.co/6zBn74lY8Z) pic.twitter.com/wSFH7Rr45G (https://t.co/wSFH7Rr45G)
>
> — ImmunotherapyPapers (@Immunotx_papers) July 26, 2018 (https://twitter.com/Immunotx_papers/status/1022578577668067328?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The approval of our anti-PD-1 therapy reflects the Chinese government's strong commitment to expedite the introduction of innovative therapies to Chinese patients," said Joseph Romanelli, president of MSD China. "The approval of KEYTRUDA in advanced melanoma marks the sixth new product approval for MSD China in 2018. We are encouraged that our scientific advancements are leading to new options for patients and their families."

REGULATORY NEWS

Positive EU CHMP opinion for Durvalumab as adjuvant maintenance therapy for unresectable Stage III PD-L1+ NSCLC patients based on Ph III PACIFIC trial data (https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2018/imfinzi-receives-positive-eu-chmp-opinion-for-locally-advanced-unresectable-non-small-cell-lung-cancer-27072018.html)

> Durvalumab Approaches EU Approval for Locally Advanced PDL1 NSCLC: The European Medicines Agency’s Committee for Medicinal Products for Human Use has recommended approval of durvalumab for the treatment of patients with locally advanced... https://t.co/5QMYPOQ5BF (https://t.co/5QMYPOQ5BF)
>
> — Cancer News (@Cancer_bio) July 27, 2018 (https://twitter.com/Cancer_bio/status/1022937186084114432?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer at AstraZeneca, said: “The CHMP positive opinion brings European patients closer to having a treatment following chemoradiation therapy. There have been no new treatments in this setting for decades. With approximately a third of European non-small cell lung cancer patients presenting with this stage of disease, we are excited by this potential new standard of care in this curative-intent setting.”

IND approval to initiate trials of anti-OX40 Agonistic Antibody IBI101 in China (http://innoventbio.com/en/#/news/104)

> Innovent Receives IND Approval to Initiate Clinical Trials in China with its anti-OX40 Agonistic Antibody IBI101 and its anti-RANKL Antibody IBI307 https://t.co/S5g1hAt2xB (https://t.co/S5g1hAt2xB)
>
> — DennisPartners (@DennisPartners) July 26, 2018 (https://twitter.com/DennisPartners/status/1022370956767944704?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“The IND approvals for IBI101 and IBI307 by CFDA once again demonstrate Innovent’s capability and commitment to lead the rapid development of China’s biopharmaceutical market. As part of our 17 drug candidates under development, we will prepare to bring these two targeted therapeutic agents into clinical trials quickly,” said Michael Yu, Founder, Chief Executive Officer and Chairman. “Innovent will continue to discover and develop new biopharmaceutical drugs to expand our portfolio of products to treat patients. With today’s rapid improvements in cancer treatment modalities, we will utilize our well-established platform to discover, develop, manufacture and commercialize innovative high-quality biopharmaceutical drugs.”

FDA accepts INDA for CYAD-101, first-in-class non-gene edited allogeneic CAR-T candidate; Allo-SHRINK trial in CRC patients to start (https://www.celyad.com/en/nouvelles/la-fda-a-accepte-l-ind-de-celyad-pour-cyad-101-un-premier-candidat-car-t-allogenique-ne-faisant-pas-appel-a-de-l-edition-du-genome)

> $A1W7Q9 #CELYAD (https://twitter.com/hashtag/CELYAD?src=hash&ref_src=twsrc%5Etfw) Celyad: allogeneic CYAD-101 phase I trial cleared by the FDA: Brief Comment – Celyad: (BUY, Fair Value EUR46 (+85%)) allogeneic CYAD-101 phase I trial cleared by the FDA https://t.co/GgMWupdAR7 (https://t.co/GgMWupdAR7) pic.twitter.com/lJXJJSt9bW (https://t.co/lJXJJSt9bW)
>
> — ResearchPool (@ResearchPool) July 24, 2018 (https://twitter.com/ResearchPool/status/1021678952543268865?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Dr. Christian Homsy, CEO of Celyad: “We are pleased to have achieved this important milestone. Celyad is the first company clinically evaluating a non-gene edited CAR-T candidate, which, we believe, offers significant advantages over gene edited approaches. Our non-gene edited program consists of a family of technologies aimed at reducing or eliminating T cell receptor (TCR) signaling without requiring genetic manipulation. CYAD-101 is part of a robust clinical development plan, establishing the foundations of next generation CAR-T products.”

Immunicum gets protocol approval by FDA to initiate expanded multi-indication Ph Ib/II trial of ilixadencel + Pembrolizumab (http://immunicum.se/investors/press-releases/)

> Swedish Immunicum targets tumors with immune primer: Ilixadencel https://t.co/bdup8N8SMC (https://t.co/bdup8N8SMC) pic.twitter.com/CDcYqWxFqF (https://t.co/CDcYqWxFqF)
>
> — Krishan Maggon (@kkmaggon) July 24, 2018 (https://twitter.com/kkmaggon/status/1021653945297641473?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“It is a great accomplishment for Immunicum to have achieved the protocol approval and it will allow us to start the trial as planned. The larger number of patients in the Phase Ib will provide significant value as well as increase the potential to observe indications of clinical activity earlier in the trial,” said Carlos de Sousa, CEO of Immunicum. “As previously communicated, the company remains funded to the end of 2019 and we will provide updates on the Phase Ib progress during this year and over the course of 2019.”

“We appreciate the contributions of the clinical experts and investigators to the design of the protocol and value the positive interactions we have had with the regulatory authorities,” added Peter Suenaert, MD, PhD, Chief Medical Officer at Immunicum. “We look forward to start enrolling patients during the second half of 2018.”

TRIAL RESULTS

Pembrolizumab met primary endpoint of OS improvement in Ph III (http://www.mrknewsroom.com/news-release/oncology/keytruda-pembrolizumab-monotherapy-met-primary-endpoint-phase-3-keynote-048-tr)

> KEYNOTE-048, the phase 3 trial studying #pembrolizumab (https://twitter.com/hashtag/pembrolizumab?src=hash&ref_src=twsrc%5Etfw) (Keytruda) as first-line treatment in patients with recurrent or metastatic head and neck #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw), has met a primary endpoint of overall survivalhttps://t.co/aYr23aGqzS (https://t.co/aYr23aGqzS) pic.twitter.com/SqZ5spJat1 (https://t.co/SqZ5spJat1)
>
> — AJMC (@AJMC_Journal) July 26, 2018 (https://twitter.com/AJMC_Journal/status/1022440141002952704?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
l in 1L PD-L1-expressing SCCHN patients

“This interim analysis of KEYNOTE-048 trial has shown that KEYTRUDA monotherapy has the potential to help patients with head and neck cancer whose tumors express high-levels of PD-L1,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. “We look forward to presenting these initial results from the KEYNOTE-048 trial at an upcoming medical meeting, and are grateful to the investigators and patients for their continued involvement in this important study.”

Ph III trial of Brigatinib met primary endpoint of PFS improvement vs. Crizotinib in ALK+, ALK inhibitor naïve, advanced NSCLC patients (https://www.takeda.com/newsroom/newsreleases/2018/takeda-announces-phase-3-trial-of-alunbrig-brigatinib-met-primary-endpoint/)

> The primary endpoint of the phase III ALTA-1L trial has been met; read the results from this trial on brigatinib as treatment for adult patients with ocally advanced or metastatic ALK-positive non–small cell lung cancer: https://t.co/UhMA5mwjQl (https://t.co/UhMA5mwjQl)#lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) #lcsm (https://twitter.com/hashtag/lcsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/cMBU87GA7M (https://t.co/cMBU87GA7M)
>
> — Targeted Oncology (@TargetedOnc) July 26, 2018 (https://twitter.com/TargetedOnc/status/1022572453862813696?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“This represents a major milestone for the ALUNBRIG program. Our goal with ALUNBRIG is to improve the lives of patients with ALK+ NSCLC by furthering the available therapeutic options,” said Jesús Gomez-Navarro, M.D., Vice President, Head of Oncology Clinical Research and Development, Takeda. “We are encouraged by the data, which demonstrated a statistically significant improvement in progression-free survival versus crizotinib in patients with ALK+ advanced NSCLC, and look forward to beginning discussions with regulatory authorities as we seek to expand ALUNBRIG’s indication into the frontline setting.”

Ph III AUGMENT study of lenalidomide + rituximab in FL and MZL patients meets primary endpoint of PFS improvement (http://ir.celgene.com/releasedetail.cfm?ReleaseID=1072723)

> Ph. III AUGMENT study of lenalidomide plus rituximab in R/R indolent lymphoma met primary endpoint https://t.co/SYRmxUXqJW (https://t.co/SYRmxUXqJW) pic.twitter.com/nEbXKsCUjO (https://t.co/nEbXKsCUjO)
>
> — DAVA Oncology (@DAVAOnc) July 24, 2018 (https://twitter.com/DAVAOnc/status/1021787121047220224?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)

“Indolent non-Hodgkin lymphomas, such as follicular lymphoma and marginal zone lymphoma, are diseases of underlying immune dysfunction with a need for new options beyond currently available therapies,” said Jay Backstrom, M.D., Chief Medical Officer for Celgene. “We are encouraged by the highly significant improvement in progression-free survival observed in this study and look forward to engaging with regulatory authorities as soon as possible. The R² regimen represents a potentially new chemotherapy-free option for these patients.”

Preliminary top-line results of pivotal trial in China of PD-1 inhibitor Tislelizumab show 73% ORR (50% CR) in Hodgkin’s Lymphoma patients (http://ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2359339)

> @BeiGeneUSA (https://twitter.com/BeiGeneUSA?ref_src=twsrc%5Etfw) just announced very promising results for its PD-1 tislelizumab, which treats classical Hodgkin’s lymphoma. It’s no wonder that Celgene signed a $1.4 billion deal to buy into the drug last year. Learn more: https://t.co/VSB2g6JpHm (https://t.co/VSB2g6JpHm)
>
> — Inova (@Inova_Software) July 23, 2018 (https://twitter.com/Inova_Software/status/1021395589513261056?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“We are excited to announce the preliminary topline results from our first pivotal trial for tislelizumab. Despite

short follow-up, we believe there was a demonstration of robust activity, with high overall and complete response rates in addition to a safety profile that is consistent with other PD-1 inhibitors. We believe these strong results will support our first regulatory filing in China for tislelizumab, which is planned for later this year," commented Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene.

TRIAL STATUSES

Ph Ib trial of PD-1 inhibitor CBT-501-01 (genolimzumab injection) started in patients with advanced solid tumors (https://www.cbtpharma.com/media/cbt-pharmaceuticals-initiates-phase-1b-clinical-trial-for-anti-pd-1-antibody-cbt-501-01-genolimzumab-injection-in-patients-with-advanced-solid-tumors/)

> CBT Pharmaceuticals Initiates Phase 1b Clinical Trial for Anti-PD-1 Antibody CBT-501-01 (genolimzumab injection) in Patients with Advanced Solid Tumors. #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) https://t.co/RSIcFoGXoF (https://t.co/RSIcFoGXoF)
>
> — cbtpharma (@cbtpharma) July 26, 2018 (https://twitter.com/cbtpharma/status/1022545116261572610?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are pleased that our PD-1 drug candidate, CBT-501, has demonstrated encouraging pharmacokinetics, pharmacodynamic engagement, a well-tolerated safety profile, and encouraging activity in advanced stage cancer patients," stated Sanjeev Redkar, PhD, President and Chief Executive Officer. "We expect the Phase 1b to further evaluate the safety profile of CBT-501 and its utility as a single agent in a number of homogenous tumor types. Results from this study may lead to a Phase 2 trial utilizing CBT-501 as a single agent or in combination with chemotherapy, radiation, targeted therapies, or other cancer immunotherapy agents."

Ph III trial of subcutaneous Pertuzumab and Trastuzumab initiated using Halozyme's ENHANZE® technology in HER2+ breast cancer patients (https://www.halozyme.com/investors/news-releases/news-release-details/2018/Phase-3-Study-Of-Subcutaneous-Pertuzumab-And-Trastuzumab-Initiated-Using-Halozymes-ENHANZE-Technology/default.aspx)

> Phase 3 Study Of Subcutaneous Pertuzumab And Trastuzumab Initiated Using Halozyme's ENHANZE® Technology – MadePress™ – https://t.co/p55579YCJK (https://t.co/p55579YCJK) pic.twitter.com/SDwjXaGrvO (https://t.co/SDwjXaGrvO)
>
> — MadePress (@MadePressMP) July 26, 2018 (https://twitter.com/MadePressMP/status/1022458486737780737?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are excited to support the initiation by Genentech of the first Phase 3 study exploring a fixed-dose combination of two therapeutics," said Dr. Helen Torley, president and CEO of Halozyme. "For breast cancer patients and healthcare professionals, the approach of administering pertuzumab and trastuzumab subcutaneously in a single injection with ENHANZE offers the potential for a new treatment administration option."

Fourth dosing cohort completed; enrollment of next cohort started in Ph I trial of L-DOS47 + chemotherapy in non-squamous NSCLC patients (http://globenewswire.com/news-release/2018/07/25/1542280/0/en/Helix-BioPharma-Corp-Completes-Fourth-Dosing-Cohort-and-Initiates-Enrollment-of-the-Next-Cohort-in-U-S-Combination-Treatment-Study-of-Its-Lung-Cancer-Drug-Candidate-L-DOS47.html?ev=1)

> Helix BioPharma Corp. Completes Fourth Dosing Cohort and Initiates Enrollment of the Next Cohort in U.S. Combination Treatment Study of Its Lung Cancer Drug Candidate L-DOS47 https://t.co/KoKlRP2ech (https://t.co/KoKlRP2ech)
>
> — SPI News (@NewsFromSPI) July 25, 2018 (https://twitter.com/NewsFromSPI/status/1022279420076032o1?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are very encouraged that a significant group of treated patients are experiencing a reduction in their tumor growth," said Heman Chao, CEO Helix's Chief Executive Officer. "We look forward to receiving more data and continuing to advance the L-DOS47 development program."

Global Ph III trial of PARP Inhibitor Pamiparib initiated in 1L maintenance advanced Gastric Cancer patients (http://ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2359579)

"We are pleased to announce the initiation of the first global Phase 3 trial of pamiparib, an important compound in our clinical pipeline. With our recently announced Phase 3 clinical trial of pamiparib in China for patients with platinum-sensitive recurrent ovarian cancer and now with this global Phase 3 trial in gastric cancer, we are striving to maximize opportunities for patients with a broad range of cancer diagnoses to be treated with and potentially benefit from pamiparib," commented John V. Oyler, Founder, Chief Executive Officer, and Chairman of BeiGene.

> BeiGene Initiates Global Phase 3 Trial of PARP Inhibitor Pamiparib in Patients with Advanced Gastric Cancer#gastriccancer (https://twitter.com/hashtag/gastriccancer?src=hash&ref_src=twsrc%5Etfw)#CancerAwareness (https://twitter.com/hashtag/CancerAwareness?src=hash&ref_src=twsrc%5Etfw) https://t.co/NVtoKfQeTY (https://t.co/NVtoKfQeTY) pic.twitter.com/oBcPSPQa4w (https://t.co/oBcPSPQa4w)
>
> — StomachCancerCa (@StomachCancerCa) July 25, 2018 (https://twitter.com/StomachCancerCa/status/1022150231385825280?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Our focus at BeiGene is on developing treatments for patients who often have limited options. We are excited about this opportunity to evaluate our PARP inhibitor as maintenance therapy for patients with platinum-sensitive gastric cancer, especially considering more than 50 percent of these patients worldwide live in Eastern Asia, mainly China1," commented Amy Peterson, M.D., Chief Medical Officer for Immuno-Oncology at BeiGene.

Ph III pivotal trial of PD-1 inhibitor Tislelizumab + chemotherapy initiated in 1L non-sqNSCLC patients in China (ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2359778)

"We are pleased to be enrolling patients in this important trial evaluating the potential impact of adding tislelizumab, an investigational immuno-oncology therapy, to platinum plus pemetrexed chemotherapy, the current global standard of care in first-line treatment of patients with advanced stage non-squamous NSCLC," commented Amy Peterson, M.D., Chief Medical Officer for Immuno-Oncology at BeiGene.

> BeiGene Initiates Ph III Trial of PD-1 Inhibitor Tislelizumab + Chemotherapy in Advanced Non-Squamous Non-Small Cell Lung Cancer in China: * Tislelizumab is a monoclonal antibody PD-1 checkpoint inhibitor * BeiGene and Celgene have a global collaboration... https://t.co/X9sm5BHbhb (https://t.co/X9sm5BHbhb)
>
> — cafepharma (@cafepharma) July 25, 2018 (https://twitter.com/cafepharma/status/1022198071487160320?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"As shown by the most recent data from other checkpoint inhibitors, combining immunotherapy and chemotherapy can improve anti-tumor activity and significantly improve outcomes for patients. Our Phase 3 study will assess whether the addition of tislelizumab to standard-of-care chemotherapy will improve outcomes in Chinese patients with advanced lung cancer, a disease known for its poor prognoses even with chemotherapy treatment," commented Lai Wang, Ph.D., Senior Vice President and Head of China Development at BeiGene.

First patient dosed with investigational agent TP-0184, an Activin A Receptor Type 1 (ACVR1) inhibitor, in Ph I trial of patients with advanced solid tumors (https://www.prnewswire.com/news-releases/tolero-pharmaceuticals-announces-first-patient-dosed-with-investigational-agent-tp-0184-an-activin-a-receptor-type-1-acvr1-inhibitor-in-phase-1-study-of-patients-with-advanced-solid-tumors-300686062.html)

> Study of Oral TP 0184 looks to understand more about the profile of TP-0184 and its role in inhibiting ACVR1, which is mutated 32% of diffuse intrinsic pontine gliomas @Toleropharma (https://twitter.com/Toleropharma?ref_src=twsrc%5Etfw) https://t.co/lu7BDQJsAi (https://t.co/lu7BDQJsAi) #DIPG (https://twitter.com/hashtag/DIPG?src=hash&ref_src=twsrc%5Etfw) @jonathanagin (https://twitter.com/jonathanagin?ref_src=twsrc%5Etfw) @AbbiesArmy (https://twitter.com/AbbiesArmy?ref_src=twsrc%5Etfw) @DefeatDIPG (https://twitter.com/DefeatDIPG?ref_src=twsrc%5Etfw) @CureStartsNow (https://twitter.com/CureStartsNow?ref_src=twsrc%5Etfw) @PBTF (https://twitter.com/PBTF?ref_src=twsrc%5Etfw) pic.twitter.com/Lj2pufcff3 (https://t.co/Lj2pufcff3)
>
> — Amanda Erin Griffin (@erinforever14) July 27, 2018 (https://twitter.com/erinforever14/status/1022813362713964544?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The initiation of this study of TP-0184 represents an important milestone for Tolero Pharmaceuticals, as it marks the second investigational agent from our development program to enter the clinical research stage this year," said David J. Bearss, Ph.D., Chief Executive Officer of Tolero Pharmaceuticals, Inc. "We look forward to understanding more about the profile of TP-0184 and its role in inhibiting ACVR1, which is mutated in approximately 1-4 percent of solid tumors and 32 percent of diffuse intrinsic pontine gliomas (DIPGs), an aggressive form of pediatric brain cancer."

Ph II Zella 201 Study of CDK9 inhibitor Alvocidib advances in R/R MCL-1-Dependent AML patients (http://www.toleropharma.com/press07232018.html)

> AML clinical trial update: Tolero Pharmaceuticals Advances Investigational Agent Alvocidib into Second Stage of Phase II Zella 201 Study in Patients w/ Relapsed Refractory MCL-1-Dependent AML @Toleropharma (https://twitter.com/Toleropharma?ref_src=twsrc%5Etfw) https://t.co/8llDoHYqZx (https://t.co/8llDoHYqZx) pic.twitter.com/J3HJRyRp9D (https://t.co/J3HJRyRp9D)
>
> — Hematopoiesis News (@Hema_News) July 27, 2018 (https://twitter.com/Hema_News/status/1022901978136014848?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The advancement of this study marks an important milestone for our company as we continue to progress the Phase 2 clinical program for alvocidib," said David J. Bearss, Ph.D., Chief Executive Officer of Tolero Pharmaceuticals, Inc. "We believe the second stage of this study will deepen our understanding of the activity of alvocidib in relapsed or refractory MCL-1-dependent acute myeloid leukemia. This will allow us to build upon preliminary clinical data from the Stage 1 of the Zella 201 study that were recently presented at the 23rd Annual Congress of the European Hematology Association."

BeiGene plans to submit NDA for BTK Inhibitor Zanubrutinib in Waldenström Macroglobulinemia (WM) based on Ph I trial results (http://ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2359338)

> .@BeiGeneUSA (https://twitter.com/BeiGeneUSA?ref_src=twsrc%5Etfw) to seek accelerated US approval of zanubrutinib; new data on PD-1 antibody https://t.co/j5NlCEKvMK (https://t.co/j5NlCEKvMK) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw)
>
> — ThePharmaLetter (@ThePharmaLetter) July 24, 2018 (https://twitter.com/ThePharmaLetter/status/1021759014072446978?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We believe zanubrutinib is a differentiated BTK inhibitor based on the depth and durability of responses observed in our ongoing global Phase 1 trial of zanubrutinib in WM patients. We look forward to working closely with the FDA in the continuing development of zanubrutinib for the treatment of this disease," commented John Oyler, co-founder, CEO and Chairman of BeiGene. "We are hopeful that zanubrutinib, if approved, may represent a valuable and important treatment option for patients with WM."

LICENSING DEALS

GSK to develop and commercialize NY-ESO SPEAR T-cell therapy program (http://ir.adaptimmune.com/phoenix.zhtml?c=253991&p=irol-newsArticle&ID=2359593)

Dr. Hal Barron, President R&D, GSK said, "The data we've seen for GSK '794 point to the potentially transformational nature of this T-cell therapy, as this is the first cell therapy to show clinical response in solid tumours. The concept of cells as medicines is an exciting component of our immuno-oncology portfolio and leverages our expertise in manufacturing T-cell therapies. This has been a productive collaboration on GSK '794 and we look forward to continued collaboration with Adaptimmune."

> Following the transition of the NY-ESO SPEAR T-cell program to @GSK (https://twitter.com/GSK?ref_src=twsrc%5Etfw), you can find more information here (https://t.co/lGYcDxFyEa (https://t.co/lGYcDxFyEa)) about how we transform T-cell therapy for #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) patients with our pipeline of SPEAR T-cell therapies inc. MAGE-A4, MAGE-A10 and AFP pic.twitter.com/XsTnnXYpHp (https://t.co/XsTnnXYpHp)
>
> — Adaptimmune (@Adaptimmune) July 27, 2018 (https://twitter.com/Adaptimmune/status/1022869218792861696?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"This is a turning point for Adaptimmune. We are extremely proud of the partnership with GSK and the pioneering work we have led over the years with NY-ESO SPEAR T-cells, as the foundation of our targeted TCR therapies, showing responses in two solid tumors and treating more than 80 patients in six different indications," said James Noble, Chief Executive Officer at Adaptimmune. "With the NY-ESO program transitioned, Adaptimmune can focus its clinical, regulatory and manufacturing resources on the development of our wholly owned therapies MAGE-A4, MAGE-A10, and AFP. We will continue the preclinical work with GSK on its next target, PRAME."

Immunomedics and AstraZeneca to assess PD-L1 inhibitor Durvalumab and TROP2 targeting ADC sacituzumab govitecan in 1L TNBC and urothelial cancers (https://immunomedics.com/2018/immunomedics-announces-clinical-collaboration-with-astrazeneca-in-first-line-triple-negative-breast-and-urothelial-cancers/)

"We are pleased to be partnering with AstraZeneca, a global leader in oncology drug development, to advance sacituzumab govitecan into potential first line of use, which could benefit a significantly larger patient population," said Usama Malik, Chief Business Officer of Immunomedics.

> Hot on the heels of Immunomedics priority review news for its ADC Sacituzumab comes the news of clinical investigations of checkpoint combination therapy with MedImmune's Durvalumab vs TNBC and urothelial cancer. https://t.co/r55cBZAdHF (https://t.co/r55cBZAdHF)
>
> — Beacon Intelligence (@BeaconIntel) July 24, 2018 (https://twitter.com/BeaconIntel/status/1021671949666201600?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
David Berman, Senior Vice President, Head of IO Franchise, AstraZeneca said, "Our collaboration with Immunomedics will focus on the combination of sacituzumab govitecan with Imfinzi® (durvalumab), expanding our efforts in triple-negative breast cancer and bladder cancer where unmet medical needs still exist. We believe combining Immunomedics' antibody-drug conjugate, a late-stage agent that has demonstrated encouraging clinical activity, with Imfinzi will complement our existing clinical trial efforts in this area and maximize benefit to patients."

Leap Therapeutics, Merck KGaA and Pfizer to evaluate combination of GITR agonist TRX518, PD-L1 inhibitor Avelumab, and chemotherapy in advanced R/R Solid Tumors (http://www.investors.leaptx.com/phoenix.zhtml?c=254460&p=irol-newsArticle&ID=2359396)

"The combination of TRX518 with anti-PD-L1 immunotherapy and cyclophosphamide has a solid scientific rationale and we look to build upon our early clinical and preclinical data highlighting the potential benefits of such a combination," commented Cynthia Sirard, M.D., Vice President, Clinical Development of Leap Therapeutics.

Leap Therapeutics will collaborate with Merck KGaA and Pfizer – https://t.co/3RiIRorz54 (https://t.co/3RiIRorz54) pic.twitter.com/4boc2rcazR (https://t.co/4boc2rcazR)

— GMPnews.Net (@GMPnewsNet) July 23, 2018 (https://twitter.com/GMPnewsNet/status/1021538528960962561?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"TRX518 has demonstrated encouraging potential with early clinical activity in patients with advanced solid tumors," said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-oncology, Early Development and Translational Oncology, Pfizer Global Product Development. "This collaboration with Leap Therapeutics to evaluate TRX518 in combination with avelumab gives us the opportunity to investigate a potential novel immunotherapy treatment regimen as we pursue our mission of improving outcomes for patients living with hard-to-treat cancers."

"Combination therapy remains a major focus in our clinical development program for avelumab in an effort to advance the treatment landscape for patients with challenging cancers," said Alise Reicin, Head of Global Clinical Development at the Biopharma business of Merck KGaA, Darmstadt, Germany, which in the US and Canada operates as EMD Serono. "Through our collaboration with Leap Therapeutics, we are eager to further understand the potential of this novel immunotherapy combination in this patient population."

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: (Cell Image Library) Description- "Tissue section of human prostate containing adenocarcinoma that has been immunostained for the cell-surface antigen CD90. Nuclei are stained in blue. This image is part of a large collection of images generated from numerous specimens to characterize the distribution of CD90 in human prostate tissue. It was noted in Liu et al. (Am J Pathol 165 (2004) 1543-1556) that stromal fibromuscular cells associated with primary prostate cancer differ from stromal cells in benign prostate tissue by an increased level of expression of the cell activation molecule, CD90."- Source (http://cellimagelibrary.org/images/34089#download_options_button)

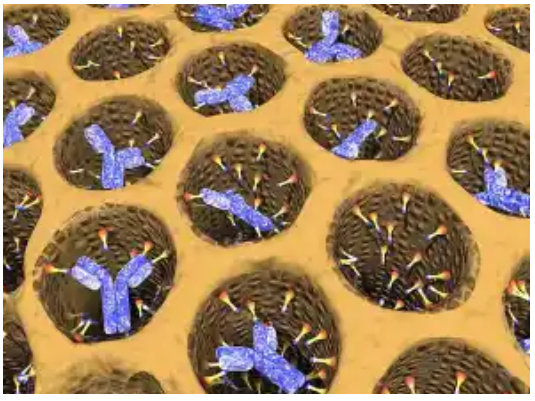
***Disclaimer**: The authors and editors for Onco-this-week declare no financial benefits or remuneration from the sponsors. The sponsorships support the non-profit organization, PhD Career Support Group. The research conducted by authors and editors is a voluntary effort to popularize science for the public on behalf of 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/6146)

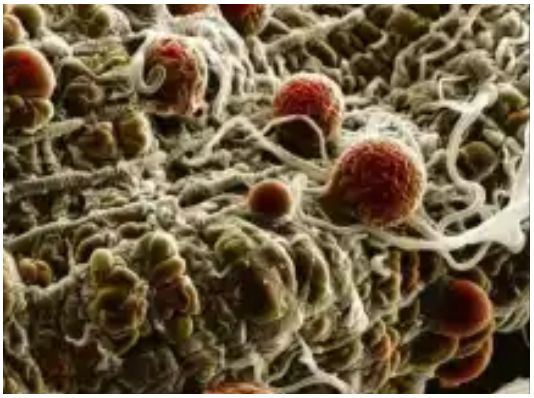
Onco-this-Week (https://sciwri.club/archives/6146)

(https://sciwri.club/archives/2602)

Nature vs Nurture- The Allegory of Research (https://sciwri.club/archives/2602)

(https://sciwri.club/archives/3922)

Confluence of Intellect: The 2017 IISc Alumni Meet (Washington, DC) (https://sciwri.club/archives/3922)

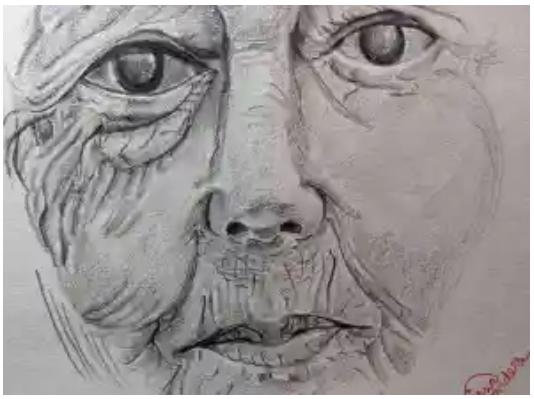


(https://sciwri.club/archives/7383)

Medness Plus (https://sciwri.club/archives/7383)

(https://sciwri.club/archives/1732)

Transitioning to a faculty position in India – skills that defines one during screening (https://sciwri.club/archives/1732)



(https://sciwri.club/archives/2171)

Turning back the hands of time (https://sciwri.club/archives/2171)

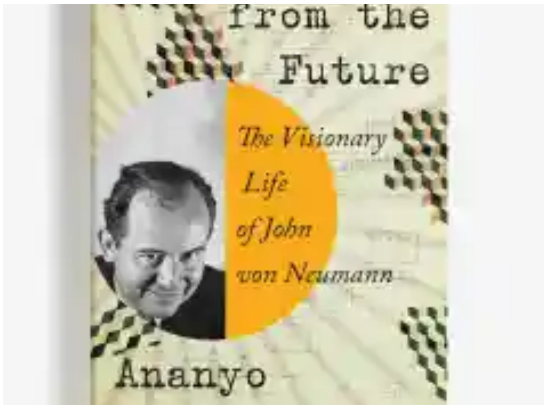
LATEST FROM CLUB SCIWRI

(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)

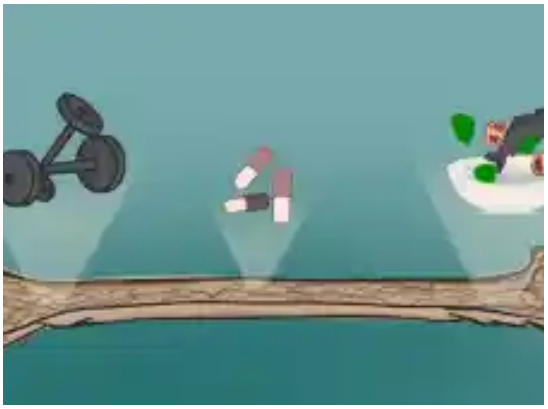
(https://sciwri.club/archives/13267)

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)