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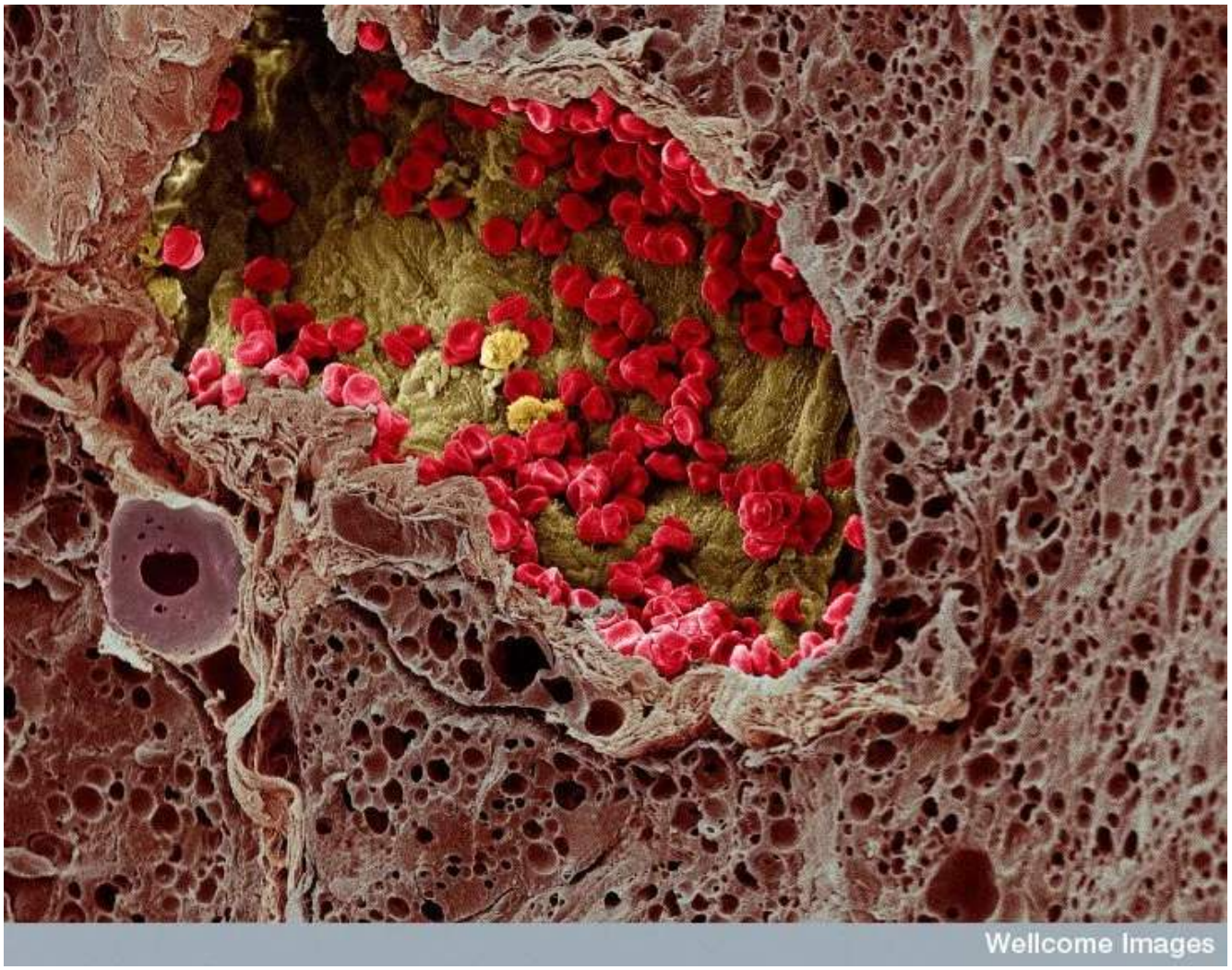
Onco-this-Week

January 13, 2019(https://sciwri.club/archives/date/2019/01/13)



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OTW in a Capsule

HIGHLIGHTS

1. **FDA Breakthrough Device Designation granted to ArcherDx's companion diagnostic assay application:** Almost all available companion diagnostic assays used either plasma samples or FFPE samples – sequencing-based multi-gene ArcherDx companion diagnostic assay, if approved, would become the first in-vitro diagnostic (IVD) test to accept both plasma and FFPE-based inputs. It would be used to detect possible somatic alterations in more than 50 genes and will be used to identify NSCLC patients for whom treatment with a specific targeted therapy is being considered.
2. **Association of BRCA2 mutations in prostate cancer with worse outcomes and poor responses:** Recent analysis from observational PROREPAIR-B trial connected the presence of BRCA2 mutations in prostate cancer patients to worse prognosis and poor responses to standard therapies. Though the role of BRCA mutations in breast cancer is widely known, these results consolidated the connection of these mutations with prostate cancer prognosis. Though the prevalence of these mutations is estimated at 3%, this quickly becomes a big population given the high incidence of prostate cancer.
3. **OS improvement with Nivolumab in unresectable advanced or recurrent Esophageal Cancer patients:** As per recent analysis of Ph III ATTRACTION-3 trial, Nivolumab becomes the first checkpoint inhibitor to show a statistically significant OS improvement in this patient population. This comes as a good news for physicians, oncologists and patients suffering from esophageal cancer, since there are currently no effective second line treatments options for recurrent patients who progress on cisplatin + 5-FU in front-line regimen.

(https://goo.gl/XM63s6)

DRUG APPROVALS

Toripalimab gets Chinese approval in Melanoma patients (http://www3.hkexnews.hk/listedco/listconews/sehk/2018/1219/LTN20181219850.pdf)

“Chinese pharmaceutical companies lag behind multinationals in the chemical drugs sector, but it is a different story for biomedicine and innovative drugs R&D,” Shi said.

“The approval of the first Chinese anti-PD-1 treatment just proved that.”

> Breaking News! First China PD-1 toripalimab(JS001,特瑞普利单抗) was granted accelerated approval by National Medical Products Administration, which came from TopAlliance(君实), for the treatment of patients with unresectable or metastatic advanced melanoma. pic.twitter.com/9JiQhRpx03 (https://t.co/9JiQhRpx03)
>
> — PharmCube (@pharmcube) December 17, 2018 (https://twitter.com/pharmcube/status/1074597850774814721?ref_src=twsrc%5Etfw)

REGULATORY NEWS

MAA submitted for Selinexor in penta-refractory Multiple Myeloma in EMA; to be Reviewed Under Accelerated Assessment (https://investors.karyopharm.com/news-releases/news-release-details/karyopharm-announces-submission-marketing-authorization)

“The MAA submission for selinexor is an important milestone for Karyopharm and the CHMP’s granting of accelerated assessment further underscores the urgent need to improve outcomes for patients with highly refractory multiple myeloma,” said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm. “The results from the pivotal Phase 2b STORM study provide compelling evidence that selinexor in combination with low-dose dexamethasone has the potential to be an effective new treatment option for patients with this difficult to treat disease. With the filing of the MAA and an accelerated assessment designation from the EMA, we hope to make oral selinexor available as quickly as possible to patients throughout Europe.”

"The STORM study was designed to target relapsed/refractory multiple myeloma," Dr. Gasparetto explained: https://t.co/Yr8iBRElYa (https://t.co/Yr8iBRElYa) "Selinexor was combined with different backbone therapies for myeloma..."#MultipleMyeloma (https://twitter.com/hashtag/MultipleMyeloma?src=hash&ref_src=twsrc%5Etfw) #Myeloma (https://twitter.com/hashtag/Myeloma?src=hash&ref_src=twsrc%5Etfw) #mmsm (https://twitter.com/hashtag/mmsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/rwHhHzRNxI (https://t.co/rwHhHzRNxI)

— Targeted Oncology (@TargetedOnc) January 11, 2019 (https://twitter.com/TargetedOnc/status/1083589352515686401?ref_src=twsrc%5Etfw)

IRB approval obtained for trial of dsRNA TLR3 agonist Ampligen + Pembrolizumab in mTNBC patients (ir.hemispherx.net/profiles/investor/ResLibraryView.asp?ResLibraryID=89469&BzID=2265&g=980&Nav=0&LangID=1&s=0)

Hemispherx Biopharma all set to evaluate dsRNA TLR3 agonist Ampligen+ Keytruda in triple negative #Metastaticbreastcancer (https://twitter.com/hashtag/Metastaticbreastcancer?src=hash&ref_src=twsrc%5Etfw). A 2nd clinical trial with same combination but in #ovariancancer (https://twitter.com/hashtag/ovariancancer?src=hash&ref_src=twsrc%5Etfw) is scheduled to launch later this month at Pittsburgh's Universityhttps://t.co/vCoL5SFgcN (https://t.co/vCoL5SFgcN)

— Beacon Intelligence (@BeaconIntel) January 9, 2019 (https://twitter.com/BeaconIntel/status/1082928967311679489?ref_src=twsrc%5Etfw)

"At Team Hemispherx we are determined to pursue an aggressive R&D program focused on improved immune therapies for lethal malignancies, and we are grateful for the support and attention we are getting from big pharma and these major research institutions," said Hemispherx CEO Thomas K. Equels. "The work beginning at Roswell Park Comprehensive Cancer Center is an important step in Hemispherx' overall clinical plan in immuno-oncology. Relevant preclinical experiments in several types of solid tumors and conducted at different major U.S. cancer research centers support the proposition that Ampligen can change the micro-environment of tumors so as to create a robust and significant positive synergy with check point blockade therapies. We have seen a clear synergistic effect in our laboratory studies, and human tumor explants indicate this phenomenon is extended to humans. To the extent this follows through in vivo with humans in these clinical trials, that synergy with the checkpoint inhibitors will put Ampligen at the forefront of a major medical breakthrough in immuno-oncology."

Updates on AU-011 program in choroidal melanoma provided (http://www.aurabiosciences.com/news-archive/2019/1/4/aura-biosciences-announces-successful-outcome-of-end-of-phase-2-meeting-with-fda-for-au-011-for-the-treatment-of-patients-with-choroidal-melanoma)

Aura Biosciences Announces Successful Outcome of End of Phase 2 Meeting with FDA for AU-011 for the Treatment of Patients with Choroidal Melanomahttps://t.co/nTmnlcaIQq (https://t.co/nTmnlcaIQq)#ingentium (https://twitter.com/hashtag/ingentium?src=hash&ref_src=twsrc%5Etfw) #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/Jtsn5L6kno (https://t.co/Jtsn5L6kno)

— Ingentium Melanoma (@ingentium_mel) January 6, 2019 (https://twitter.com/ingentium_mel/status/1081943619462987778?ref_src=twsrc%5Etfw)

“We are pleased to have received such clear guidance from the FDA with respect to the Phase 3 STARBRIGHT program to be able to meet the scientific and regulatory requirements for marketing approval in the U.S.” said Elisabet de los Pinos, Ph.D., Chief Executive Officer of Aura.

“We believe that a minimally invasive, non-radiation-based treatment option that enables early intervention while preserving vision has the potential to transform the therapeutic landscape for this difficult to treat, often deadly form of melanoma,” said Cadmus Rich, M.D., Chief Medical Officer of Aura. “Overall, the meeting removed any remaining uncertainty on the regulatory path to approval and highlighted FDA’s commitment to guide Aura toward a potential first drug approved for patients with this highly unmet medical need.”

Updates on Avaprinitib, BLU-667, and BLU-554 programs provided (ir.blueprintmedicines.com/news-releases/news-release-details/blueprint-medicines-announces-2020-blueprint-global-business)

“Our vision is to rapidly evolve Blueprint Medicines into the leading global precision therapy company, with a robust scientific platform reproducibly designing innovative compounds and an effective and nimble commercial organization delivering a portfolio of important medicines to patients worldwide,” said Jeff Albers, Chief Executive Officer of Blueprint Medicines. “As we enter the new year, we are at the precipice of this transformation with the planned submission of our first new drug application for our lead therapeutic candidate avapritinib and growing momentum in building our commercial capabilities. Combined with seven ongoing or planned registration-enabling clinical trials for avapritinib and BLU-667, we believe Blueprint Medicines is well-positioned to quickly capitalize on this first potential regulatory approval and realize our goal of becoming a portfolio-based commercial-stage company.”

Registration path for Tazemetostat for Follicular Lymphoma and pipeline updates announced (https://epizyme.gcs-web.com/news-releases/news-release-details/epizyme-announces-registration-path-tazemetostat-follicular)

> New Post: Epizyme Planning to Request FDA’s Accelerated Approval of Tazemetostat for Follicular Lymphoma Patients https://t.co/f9M1ThcE2J (https://t.co/f9M1ThcE2J) pic.twitter.com/TXSCYCqyk8 (https://t.co/TXSCYCqyk8)
>
> — Lymphoma News Today (@lymphomanews) January 11, 2019 (https://twitter.com/lymphomanews/status/1083853320220037122?ref_src=twsrc%5Etfw)

“Follicular lymphoma is an incurable cancer today, and in the third line and later settings, there are limited effective treatment options. Defining a clear path to a regulatory submission for tazemetostat for this patient population marks a huge step forward for patients and an opportunity to change the course of FL treatment,” said Shefali Agarwal, M.D., chief medical officer of Epizyme. “This FL NDA submission would mark the second for tazemetostat in one year, following our first submission for epithelioid sarcoma, which is on track for the second quarter of 2019. If successful, tazemetostat is poised to be the first commercially available EZH2 inhibitor. We look forward to advancing our submission preparations and further engaging with FDA, as we work expeditiously to bring tazemetostat to the patients who need it.”

SPECIAL STATUSES

Orphan drug designation grated to Altered Energy Metabolism Directed (AEMD) drug CPI-613 for Treatment of

R/R AML patients (http://www.globenewswire.com/news-release/2019/01/10/1686285/0/en/EMA-Grants-Orphan-Drug-Designation-to-Rafael-Pharmaceuticals-devimistat-CPI-613-for-Treatment-of-Patients-with-Relapsed-or-Refractory-Acute-Myeloid-Leukemia-AML.html)

> Rafael Pharmaceuticals' Devimistat (CPI-613) Receives EMA's ODD for R/R Acute Myeloid Leukemia (AML) and Metastatic Pancreatic Cancer (mPC) https://t.co/smFDDDfGVK (https://t.co/smFDDDfGVK) pic.twitter.com/63YjojOJ15 (https://t.co/63YjojOJ15)
>
> — PharmaShots (@Pharmashot) January 11, 2019 (https://twitter.com/Pharmashot/status/1083700035836088322?ref_src=twsrc%5Etfw)

Sanjeev Luther, President and Chief Executive Officer of Rafael Pharmaceuticals, commented, "Our motto, 'To Save A Life Is To Save A Universe,' reflects our commitment to developing potential treatments for patients with significant unmet clinical needs. We are glad that the EMA has granted Orphan Designation to devimistat for the treatment of patients with Relapsed or Refractory Acute Myeloid Leukemia (AML)."

Dr. Timothy Pardee, Chief Medical Officer of Rafael Pharmaceuticals, said, "Elderly patients with relapsed or refractory AML have so few options. Obtaining orphan drug designation from the EMA is very encouraging and is an important step in the development of devimistat for patients who suffer from this terrible disease."

FDA Breakthrough Device Designation granted to ArcherDx's companion diagnostic assay application (https://archerdx.com/company/blog/news/press-release-archerdx's-companion-diagnostic-assay-for-both-liquid-biopsy-and-tissue-specimens-granted-breakthrough-device-designation-by-u.s.-food-and-drug-administration)

> Press release: ArcherDX's Companion Diagnostic Assay for both Liquid Biopsy and Tissue Specimens Granted Breakthrough Device Designation by U.S. Food and Drug Administration #NGS (https://twitter.com/hashtag/NGS?src=hash&ref_src=twsrc%5Etfw) #genomics (https://twitter.com/hashtag/genomics?src=hash&ref_src=twsrc%5Etfw) #precisionmedicince (https://twitter.com/hashtag/precisionmedicince?src=hash&ref_src=twsrc%5Etfw) https://t.co/MHDxWHY8DW (https://t.co/MHDxWHY8DW) pic.twitter.com/rsd7iwHqWz (https://t.co/rsd7iwHqWz)
>
> — ArcherDX, Inc. (@archerdxinc) January 12, 2019 (https://twitter.com/archerdxinc/status/1084150267833171968?ref_src=twsrc%5Etfw)

"The acceptance of this assay for Breakthrough Device designation is a key milestone for our collaboration with the FDA and is an important step to advancing precision medicine options for patients and our biopharma partners," said Josh Stahl, chief scientific officer and executive vice president of ArcherDX. "This designation allows us to work closely with the FDA as we prepare our submission for this unique offering that empowers pathologists in the U.S. and around the world to run this test in their local lab, helping to reduce costs and improve test turn around time for these critically ill patients."

Fast Track Designation Granted to Vofatamab in FGFR3+ve advanced/metastatic bladder cancer (http://www.rainierrx.com/wp-content/uploads/2019/01/Fast-Track-release-Rainier.pdf)

FDA grants fast track designation to vofatamab for bladder cancer subset https://t.co/qjkQtKnnbm (https://t.co/qjkQtKnnbm) #bladdercancer (https://twitter.com/hashtag/bladdercancer?src=hash&ref_src=twsrc%5Etfw)

— Crush It For Curtis Foundation (@C_I_F_C_F) January 9, 2019 (https://twitter.com/C_I_F_C_F/status/1082807970415722496?ref_src=twsrc%5Etfw)

"This Fast Track designation underscores the great unmet medical need that exists for the treatment of bladder cancer," said Scott Myers, Chairman and CEO of Rainier Therapeutics. "As the only antibody specifically targeted to FGFR3 we know to be in clinical development, we believe vofatamab offers a promising therapeutic option. We look forward to further data from our ongoing trials and working to advance our development efforts."

TRIAL RESULTS

Prostate cancer in men with BRCA2 mutations associated with worse outcomes and poor responses to standard treatments as per observational PROREPAIR-B trial (https://www.cnio.es/en/news/publications/cnio-researchers-confirm-links-between-aggressive-prostate-cancer-and-hereditary-breast-cancer/)

"This is the first prospective study – that is, not looking back in time but watching for outcomes from the moment patients are diagnosed with advanced cancer – that shows BRCA2 mutations themselves, regardless of other factors, are responsible for poor prognosis and can have an impact on treatment responses," explains Castro, the article's first author.

"It should be noted that we identified germline mutations, although in a number of patients there were no familial cancer cases that might have indicated the presence of such genetic alterations. These mutations should be identified in patients with metastatic prostate cancer, since detecting such alterations is important for the diagnosis and management of the disease and for the patients' families, whose risk of developing breast, ovarian or pancreatic cancer is increased," explains Castro.

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)

"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."

PRs/SDs observed with Atezolizumab in alveolar soft part sarcoma (ASPS) patients (https://www.cancer.gov/news-events/cancer-currents-blog/2019/atezolizumab-alveolar-soft-part-sarcoma-trial?cid=eb_govdel)

"For patients whose disease has metastasized, it's exciting that there may now be a whole new class of drugs that have [anticancer] activity," said Scott Schuetze, M.D., Ph.D., who specializes in treating sarcomas at the University of Michigan but was not involved in the study.

ABACUS trial: preoperative atezolizumab in urothelial carcinoma https://t.co/EnddfgLaIq (https://t.co/EnddfgLaIq) pic.twitter.com/kwfmW9Ih8R (https://t.co/kwfmW9Ih8R)

— Oncology Tube (@oncologytube) January 12, 2019 (https://twitter.com/oncologytube/status/1084163953511489536?ref_src=twsrc%5Etfw)

Clinical data of microRNA-155 inh Cobomarsen presented from Ph I CTCL, Ph I ATLL, and Ph I DLBCL trials (http://investors.miragen.com/file/Index?KeyFile=396327008)

miRagen to recount positive Ph1 #clinicaltrials (https://twitter.com/hashtag/clinicaltrials?src=hash&ref_src=twsrc%5Etfw) results for cobomarsen to T-cell #Lymphoma (https://twitter.com/hashtag/Lymphoma?src=hash&ref_src=twsrc%5Etfw) Forum

Many CTCL, ATLL & DLBCL patients see sustained response & improvements w/ #microRNA (https://twitter.com/hashtag/microRNA?src=hash&ref_src=twsrc%5Etfw)-155 inhibitorhttps://t.co/KXw3KzG4ZY (https://t.co/KXw3KzG4ZY)#oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancers (https://twitter.com/hashtag/cancers?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/iQSqLKJNr7 (https://t.co/iQSqLKJNr7)

— DDNews Online (@DDNewsOnline) January 10, 2019 (https://twitter.com/DDNewsOnline/status/1083406967727509504?ref_src=twsrc%5Etfw)

“The ATLL clinical data shows that cobomarsen provided sustained disease stabilization in five patients for up to 13 months after completing chemotherapy or experimental treatment and an improvement in the levels of normal circulating blood cells. In addition, patients did not report any significant side effects attributed to cobomarsen. We believe these data are particularly encouraging, as the patients in this study had previously failed on other therapies and the median survival for patients with acute disease typically ranges from four to ten months after diagnosis,” stated Paul Rubin M.D. Executive Vice President, R&D, at miRagen. “We are encouraged by our early experience in the ABC subtype of DLBCL, as we have observed an improvement in a patient that had long-standing disease and had previously been on multiple chemotherapeutic regimens.”

Nivolumab demonstrates a significant extension in OS vs chemotherapy in unresectable advanced or recurrent Esophageal Cancer pts in Ph III ATTRACTION-3 trial (https://www.ono.co.jp/eng/news/pdf/sm_cn190109.pdf)

Nivolumab becomes the first checkpoint inhibitor to show a statistically significant OS improvement in this patient population (unresectable advanced or recurrent esophageal cancer, regardless of PD-L1 status) according to top-level results from Ph III ATTRACTION-3 study (ONO-4538-24/CA209-473). Results of the trial will be presented at an upcoming medical meeting.

Positive data reported from registrational Ph II trial of FGFRi derazantinib (BAL087) in intrahepatic cholangiocarcinoma (iCCA) patients (http://www.basilea.com/News-and-Media/Basilea-reports-positive-interim-results-from-registrational-phase-2-study-with-oncology-drug-candidate-derazantinib-in-intrahepatic-cholangiocarcinoma-iCCA/2417ffe5-53bf-35ad-e351-bc3c38eb6454)

Dr. Marc Engelhardt, Chief Medical Officer of Basilea, said: “We are very pleased to have achieved this important milestone. The response rate and the safety profile at the time of the interim analysis are promising, especially

considering the poor outcomes with chemotherapy in this group of patients reported in the literature. We are looking forward to the final data once the study is completed mid-2020."

> #Basilea (https://twitter.com/hashtag/Basilea?src=hash&ref_src=twsrc%5Etfw) reported positive interim results from the derazantinib Phase II registration trial in intrahepatic cholangiocarcinoma. Full detail here @Edison_Inv_Res (https://twitter.com/Edison_Inv_Res?ref_src=twsrc%5Etfw) #shares (https://twitter.com/hashtag/shares?src=hash&ref_src=twsrc%5Etfw) #invest (https://twitter.com/hashtag/invest?src=hash&ref_src=twsrc%5Etfw)https://t.co/jHCcBgxeR5 (https://t.co/jHCcBgxeR5) pic.twitter.com/gLx9LBaAN8 (https://t.co/gLx9LBaAN8)
>
> — Research Tree (@research_tree) January 11, 2019 (https://twitter.com/research_tree/status/1083664936507723777?ref_src=twsrc%5Etfw)

Positive results announced from pivotal Ph III OLYMPUS trial in low-grade upper tract urothelial cancer (http://investors.urogen.com/phoenix.zhtml?c=254372&p=irol-newsArticle&ID=2382574)

"We are pleased to report that the CR and durability data remain consistent with the Interim Analysis presented in May 2018. These results continue to validate the potential of UGN-101 to shift the surgical treatment paradigm and benefit patients whose only alternative would be repetitive endoscopic surgical intervention or complete loss of a kidney," said Mark P. Schoenberg, M.D., Chief Medical Officer of UroGen. "The durability observed in the OLYMPUS study provides further evidence that the non-surgical treatment of LG UTUC with UGN-101 may result in clinically-meaningful, recurrence free survival. We are grateful to the patients, their families, and clinical investigators who have made this important study possible."

> UroGen Pharma Announces Positive Results of UGN-101 from Pivotal Phase 3 OLYMPUS Trial for the Non-Surgical Treatment of Patients with Low-Grade Upper Tract Urothelial Cancer (LG UTUC) https://t.co/IiYO2moDIs (https://t.co/IiYO2moDIs) pic.twitter.com/RTqYWxUwNz (https://t.co/RTqYWxUwNz)
>
> — PharmaMKT (@PharmaMKTnet) January 8, 2019 (https://twitter.com/PharmaMKTnet/status/1082687665655504896?ref_src=twsrc%5Etfw)

mOS of 22 months observed in RRMM patients in Ph I trial of radioiodinated PDC asset CLR 131 (https://www.cellectar.com/news-media/press-releases/detail/199/cellectar-provides-update-on-phase-1-trial-of-clr-131-in)

"The median overall survival of 22 months in this heavily pretreated patient population is very encouraging. These are patients with limited therapeutic options and, unfortunately, face poor prognoses," said James Caruso, president and chief executive officer of Cellectar Biosciences. "The convenience afforded by CLR 131 delivered in only one or two doses as currently administered in our ongoing hematology studies makes it a far less intrusive regimen than other treatments that must be administered at regular dosing intervals. We believe extending mOS with a more patient-friendly dosing regimen provides both a distinctive product profile and the potential to provide beneficial patient outcomes even in later lines of therapy."

$CLRB (https://twitter.com/search?q=%24CLRB&src=ctag&ref_src=twsrc%5Etfw) Cellectar Provides Update on Phase 1 Trial of CLR 131 in Relapsed/Refractory Multiple Myeloma https://t.co/eUeSjoGSNi (https://t.co/eUeSjoGSNi) #JPM2019 (https://twitter.com/hashtag/JPM2019?src=hash&ref_src=twsrc%5Etfw) #BiotechShowcase (https://twitter.com/hashtag/BiotechShowcase?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/RxZqAqc6Ig (https://t.co/RxZqAqc6Ig)

— Cellectar Bioscience (@CellectarBio) January 7, 2019 (https://twitter.com/CellectarBio/status/1082318390520360960?ref_src=twsrc%5Etfw)

TRIAL STATUSES

Ph II trial of lipoic acid analog CPI-613 + mFOLFIRINOX started in locally advanced pancreatic cancer patients (http://www.globenewswire.com/news-release/2019/01/09/1682730/0/en/Rafael-Pharmaceuticals-Announces-Initiation-of-Phase-II-Trial-of-CPI-613-in-Combination-with-Modified-FOLFIRINOX-in-Locally-Advanced-Pancreatic-Cancer.html)

Sanjeev Luther, President and Chief Executive Officer of Rafael Pharmaceuticals, commented: "Our motto, 'To Save A Life Is To Save A Universe,' illustrates our desire to develop potential treatments for patients with significant unmet clinical need. Initiation of this trial in collaboration with University Hospitals Cleveland Medical Center is a significant milestone in that direction."

Jeffery Hardacre, MD, a pancreatic surgeon and lead investigator for the study, commented, "University Hospitals is committed to leading the way in the fight against pancreatic cancer. Through this trial, we hope to identify a strategy to extend the lives of patients with pancreatic cancer, and increase the patient eligibility for surgery for those with locally advanced disease."

Enrolment completed in pivotal Ph III trial of Niraparib in 2L maintenance Ovarian CAncer settings in China (https://zailab.gcs-web.com/news-releases/news-release-details/zai-lab-completes-enrollment-china-pivotal-trial-niraparib)

"Completion of patient enrollment of this pivotal trial is an important milestone for Zai as it further demonstrates our clinical development capabilities and commitment to our clinical investigators and ovarian patients in China," said Dr. Samantha Du, Founder and Chief Executive Officer of Zai Lab. "We are encouraged by the early acceptance of our NDA submission for niraparib by the NMPA based on the comprehensive data package."

Ph II of haNK cell therapy + superagonist IL-15 cytokine therapy N-803 + Avelumab planned in MCC patients (https://nantkwest.com/nantkwest-announces-launch-of-merkel-cell-carcinoma-phase-ii-trial-deploying-novel-triple-combination-of-off-the-shelf-natural-killer-hank®-cell-therapy-with-superagonist-il-15-cytokine-therap/)

Commenting on the initiation of this novel triple combination trial in MCC, Patrick Soon-Shiong, MD, Chairman and CEO of NantKwest said, "Even in a heavily pretreated patient population, including patients who have failed checkpoint inhibitor therapy, we were encouraged to see our combination of aNK cell and N-803 therapy exhibit preliminary clinically meaningful antitumor activity, including objective response in this resistant setting."

Dr. Soon-Shiong continued, "Building upon this human clinical trial data, we are pleased to announce the transition of this earlier study to include haNK cell therapy in combination with the IL-15 superagonist N-803 and the PD-L1 checkpoint inhibitor avelumab, which we believe, when used together, will offer synergies and the potential to improve response rates for patients with MCC that may also potentially translate to a number of additional solid tumor indications."

Ph I/II trial of MIF/PDE-4/10 dual inhibitor MN-166 (ibudilast) + TMZ initiated in recurrent Glioblastoma patients (http://investors.medicinova.com/phoenix.zhtml?c=183833&p=irol-newsArticle&ID=2382746)

Patrick Y. Wen, M.D., principal investigator, commented, "We are very excited to study ibudilast with TMZ combination treatment as we believe ibudilast's mechanisms of action and good penetration of the blood-brain barrier could benefit patients with recurrent GBM."

Kerrie McDonald, Ph.D., Associate Professor, University of New South Wales, Australia, commented, "Earlier studies indicate that macrophage migration inhibitory factor (MIF) and phosphodiesterase (PDE)-4 may factor in proliferation of GBM tumors. MIF was found to be highly expressed within GBM cells, and especially around necrotic areas and in close proximity to blood vessels. Ibudilast in combination with TMZ resulted in significant blockage of MIF expression, increased apoptosis, and longer survival in vivo."

Patient enrolment in CPI-006 monotherapy and CPI-006 + CPI-444 combo trials initiated (https://corvuspharma.gcs-web.com/news-releases/news-release-details/corvus-announces-enrollment-second-arm-phase-1b-dose-escalation)

"Enrollment in our CPI-006 Phase 1/1b trial is progressing well," said Richard A. Miller, M.D., an oncologist and co-founder, president and chief executive officer of Corvus. "With this combination of drugs from our two lead programs, we believe we have initiated the first trial targeting two points in the adenosine pathway: blocking CD73 to reduce adenosine production with CPI-006, and inhibiting the binding of adenosine to its receptor with CPI-444. We believe this approach represents a unique mechanism of action that may result in a more complete adenosine blockade and immune cell activation."

Updates on development of galinpepimut-S (GPS) and nelipepimut-S (NPS) announced (https://www.sellaslifesciences.com/investors/news/News-Details/2019/SELLAS-Life-Sciences-Provides-Update-on-Late-Stage-Immunotherapy-Clinical-Development-Pipeline/default.aspx)

"In 2018, SELLAS achieved significant progress towards our corporate and clinical goals, as we advanced our immunotherapy pipeline and completed our first year as a public company," said Dr. Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "As we look to 2019, we are excited to initiate our pivotal Phase 3 program for GPS in acute myeloid leukemia (AML), and are in active discussions with the U.S. Food and Drug Administration (FDA) regarding the registration-enabling Phase 3 trial and potential consideration for accelerated approval and breakthrough designation for NPS to treat triple negative breast cancer. We also are exploring the potential of GPS in combination with pembrolizumab in additional tumor types in the context of a Phase 1/2 basket clinical study and look forward to continued progress across our broad pipeline in the year ahead."

Moderna, Inc. announces recent progress in its IO programs (https://investors.modernatx.com/news-releases/news-release-details/moderna-announces-recent-progress-its-immuno-oncology-and-rare)

"This year we are focused on making significant advances to our pipeline as we work to bring multiple programs into Phase 2 clinical trials, move programs within our rare disease portfolio toward the clinic and leverage our mRNA platform to create both new development candidates and potential new modalities where we believe there is an opportunity to develop therapies for a broad range of diseases," said Stéphane Bancel, Moderna's Chief Executive Officer. "I am pleased with the continued progress of our pipeline, our ability to now manufacture mRNA for clinical development at our new site in Norwood and the relentless work of our team. I

believe we are better positioned than we have ever been to deliver on the promise of our science to bring forward mRNA medicines that have the potential to improve the lives of patients."

Ph II trial of lipoic acid analog CPI-613 initiated in R/R Burkitt Lymphoma/Leukemia patients (https://rafaelpharma.com/press-releases/)

Sanjeev Luther, President and Chief Executive Officer of Rafael Pharmaceuticals, commented: "Our motto, 'To Save A Life Is To Save A Universe,' illustrates our desire to develop potential treatments for patients with significant unmet clinical need. After receiving orphan drug designation earlier this year, this trial marks another positive step toward realizing our vision."

Dose escalation in HCC trial with ADP-A2AFP (AFP) SPEAR T-cells and moving to expansion phase in ADP-A2M10 (MAGE-A10) NSCLC trial after favorable safety reviews (http://phx.corporate-ir.net/phoenix.zhtml?c=253991&p=irol-newsArticle&ID=2382311)

"We are pleased that the SRC has endorsed moving to the expansion phase of the ADP-A2M10 lung cancer study. Additionally, our ADP-A2AFP study has progressed to the next dose level of 1 billion transduced cells. Importantly, we did not observe liver toxicity in the two patients treated at a dose of 100 million transduced cells. In our other studies, we continue to enroll in the expansion phases and, as we previously have said, we are on track to report our next clinical data by May this year," said Rafael Amado, Adaptimmune's President of Research & Development.

Agios highlights 2018 milestones and 2019 initiatives (https://agiospharmaceuticalsinc.gcs-web.com/node/12041)

"During 2018, just 10 years after the founding of Agios, we achieved approval of our second internally discovered oncology medicine, launched a robust registrational program in PK deficiency and successfully opened the company's seventh IND," said David Schenkein, M.D., chief executive officer at Agios. "Our validated research platform and proven drug development strategy are poised to help drive future growth across our oncology and rare genetic disease portfolios. Our priorities for 2019 include expanding the reach of our IDH inhibitors into the frontline AML and solid tumor settings, completing enrollment in two pivotal studies of mitapivat, exploring the utility of PKR activators in other hemolytic anemias, and furthering clinical development for AG-270 in MTAP deleted tumors and AG-636 in lymphoma."

Ph III trial planned to evaluate mOS with multi TKI Sitravatinib + Nivolumab or docetaxel in NSCLC (http://ir.mirati.com/news-releases/news-release-details/mirati-announces-clinical-collaboration-bristol-myers-squibb)

"Our Phase 2 clinical trial of sitravatinib plus nivolumab in patients with checkpoint refractory NSCLC has shown promising activity and a well-tolerated safety profile," said Charles Baum, M.D., Ph.D., President and Chief Executive Officer of Mirati. "The trial is expected to result in a new drug application (NDA) for sitravatinib for the treatment of NSCLC patients whose tumors have progressed following treatment with a platinum containing regimen and a checkpoint inhibitor. This collaboration further validates the potential of sitravatinib and allows Mirati to invest in and expand the development of our clinical and pre-clinical programs."

Registrational trials of PD-L1 inhibitor CK-301 expanded to add cohorts in MSI-H and MSS endometrial cancer and MSI-H or dMMR CRC patients (http://ir.checkpointtx.com/file/Index?KeyFile=396287842)

"We are excited to advance our first immuno-oncology drug candidate, CK-301, into these potentially registration-enabling cohorts, representing a significant milestone in the execution of our strategy to obtain multiple accelerated approvals for our anti-PD-L1 antibody," said James F. Oliviero, President and Chief Executive Officer of Checkpoint. "We look forward to presenting interim safety and efficacy data from the ongoing clinical trial in the coming months."

Pivotal trial of TAVO + Pembrolizumab planned for treatment of late stage cervical cancer (https://ir.oncosec.com/press-releases/detail/1977/oncosec-and-gynecologic-oncology-group-gog-foundation)

"KEYTRUDA is only the second drug in 30 years to be approved for the treatment of cervical cancer and, though it represents significant progress, the number of patients who can benefit is limited. Our goal is to improve upon the 14% KEYTRUDA response rate with the addition of TAVO," said Daniel J. O'Connor, President and Chief Executive Officer of OncoSec. "We believe that TAVO, our proprietary intratumoral plasmid-based IL-12, is an excellent complement for expanding the clinical benefit of anti-PD-1 therapies, especially for those patients that are resistant to anti-PD-1 therapies. Given that KEYTRUDA is already approved and reimbursed for this indication, this study fits perfectly with our strategy of identifying opportunities to conduct small, relatively low-cost single-arm clinical studies that have the potential to offer a rapid path to drug approval and commercialization."

First patient dosed in Ph I/II trial of EDP1503 + Pembrolizumab in patients with MSS CRC, TNBC and PD-(L)1 progressors (http://ir.evelobio.com/news-releases/news-release-details/evelo-biosciences-announces-dosing-first-patient-phase-12)

"This clinical trial of EDP1503 will allow us to explore the potential synergies between EDP1503 and KEYTRUDA® and offers the potential to treat multiple cancer types that are otherwise poorly responsive to checkpoint inhibitors," said Humphrey Gardner, M.D., FCAP, chief of medical oncology at Evelo.

HER2-targeting Dolaflexin ADC, XMT-1522, to be discontinued (http://ir.mersana.com/news-releases/news-release-details/mersana-therapeutics-announces-strategic-priorities-and-goals)

"While still in early clinical development, we are encouraged with the safety, tolerability, and activity of XMT-1536 as well as the pace at which the current study is advancing. For this reason, we have decided to focus our resources on advancing XMT-1536, our first-in-class ADC candidate targeting NaPi2b, a clinically validated ADC target broadly expressed in ovarian and non-small cell lung cancer (NSCLC) adenocarcinoma, for which there remains a significant unmet medical need," said Anna Protopapas, President and CEO, Mersana Therapeutics. "We have made the difficult decision to terminate the further development of XMT-1522 despite a favorable emerging profile of efficacy and tolerability due to the competitive environment for HER2-targeted therapies."

FINANCIAL NEWS

Halozyme provides 2019 pipeline update and financial guidance (https://www.halozyme.com/investors/news-releases/news-release-details/2019/Halozyme-Provides-2019-Pipeline-Update-And-Financial-Guidance-At-37th-Annual-JP-Morgan-Healthcare-Conference/default.aspx)

"Looking ahead, our ENHANZE business is gaining momentum with key product development milestones expected this year, including potential FDA approval of a subcutaneous formulation of Herceptin® and regulatory submissions for the subcutaneous formulation of Darzalex® each representing important near-term catalysts," said Dr. Helen Torley, president and chief executive officer. "In our oncology business, HALO-301 has

completed enrollment and topline results are projected in the second half of 2019."

LICENSING DEALS & COLLABORATIONS

Xencor regains ex-U.S. commercial rights to CD20 x CD3 bispecific antibody XmAb®13676 (https://investors.xencor.com/news-releases/news-release-details/xencor-regains-ex-us-commercial-rights-xmabr13676-cd20-x-cd3)

"We continue to work closely with Novartis across multiple programs in the collaboration, and both companies are eager to advance XmAb14045 in clinical development. Recently we presented encouraging early data from our Phase 1 study in patients with relapsed/refractory AML, observing multiple complete remissions on a weekly dosing schedule, and we continue to optimize dose in that study. Novartis also has internal XmAb preclinical bispecific programs progressing," said Bassil Dahiyat, Ph.D., president and chief executive officer at Xencor. "Xencor will continue to develop XmAb13676 as planned, and we believe its tuned potency holds potential for the treatment of patients with B-cell malignancies."

Ascentage Pharma and MDACC to develop Bcr-Abl inh HQP1351, Bcl-2/xL inh APG-1252, Bcl-2 selective inh APG-2575, IAP inh APG-1387 and MDM2-p53 inh APG-115 in heme malignancies (https://www.ascentagepharma.com/press-releases/ascentage-pharma-and-md-anderson-cancer-center-announce-strategic-alliance-in-cancer-drug-development/)

"MD Anderson is highly dedicated to developing and providing more effective therapies for patients. This strategic alliance is important for our work towards finding cures to treat cancers. We will be investigating this pipeline of candidate therapies, and we are interested in the novel mechanism of their actions," said Dr. Kantarjian.

"We are pleased to announce this important partnership with MD Anderson," said Dr. Dajun Yang, Chairman & CEO of Ascentage Pharma. "We look forward to working closely with the investigators in MDACC in the hopes of accelerating the clinical development of these important candidates to provide new treatment options for cancer patients in the US and worldwide."

Lilly to acquire Loxo Oncology (https://investor.lilly.com/news-releases/news-release-details/lilly-announces-agreement-acquire-loxo-oncology)

> Eli Lilly to buy Loxo Oncology for $8 billion in huge bet on cancer genetics https://t.co/omTF3Ucooc (https://t.co/omTF3Ucooc) via @statnews (https://twitter.com/statnews?ref_src=twsrc%5Etfw) #healthcare (https://twitter.com/hashtag/healthcare?src=hash&ref_src=twsrc%5Etfw) #curecancer (https://twitter.com/hashtag/curecancer?src=hash&ref_src=twsrc%5Etfw)
>
> — iQuantified (@iquantified) January 13, 2019 (https://twitter.com/iquantified/status/1084306548493557761?ref_src=twsrc%5Etfw)

"Using tailored medicines to target key tumor dependencies offers an increasingly robust approach to cancer treatment," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific officer and president of Lilly Research Laboratories. "Loxo Oncology's portfolio of RET, BTK and TRK inhibitors targeted specifically to patients with mutations or fusions in these genes, in combination with advanced diagnostics that allow us to know exactly which patients may benefit, creates new opportunities to improve the lives of people with advanced cancer."

Adaptive Biotechnolgies and Genentech to develop, manufacture and commercialize novel neoantigen directed T-cell therapies with TruTCR™ platform (https://www.biospace.com/article/releases/adaptive-biotechnologies-to-enter-into-worldwide-collaboration-and-license-agreement-with-genentech-to-develop-personalized-cellular-therapies-for-the-treatment-of-cancer/)

> Adaptive Biotechnologies signs blockbuster deal with Genentech for personalized cancer treatments worth up to $2 billion https://t.co/Y8uwpp7XoI (https://t.co/Y8uwpp7XoI)
>
> — Josephine Zimmermann (@titejoey) January 10, 2019 (https://twitter.com/titejoey/status/1083362830911451136?ref_src=twsrc%5Etfw)

"We are thrilled that Genentech has selected Adaptive as a partner to develop neoantigen directed T-cell therapies, a personalized approach to cellular therapy," said Chad Robins, chief executive officer and co-founder of Adaptive Biotechnologies. "Genentech brings an industry-leading team of scientists and drug development experts who could potentially enable our patented TCR discovery and immune profiling platform to help as many patients as possible."

OTW Trivia

Cancer Stat Facts: Common Cancer Sites

In the United States, breast cancer, lung cancer (NSCLC, SCLC), prostate cancer, and CRC account for almost 50% of all new cancer cases. All these and pancreatic cancers are responsible for nearly 50% of all deaths.

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.

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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: A color-enhanced, freeze-fracture scanning electron micrograph of a blood vessel that has grown into a melanoma and is providing nourishment to it. Numerous red blood cells and three white blood cells can be seen within the blood vessel. Source (http://cellimagelibrary.org/images/38960)

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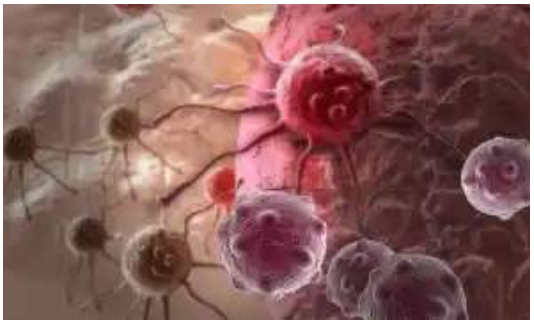

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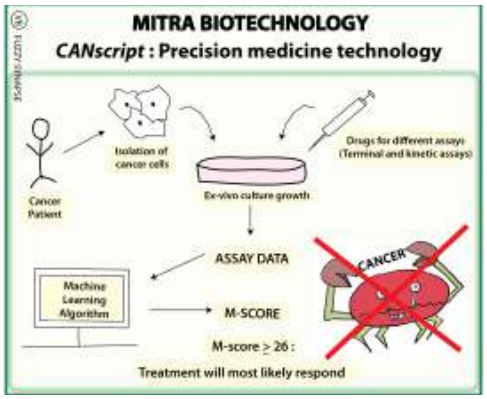

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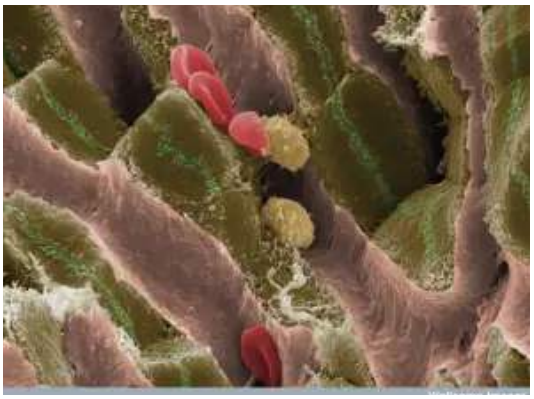

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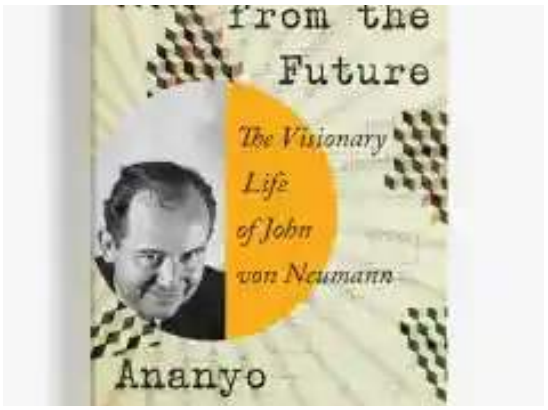

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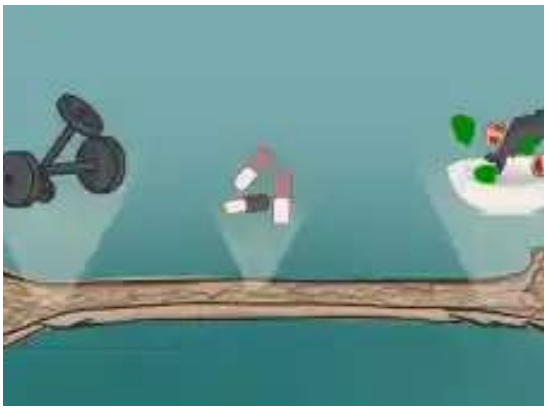

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