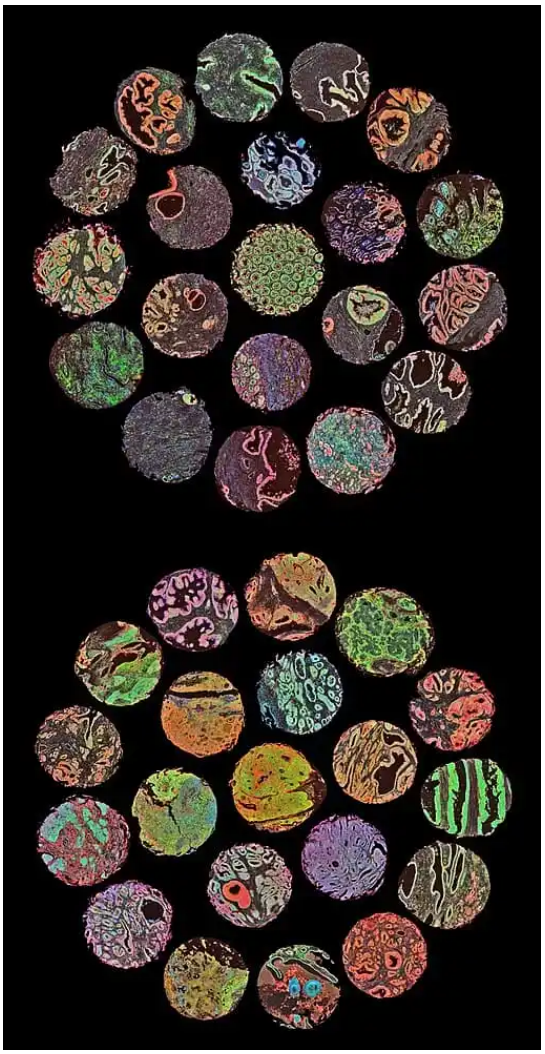
Onco-this-Week

April 7, 2018(https://sciwri.club/archives/date/2018/04/07)



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(https://io.wp.com/sciwri.club/wp-content/uploads/2018/04/ecg-1953179_1920.jpg?ssl=1)

Editor's Note: With Recuparib getting the FDA approval after a significant Phase 3 trial, several patients of recurrent ovarian cancer can look forward to a lesser risk of disease progression post-chemotherapy. Check out the latest news on this FDA approval and more, including an RNAi nanoparticle based drug showing early anti-leukemic activity in AML patients in Phase II trials. Also in this edition, we have an educational video that explains the FDA's Accelerated Drug approval program and an infographic from Mount Sinai Medical Center (NY) that summarizes Ovarian Cancer. We hope you enjoy reading this edition of Onco-this-Week compiled by Richa Tewari and cherish the wealth of health.- Abhi Dey (https://www.linkedin.com/in/abhinavdey/)

SPECIAL STATUSES

Fast track designation granted to TAR-200 (GemRIS™) in MIBC (http://www.tarisbiomedical.com/docs/2018%2004%2003%20TARIS%20TAR-200%20Fast%20Track%20FINAL.pdf)

"This Fast Track designation reinforces the high unmet need in the treatment of muscle invasive bladder cancer patients, especially those who cannot receive curative intent therapy. It further highlights the potential of GemRIS to benefit this underserved population," said Purnanand Sarma, Ph.D., President and CEO of TARIS. "Taken together, the combination of Fast Track, our ongoing clinical study, and our research collaboration in Sweden, form the foundation to rapidly advance the development of GemRIS. We look forward to working closely with the FDA to bring this important therapy to patients as quickly as possible."

Educational Video: About FDA Accelerated Approval Program

"The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a marker that is used in clinical trials as an indirect or substitute measurement that represents a clinically meaningful outcome. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval. Drug companies are still required to conduct studies to confirm the anticipated clinical benefit. These studies are known as phase 4 confirmatory trials. If the confirmatory trial shows that the drug actually provides a clinical benefit, then the FDA grants traditional approval for the drug. If the confirmatory trial does not show that the drug provides clinical benefit, FDA has regulatory procedures in place that could lead to removing the drug from the market."- Source- FDA (https://youtu.be/fzlePvW-Dg4)

APPROVALS

via GIPHY (https://giphy.com/gifs/approve-4nmoWxYUcVghG)

Based on Ph III ARIEL3 trial data, Rucaparib gets approval in 2L+ maintenance settings in Ovarian Cancer patients (http://phx.corporate-ir.net/phoenix.zhtml?c=247187&p=irol-newsArticle&ID=2341439)

"Rubraca provided statistically-significant improvement in PFS versus placebo to all patients, regardless of BRCA mutation status," said Robert L. Coleman, MD, Professor & Executive Director, Cancer Network Research, Ann Rife Cox Chair in Gynecology, Department of Gynecologic Oncology and Reproductive Medicine at University of Texas MD Anderson Cancer Center in Houston and one of the Principal Investigators in the ARIEL3 clinical trial program. "Both the efficacy and safety results from the ARIEL3 study reinforce the important role of Rubraca in the treatment of recurrent ovarian cancer and expands the treatment options for patients and physicians battling this disease."

"This FDA approval provides a meaningful advancement for the treatment of women with recurrent ovarian cancer, offering them the potential to reduce their risk of disease progression following platinum-based chemotherapy," said Patrick J. Mahaffy, CEO and President of Clovis Oncology. "We are grateful that the FDA expedited review of this maintenance treatment indication, so that physicians can begin offering it to appropriate patients beginning today."

> $CLVS (https://twitter.com/search?q=%24CLVS&src=ctag&ref_src=twsrc%5Etfw) flying high on good news! FDA approved another use for its ovarian cancer drug "Rubraca" #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/1CaMrgXTvk (https://t.co/1CaMrgXTvk)
>
> — Gi Dunham (@GiDunham) April 6, 2018 (https://twitter.com/GiDunham/status/982348221128347648?ref_src=twsrc%5Etfw)

Ovarian Cancer: What is Ovarian Cancer? (https://visual.ly/community/infographic/health/ovarian-cancer-what-ovarian-cancer/?utm_source=visually_embed)

by MountSinaiNYC (http://www.mountsinai.org?utm_source=visually_embed).
From Visually (https://visual.ly?utm_source=content-embed&utm_medium=embed).

European Commission Approves Amgen's XGEVA® (Denosumab) For The Prevention Of SREs In Patients With Multiple Myeloma (http://www.amgen.com/media/news-releases/2018/04/european-commission-approves-expanded-indication-for-amgens-xgeva-denosumab-for-the-prevention-of-skeletalrelated-events-in-patients-with-multiple-myeloma/)

"Many patients with multiple myeloma have bone lesions at diagnosis, which can result in serious and devastating complications, including broken bones, the need for surgery or radiation to the bone and spinal cord compression," said David M. Reese, M.D., senior vice president of Translational Sciences and Oncology at Amgen. "Until now, treatment options for the prevention of bone complications were limited to bisphosphonates, which unlike XGEVA, are cleared by the kidneys and can be associated with increased renal toxicity. We are pleased with the expanded indication for XGEVA in Europe, underscoring our dedication to advancing care for patients with multiple myeloma."

> Amgen's Xgeva approved in new European multiple myeloma indication https://t.co/cMCi8OBozF (https://t.co/cMCi8OBozF) pic.twitter.com/fpGnAnFVBq (https://t.co/fpGnAnFVBq)
>
> — Zenopa Recruitment (@ZenopaLtd) April 6, 2018 (https://twitter.com/ZenopaLtd/status/982196443396980737?ref_src=twsrc%5Etfw)

RESULTS

via GIPHY (https://giphy.com/gifs/simulation-wm6QNgVc5x8wo)

Ph III ECHO-301/KEYNOTE-252 trial of Epacadostat + Pembrolizumab in unresectable/metastatic Melanoma patients failed to meet primary endpoint of PFS; not expected to meet OS either (http://www.incyte.com/ir/press-releases.aspx)

"While we are disappointed that this study did not confirm the efficacy of epacadostat in combination with KEYTRUDA in patients with unresectable or metastatic melanoma, data from ECHO-301/KEYNOTE-252, including analyses of an extensive biomarker panel, will contribute to our understanding of the role of IDO1 inhibition in combination with PD-1 antagonists, and may inform our broader epacadostat clinical development program," said Steven Stein, M.D., Chief Medical Officer, Incyte. "We remain dedicated to transforming the treatment of cancer and will continue to explore how IDO1 inhibition and other novel mechanisms can potentially improve outcomes for patients in need."

> Dramatic outcome for combination of epacadostat $INCY (https://twitter.com/search?q=%24INCY&src=ctag&ref_src=twsrc%5Etfw) with pembrolizumab $MRK (https://twitter.com/search?q=%24MRK&src=ctag&ref_src=twsrc%5Etfw) in pivotal Phase 3 ECHO-301/KEYNOTE-252; https://t.co/9pWoar1Gqo (https://t.co/9pWoar1Gqo)
>
> Is there any future for IDO/Kyn/AhR inhibitors?#immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) #immunooncology (https://twitter.com/hashtag/immunooncology?src=hash&ref_src=twsrc%5Etfw) #io (https://twitter.com/hashtag/io?src=hash&ref_src=twsrc%5Etfw)
>
> — immuno-oncology.io (@immunoonco_io) April 6, 2018 (https://twitter.com/immunoonco_io/status/982264043544100869?ref_src=twsrc%5Etfw)

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

Encouraging antitumour activity observed with Larotrectinib in paediatric NTRK fusion +ve solid tumours patients enrolled in phase 1/2 study (http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30119-0/fulltext)

The TRK inhibitor larotrectinib was well tolerated in pediatric patients and showed encouraging antitumour activity in all patients with TRK fusion-positive tumours. The recommended phase 2 dose was defined as 100mg/m² (maximum 100 mg per dose) for infants, children, and adolescents, regardless of age.

> A first-of-its-kind drug shows promise for #pediatric (https://twitter.com/hashtag/pediatric?src=hash&ref_src=twsrc%5Etfw) patients who are battling cancer. #Larotrectinib (https://twitter.com/hashtag/Larotrectinib?src=hash&ref_src=twsrc%5Etfw), a breakthrough cancer drug, was effective in 93% of pediatric patients who were tested. https://t.co/vIRkdOEAPX (https://t.co/vIRkdOEAPX) #utsw (https://twitter.com/hashtag/utsw?src=hash&ref_src=twsrc%5Etfw) #utswmed (https://twitter.com/hashtag/utswmed?src=hash&ref_src=twsrc%5Etfw) #patientcare (https://twitter.com/hashtag/patientcare?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/CB7DAF2Rx1 (https://t.co/CB7DAF2Rx1)
>
> — UT Southwestern News (@UTSWNews) April 4, 2018 (https://twitter.com/UTSWNews/status/981335572026482688?ref_src=twsrc%5Etfw)

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

Ramucirumab Ph III REACH-2 Study in 2L HCC patients met overall survival endpoint (https://investor.lilly.com/news-releases/news-release-details/lilly-announces-cyramzar-ramucirumab-phase-3-reach-2-study)

"Advanced liver cancer is an aggressive disease that has a poor prognosis – and for those that have elevated AFP levels, the prognosis is even more dismal. The expected survival of these patients is only a few months following first-line treatment if they don't go onto second-line therapy. For this reason, Lilly is encouraged by the results of REACH-2 and the potential for CYRAMZA to benefit patients in this setting," said Levi Garraway, M.D., Ph.D., senior vice president, global development and medical affairs, Lilly Oncology.

> Lilly announces positive results of #ramucirumab (https://twitter.com/hashtag/ramucirumab?src=hash&ref_src=twsrc%5Etfw) in second line for the treatment of #hepatocellular (https://twitter.com/hashtag/hepatocellular?src=hash&ref_src=twsrc%5Etfw) #carcinoma (https://twitter.com/hashtag/carcinoma?src=hash&ref_src=twsrc%5Etfw) #liver (https://twitter.com/hashtag/liver?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw)https://t.co/9IGO4U7kZb (https://t.co/9IGO4U7kZb) pic.twitter.com/9rSAkRQATR (https://t.co/9rSAkRQATR)
>
> — Álvaro Díaz-González (@adiazgonzalezMD) April 4, 2018 (https://twitter.com/adiazgonzalezMD/status/981567833543970817?ref_src=twsrc%5Etfw)

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

Grb2-targeting RNAi nanoparticle drug Prexigebersen+LDAC show early anti-leukemic activity in AML patients in Ph II trial (http://www.biopathholdings.com/wp-content/uploads/2018/04/BPTH_Interim_Phase_2_AML_Data_Release.pdf)

"We are very pleased with these encouraging interim data as they demonstrate the potential for the combination of prexigerbesen and LDAC to effectively treat these de novo AML patients. These early results are encouraging when you consider that the complete response rate in elderly AML patients greater than 65 years of age on LDAC alone have been estimated (Lin Journal of Clinical Oncology Abstract) to be only 10%1," noted Peter H. Nielsen, chief executive officer of Bio-Path. "We look forward to advancing the planned protocol amendments as we expect they will provide even better results for these patients suffering with AML. If successful, it will provide for approvals in the U.S. and Europe for both combination therapies."

> A genomic study reveals differences between acute myeloid leukemia in adults and children: https://t.co/VICDpixGXI (https://t.co/VICDpixGXI) pic.twitter.com/INdMpVd6Xa (https://t.co/INdMpVd6Xa)
>
> — National Cancer Inst (@theNCI) April 6, 2018 (https://twitter.com/theNCI/status/982212632806477826?ref_src=twsrc%5Etfw)

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

AUA 2018: Ph III VISTA trial data of Vicinium in BCG-refractory NMIBC patients to be presented (http://ir.elevenbio.com/news-releases/news-release-details/preliminary-data-phase-3-vista-trial-bladder-cancer-be-presented)

"When treatment with today's standard of care, BCG, is no longer an option, the next treatment option is typically removal of the patient's bladder, a challenging, life-altering procedure that many patients elect not to undergo," said Stephen Hurly, president and chief executive officer of Eleven Biotherapeutics. "Vicinium has demonstrated that it is a well-tolerated and active agent in patients with BCG unresponsive NMIBC in studies to-date. We are excited to be presenting the first preliminary data from our Phase 3 VISTA trial of Vicinium for patients with NMIBC at this year's AUA meeting. During our plenary presentation, we will share initial efficacy findings and data supporting the favorable safety we have observed so far with Vicinium. We believe Vicinium holds tremendous potential as a treatment for bladder cancer, and we look forward to sharing these and additional data later in the year."

> Bladder cancer is often diagnosed at an early stage, when the cancer is easier to treat. An overview of this disease: https://t.co/ooFFCyr8hv (https://t.co/ooFFCyr8hv) pic.twitter.com/NzgqIzr5Q2 (https://t.co/NzgqIzr5Q2)
>
> — National Cancer Inst (@theNCI) April 4, 2018 (https://twitter.com/theNCI/status/981667765080686594?ref_src=twsrc%5Etfw)

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

AACR 2018, ELCC 2018: AstraZeneca to present updates from several studies (https://www.astrazeneca.com/media-centre/press-releases/2018/astrazenecas-early-and-late-stage-oncology-portfolio-showcased-at-aacr-annual-meeting-and-elcc-04042018.html)

Dave Fredrickson, Executive Vice President, Head of Oncology Business Unit said: "Building on major regulatory approvals in the first quarter of 2018, AstraZeneca continues to deliver strong results from our innovative science and accelerated development programmes in oncology. At ELCC, we are sharing new data from two pivotal trials in lung cancer that will help inform treatment strategies for patients who, until now, have had very few options. At the AACR meeting, we will share pioneering early science across multiple tumour types."

> Leveraging our collective heritage in oncology, we aim to transform the lives of people living with #BloodCancer (https://twitter.com/hashtag/BloodCancer?src=hash&ref_src=twsrc%5Etfw) as we work toward eliminating #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) as a cause of death. pic.twitter.com/YJni2ESPRu (https://t.co/YJni2ESPRu)
>
> — AstraZeneca (@AstraZeneca) April 4, 2018 (https://twitter.com/AstraZeneca/status/981540410802622464?ref_src=twsrc%5Etfw)

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

ASCO 2018: Data from ongoing Ph I trial of RET inhibitor, LOXO-292, to be presented (https://ir.loxooncology.com/press-releases/loxo-oncology-announces-acceptance-of-loxo-292-oral-presentation-at-the-american-society-of-clinical-oncology-asco-annual-meeting)

Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers, today announced that interim clinical data from the ongoing Phase 1 clinical trial for LOXO-292, the company's highly selective RET inhibitor, will be presented in an oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting held June 1 – 5, 2018 in Chicago, Illinois. The presentation is entitled "A Phase 1 Study of LOXO-292, A Potent and Highly Selective RET Inhibitor, in Patients with RET-Altered Cancers."

> RET a driver oncogene with yet some frustrating level of actionability? https://t.co/ZFZ6EtCUp8 (https://t.co/ZFZ6EtCUp8)@NatRevClinOncol (https://twitter.com/NatRevClinOncol?ref_src=twsrc%5Etfw) pic.twitter.com/ob5wy05bfz (https://t.co/ob5wy05bfz)
>
> — soria (@jsoriamd) February 27, 2018 (https://twitter.com/jsoriamd/status/968470712993419264?ref_src=twsrc%5Etfw)

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

Follow-up data of Ph II CheckMate-205 trial shows Nivolumab getting durable responses in Hodgkin Lymphoma (http://ascopubs.org/doi/abs/10.1200/JCO.2017.76.0793?af=R)

"Sustained benefits were seen across different patient populations, including patients refractory to prior therapies and patients with and without prior BV (brentuximab vedotin [Adcetris]) exposure, and were not dependent on achieving CR," first author Philippe Armand, MD, Dana-Farber Cancer Institute, and colleagues wrote.

"The exploratory analyses presented here lend further support to the hypothesis that PD-1 blockade may provide durable benefit even in patients who do not achieve objective responses, including a subset of patients who experience conventional progressive disease. Altogether, the results of this study suggest that nivolumab treatment may provide long-term benefits to a broad spectrum of patients with relapsed/refractory cHL after auto-HCT," Armand added.

> Armande et al – long term FU of checkmate 205 (nivo in R/R classical #Hodgkin (https://twitter.com/hashtag/Hodgkin?src=hash&ref_src=twsrc%5Etfw) #Lymphoma (https://twitter.com/hashtag/Lymphoma?src=hash&ref_src=twsrc%5Etfw)). Median DOR 16.7 months and PFS 14.7 months. Impressive but no evidence so far of a cure rate. https://t.co/B3H2ilp9DD (https://t.co/B3H2ilp9DD) pic.twitter.com/XuY6QXT7Co (https://t.co/XuY6QXT7Co)
>
> — Graham Collins (@graham74GC) March 29, 2018 (https://twitter.com/graham74GC/status/979473128790331392?ref_src=twsrc%5Etfw)

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

AACR 2018: Parker Institute for Cancer Immunotherapy Scientists to Present Immuno-oncology Research on Personalized Cancer Vaccines, New Checkpoint Inhibitor Combinations, the Microbiome and Cell Therapy (https://www.parkerici.org/2018/04/05/aacr18-parker-institute/)

Parker Institute for Cancer Immunotherapy investigators will present some of the most anticipated immuno-oncology research at the 2018 American Association for Cancer Research (AACR) Annual Meeting. More than 70 abstracts and events at AACR 2018 feature scientists affiliated with the Parker Institute.

> Parker Institute for Cancer Immunotherapy Scientists to Present Immuno-oncology Research on Personalized Cancer ... – PR Newswire (press release) https://t.co/FFMYEZL8wY (https://t.co/FFMYEZL8wY) pic.twitter.com/Ddi9UA8Mql (https://t.co/Ddi9UA8Mql)
>
> — Pepvax Inc (@Pepvax) April 5, 2018 (https://twitter.com/Pepvax/status/981959665108926464?ref_src=twsrc%5Etfw)

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REGULATORY NEWS

via GIPHY (https://giphy.com/gifs/aouedit-iIMlA3EBnI8F2)

EMA accepts regulatory submission for Lynparza in BRCA-mutated, HER2neg breast cancer patients (https://www.astrazeneca.com/media-centre/press-releases/2018/the-european-medicines-agency-accepts-regulatory-submission-for-lynparza-in-brca-mutated-her2-negative-metastatic-breast-cancer-03042018.html)

This is the first regulatory submission for a poly ADP-ribose polymerase (PARP) inhibitor in breast cancer in Europe. If approved, the identification of a patient's *BRCA* status could become a critical step in the management of their disease alongside current consideration of their hormone receptor and HER2 status. The MAA includes data from the randomised, open-label, Phase III OlympiAD trial (http://www.nejm.org/doi/full/10.1056/NEJMoa1706450), which investigated *Lynparza* versus chemotherapy (physician's choice of capecitabine, eribulin or vinorelbine).

> Lynparza under review by the EMA for use in #BRCA (https://twitter.com/hashtag/BRCA?src=hash&ref_src=twsrc%5Etfw) mutated Hers2 neg. metastatic breast cancer patients https://t.co/lhbgSCAr9X (https://t.co/lhbgSCAr9X) #malebreastcancer (https://twitter.com/hashtag/malebreastcancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/mhkJT2uOZM (https://t.co/mhkJT2uOZM)
>
> — Male Breast Cancer (@MBCC_MHBT) April 6, 2018 (https://twitter.com/MBCC_MHBT/status/982377155869814784?ref_src=twsrc%5Etfw)

US FDA accepts BLA for moxetumomab pasudotox in hairy cell leukaemia and granted priority review; PDUFA: Q3 2018 (https://www.astrazeneca.com/media-centre/press-releases/2018/us-fda-accepts-biologics-license-application-for-moxetumomab-pasudotox-in-hairy-cell-leukaemia-03042018.html)

AstraZeneca and MedImmune, its global biologics research and development arm, today announced that the US Food and Drug Administration (FDA) has accepted the Biologics License Application (BLA) for moxetumomab pasudotox, an investigational anti-CD22 recombinant immunotoxin and a potential new medicine for the treatment of adult patients with hairy cell leukaemia (HCL) who have received at least two prior lines of therapy. The FDA has granted the moxetumomab pasudotox BLA Priority Review status with a Prescription Drug User Fee Act date set for the third quarter of 2018.

> Potential new #Immunotoxin (https://twitter.com/hashtag/Immunotoxin?src=hash&ref_src=twsrc%5Etfw) against #hairycellleukemia (https://twitter.com/hashtag/hairycellleukemia?src=hash&ref_src=twsrc%5Etfw) – a #rarecancer (https://twitter.com/hashtag/rarecancer?src=hash&ref_src=twsrc%5Etfw). https://t.co/DUrnofT1uE (https://t.co/DUrnofT1uE) #Leukemia (https://twitter.com/hashtag/Leukemia?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) @AstraZeneca (https://twitter.com/AstraZeneca?ref_src=twsrc%5Etfw) @MedImmune (https://twitter.com/MedImmune?ref_src=twsrc%5Etfw)
>
> — MedGenera (@Medgenera) April 5, 2018 (https://twitter.com/Medgenera/status/981741141916880896?ref_src=twsrc%5Etfw)

EMA to Review Cemiplimab as a Potential Treatment for Advanced Cutaneous Squamous Cell Carcinoma

(http://files.shareholder.com/downloads/REGN/6181935288x0x975736/b1be9952-ec5a-408f-99f0-490ac853113d/REGN_News_2018_4_3_General_Releases.pdf)

The MAA for cemiplimab is based on a Phase 2 pivotal, single-arm, open-label clinical trial of cemiplimab for advanced CSCC (EMPOWER-CSCC 1) in addition to Phase 1 data from two advanced CSCC expansion cohorts. Both clinical trials enrolled patients with metastatic CSCC and patients with locally advanced CSCC who were not candidates for surgery. Topline results from EMPOWER-CSCC 1 were previously announced in December 2017, and Phase 1 expansion cohort results were presented at the 2017 American Society of Clinical Oncology Annual Meeting. Updated results from both clinical trials are being submitted for presentation at upcoming medical congresses.

> European Medicines Agency to review Sanofi-Regeneron's Dupixent, Cemiplimab PARIS (Reuters) – The European Medicines Agency (EMA) will review the Dupixent (dupilumab) and Cemiplimab products being developed by drugmakers Sanofi and Regeneron, the compani... https://t.co/Y87pkV9hBp (https://t.co/Y87pkV9hBp)
>
> — Medical Web Times (@medicalwebtimes) April 3, 2018 (https://twitter.com/medicalwebtimes/status/981052191111811072?ref_src=twsrc%5Etfw)

FDA and EMA accept Dacomitinib's application in 1L EGFRm+ NSCLC patients; PDUFA – Sep 2018 (https://www.pfizer.com/news/press-release/press-release-detail/u_s_fda_and_european_medicines_agency_accept_regulatory_submissions_for_review_of_dacomitinib_to_treat_metastatic_non_small_cell_lung_can

"While significant progress has been made in the treatment of patients with non-small cell lung cancers harboring EGFR-activating mutations, it remains a challenging disease and new treatment options are needed," said Mace Rothenberg, M.D., chief development officer, Oncology, Pfizer Global Product Development. "In the pivotal clinical trial that supports these applications, dacomitinib showed clinically meaningful improvement in progression-free survival over gefitinib, one of the first EGFR-targeted therapies to demonstrate activity in this disease. These filing acceptances are an important step toward increasing treatment options for patients with locally advanced or metastatic EGFR-mutated non-small cell lung cancer."

> New #EGFRInhibitor (https://twitter.com/hashtag/EGFRInhibitor?src=hash&ref_src=twsrc%5Etfw) dacomitinib topped commercially available #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) drug Iressa (gefitinib) in #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) growth-free survival of patients. https://t.co/DnpUD2vnc3 (https://t.co/DnpUD2vnc3) #EGFRmutation (https://twitter.com/hashtag/EGFRmutation?src=hash&ref_src=twsrc%5Etfw) @pfizer (https://twitter.com/pfizer?ref_src=twsrc%5Etfw)
>
> — MedGenera (@Medgenera) April 6, 2018 (https://twitter.com/Medgenera/status/982106455061876736?ref_src=twsrc%5Etfw)

Celltrion's Rituximab and trastuzumab biosimilar received complete response letters (CRLs) from FDA-supplementary information needed (https://www.celltrion.com/en/pr/newsDetail.do?seq=482)

Celltrion received a Complete Response Letters (CRLs) from the U.S. Food and Drug Administration (FDA) regarding the Biologics License Application (BLA) for CT-P10 (rituximab), a proposed biosimilar to Rituxan® and CT-P6 (trastuzumab), a proposed biosimilar to Herceptin®.

The FDA Warning Letter issued to Celltrion on January 26, 2018 was directly related to the receipt of the CRL.

Celltrion is making progress addressing the concerns raised by the FDA in a Warning Letter issued in January and is committed to working with the agency to fully resolve all outstanding issues with the highest priority and urgency.

> Celltrion remains hopeful for US approval of Herzuma, Truxima despite initial FDA turn-down #biosimilar (https://twitter.com/hashtag/biosimilar?src=hash&ref_src=twsrc%5Etfw) https://t.co/29H7GEUehc (https://t.co/29H7GEUehc)
>
> — Neethu Sreenivasan (@neeth_sa) April 6, 2018 (https://twitter.com/neeth_sa/status/982256327329107968?ref_src=twsrc%5Etfw)

COMPANION DIAGNOSTICS

Personal Genome Diagnostics to Develop Plasma-Based Companion Dx for Bemarituzumab (http://www.personalgenome.com/wp-content/uploads/2018/04/Personal-Genome-Diagnostics-Announces-Collaboration-to-Develop-Plasma.pdf)

"We are pleased to collaborate with PGDx, a cancer genomics pioneer with a wealth of experience in accurately identifying genomic alterations in tumors," said Aron Knickerbocker, Chief Executive Officer of Five Prime. "Patients with advanced gastric and gastroesophageal junction cancer need new treatment options. Prognosis is especially poor for patients whose tumors overexpress FGFR2b or have FGFR2 gene amplification. We believe that a targeted therapy like bemarituzumab may provide a clinical benefit in this setting and expect that PGDx's plasma-based assay will be an accessible and flexible tool to inform patient selection."

> We are excited to announce our new collaboration w/ @FivePrime_FPRX (https://twitter.com/FivePrime_FPRX?ref_src=twsrc%5Etfw). This collaboration demonstrates PGDx's commitment to providing accurate, accessible assays to help determine what patients are most likely to benefit from a drug. Read More: https://t.co/a90eEMampM (https://t.co/a90eEMampM) pic.twitter.com/ItiU0MEh69 (https://t.co/ItiU0MEh69)
>
> — Personal Genome Dx (@CancerDNA) April 3, 2018 (https://twitter.com/CancerDNA/status/981188625466646528?ref_src=twsrc%5Etfw)

TRIAL STATUSES

via GIPHY (https://giphy.com/gifs/weediquette-viceland-l2SpXygU10mMpl7XO)

First SCLC patient dosed in Pegzilarginase +/- Pembrolizumab trials (http://ir.aegleabio.com/news-releases/news-release-details/aeglea-biotherapeutics-doses-first-small-cell-lung-cancer)

"Given Aeglea's encouraging preclinical data in small cell lung cancer, we believe there is a strong rationale for arginine depletion in this cancer indication," said Anthony Quinn, M.B Ch.B, Ph.D., interim chief executive officer of Aeglea. "We are excited to be studying arginine depletion with pegzilarginase in both a monotherapy and combination setting, as the data from both trials will provide a broad understanding of the impact of arginine

depletion in small cell lung cancer."

> First patients dosed in Aeglea BioTherapeutics' pegzilarginase ... https://t.co/9HvrJuDXTt (https://t.co/9HvrJuDXTt) #AegleaBioTherapeutics (https://twitter.com/hashtag/AegleaBioTherapeutics?src=hash&ref_src=twsrc%5Etfw) #pegzilarginase (https://twitter.com/hashtag/pegzilarginase?src=hash&ref_src=twsrc%5Etfw) #SCLC (https://twitter.com/hashtag/SCLC?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/6uPmtsLtWG (https://t.co/6uPmtsLtWG)
>
> — TRM Oncology (@TRMoncology) April 6, 2018 (https://twitter.com/TRMoncology/status/982060576988975105?ref_src=twsrc%5Etfw)

First patient doses in Ph III Enzastaurin + R-CHOP trial in 1L, high risk DLBCL patients (https://www.denovobiopharma.com/DB102%20ENGINE%20first%20patient%20dosed%2020180403%20ISSUED.docx)

"The initiation of this innovative biomarker driven trial marks a significant milestone for Denovo Biopharma. Importantly, the addition of DB102 to R-CHOP may offer improved benefit over R-CHOP alone in patients with high-risk DLBCL identified by a biomarker," said Ronald Shazer, M.D., Chief Medical Officer of Denovo Biopharma. "Although treatment with R-CHOP is curative in the majority of patients with low-risk DLBCL, the same cannot be said for high-risk DLBCL and alternative treatments are urgently needed for these patients."

> First Patient Dosed In Pivotal Biomarker-Guided #PhaseIII (https://twitter.com/hashtag/PhaseIII?src=hash&ref_src=twsrc%5Etfw) Study Of First Line Therapy With #DB102 (https://twitter.com/hashtag/DB102?src=hash&ref_src=twsrc%5Etfw) + #R (https://twitter.com/hashtag/R?src=hash&ref_src=twsrc%5Etfw)-CHOP In Patients With High-Risk Diffuse Large B-Cell #Lymphoma (https://twitter.com/hashtag/Lymphoma?src=hash&ref_src=twsrc%5Etfw) https://t.co/MzyXy3wkvz (https://t.co/MzyXy3wkvz) @bizjournals (https://twitter.com/bizjournals?ref_src=twsrc%5Etfw) #DLBCL (https://twitter.com/hashtag/DLBCL?src=hash&ref_src=twsrc%5Etfw) #enzastaurin (https://twitter.com/hashtag/enzastaurin?src=hash&ref_src=twsrc%5Etfw) #DenovoBiopharma (https://twitter.com/hashtag/DenovoBiopharma?src=hash&ref_src=twsrc%5Etfw)
>
> — Plexus Ventures (@PlexusVentures) April 5, 2018 (https://twitter.com/PlexusVentures/status/981909602978750464?ref_src=twsrc%5Etfw)

Nordic Nanovector provides update on pivotal, Ph IIb PARADIGME trial in 3L FL patients (http://www.nordicnanovector.com/index.php/investors-and-media/press-releases?page=/en/pressreleases/nordic-nanovector-provides-update-on-the-paradigme-clinical-trial-1564824)

Lisa Rojkjaer MD, Nordic Nanovector CMO, said: "While we are encouraged with the progress being made to the start-up of the pivotal PARADIGME study, a re-analysis of the patient enrolment rate and the fact that it has taken longer than expected to enrol the first patient have led us to adjust the timelines we previously communicated. We now expect to deliver data from PARADIGME in the first half of 2020.

"The PARADIGME study reflects our conviction in the significant potential of Betalutin® based on the promising clinical data generated to-date. We therefore remain committed to completing this robust study, which is designed to select the best dosing regimen to support Betalutin® as an important new treatment option for 3L FL patients."

> Positive update from $NANO (https://twitter.com/search?q=%24NANO&src=ctag&ref_src=twsrc%5Etfw) SVP-IR late last night. The PARADIGME stydy can infact start screening without approval from REK. Great News in a time NoNews. #NANOVECTOR (https://twitter.com/hashtag/NANOVECTOR?src=hash&ref_src=twsrc%5Etfw) #NORDICNANOVECTOR (https://twitter.com/hashtag/NORDICNANOVECTOR?src=hash&ref_src=twsrc%5Etfw) #NORWEGIANBIOTECH (https://twitter.com/hashtag/NORWEGIANBIOTECH?src=hash&ref_src=twsrc%5Etfw) #LYMPHOMA (https://twitter.com/hashtag/LYMPHOMA?src=hash&ref_src=twsrc%5Etfw) #BETALUTIN (https://twitter.com/hashtag/BETALUTIN?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/wHD7FBWtJf (https://t.co/wHD7FBWtJf)
>
> — Lex Talionis (@Lex_Talionis_) March 27, 2018 (https://twitter.com/Lex_Talionis_/status/978509986203611136?ref_src=twsrc%5Etfw)

Ph I/II trial of pegylated cytokine inhibitor, BNZ-1, initiated in T-cell leukemia and lymphoma (https://bioniz.com/bioniz-therapeutics-initiates-phase-1-2-clinical-study-bnz-1-t-cell-leukemia-lymphoma/)

"Together with our investigators, we are eager to characterize the potential clinical benefit of BNZ-1 in patients with LGL or rCTCL," said Dr. Paul Frohna, Chief Medical Officer of Bioniz Therapeutics. "Evaluating BNZ-1 in these patients serves as an important first step in our efforts to characterize the potential of BNZ-1 across a wide range of T-cell malignancies where IL-2/9/15 are implicated as disease drivers".

"BNZ-1 holds great potential as a new therapy for LGL and relapsed CTCL as its novel mechanism of action addresses a critical driver in both these diseases, IL-15, while also inhibiting the associated cytokines IL-2 and IL-9. The results from this study will help determine if BNZ 1 has promise as a new treatment option for patients who currently have no or few alternatives, and is the only active study specifically designed to target LGL in the United States." said Dr. Jonathan Brammer, M.D., hematologist at The James Cancer Center at the Ohio State University and lead investigator of the study.

> Heading to Atlanta next month to present new and exciting clinical data for our BNZ-1 multi-cytokine inhibitor progr...https://t.co/V9hz56khRF (https://t.co/V9hz56khRF)
>
> — Paul Frohna (@PaulFrohna) November 2, 2017 (https://twitter.com/PaulFrohna/status/926208459913117696?ref_src=twsrc%5Etfw)

AACR 2018: Clinical Results for First-In-Class RORgamma Agonist LYC-55716 to be presented at AACR (https://lycera.com/press/lycera-present-clinical-results-supporting-preclinical-data-first-class-rorgamma-agonist-lyc-55716-2018-aacr-annual-meeting)

"In addition to these important preclinical results, we are excited to present the first clinical results from Lycera's RORgamma agonist program at one of the most important cancer meetings of the year," said Paul Sekhri, President and CEO of Lycera. "At Lycera, we are advancing multiple programs to assess the clinical efficacy of LYC-55716 both as a monotherapy in multiple tumor types, as well as in combination with pembrolizumab (KEYTRUDA) in advanced non-small cell lung cancer (NSCLC). For our ARGON study, we anticipate completing patient enrollment in the Phase 2a portion by mid-2018, with the expectation of reporting topline efficacy results in the first half of 2019. In addition, based on current progress, we expect our Phase 1b study assessing combination therapy with LYC-55716 and pembrolizumab will be able to report early safety and efficacy data in the middle of 2019. We are proud of this progress and are grateful to our talented R&D teams and the clinicians, researchers, and patients participating in our clinical trials program."

@LyceraCorp (https://twitter.com/LyceraCorp?ref_src=twsrc%5Etfw) to Present Clinical Results and Supporting Preclinical Data for First-in-Class RORgamma Agonist LYC-55716 at the 2018 AACR Annual Meeting #AACR18 (https://twitter.com/hashtag/AACR18?src=hash&ref_src=twsrc%5Etfw) https://t.co/YvS3BdwRsL (https://t.co/YvS3BdwRsL)

— Lycera Corp (@LyceraCorp) April 5, 2018 (https://twitter.com/LyceraCorp/status/981864909007933441?ref_src=twsrc%5Etfw)

COLLABORATIONS

via GIPHY (https://giphy.com/gifs/hello-xT9DPIlGnuHpr2yObu)

Boehringer Ingelheim and OSE Immunotherapeutic to develop OSE-172, a SIRP-alpha antagonist, in solid tumors (http://ose-immuno.com/site/wp-content/uploads/EN_180404_BI-OSE.pdf)

"This partnership with Boehringer Ingelheim is a real recognition of the value of our innovative approach to treating cancer and will create an exciting new alliance to fuel the phase 1 development of OSE-172," said Dr. Dominique Costantini, CEO of OSE Immunotherapeutics. "Boehringer Ingelheim's expertise and insights will be invaluable as we step up the clinical development and work to commercialize this new treatment paradigm."

"We are excited to partner with OSE Immunotherapeutics to develop this promising, novel cancer immunotherapy," said Jonathon Sedgwick, Ph.D., Global Head Cancer Immunology & Immune Modulation Research at Boehringer Ingelheim. "A key area of focus is the identification of drugs that target myeloid cell immune regulatory receptors of which SIRP-alpha is a leading example. We are dedicated to developing ground-breaking, first-in-class therapies that can transform the lives of patients and help win the fight against cancer."

Boehringer Ingelheim bets $1.1 billion on OSE ImmunoTherapeutics Checkpoint inhibitor OSE-172 (Effi-DEM) https://t.co/CEaWc50Zws (https://t.co/CEaWc50Zws)

— Krishan Maggon (@kkmaggon) April 5, 2018 (https://twitter.com/kkmaggon/status/981812406656622592?ref_src=twsrc%5Etfw)

PUBLICATIONS

via GIPHY (https://giphy.com/gifs/wilson-bethel-TYhuXgqYAsd5S)

Ph III COLUMBUS trial data published in LANCET Oncology; mPFS with combination double that of Vemurafenib alone (http://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30142-6/fulltext)

Encorafenib plus binimetinib and encorafenib monotherapy showed favourable efficacy compared with vemurafenib. Overall, encorafenib plus binimetinib appears to have an improved tolerability profile compared with encorafenib or vemurafenib. Encorafenib plus binimetinib could represent a new treatment option for patients with *BRAF*-mutant melanoma.

Encorafenib with binimetinib may be a promising combination treatment for patients with BRAF-mutant #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw). https://t.co/hAhvuqoQFo (https://t.co/hAhvuqoQFo)

— Dermatology Advisor (@DermAdvisor) April 3, 2018 (https://twitter.com/DermAdvisor/status/981245084875284482?ref_src=twsrc%5Etfw)

GUIDELINES

via GIPHY (https://giphy.com/gifs/loop-eternal-3085xonfOvQzN3eCNG)

ASTRO guideline update recommends addition of chemotherapy to radiation therapy for stage III NSCLC patients (https://www.astro.org/News-and-Publications/News-and-Media-Center/News-Releases/2018/Updated-ASTRO-guideline-for-palliative-lung-radiation-now-recommends-concurrent-chemotherapy-for-some-stage-III-patients/)

"The primary question we faced with this revision was whether providers can enhance the impact of moderate, palliative doses of radiation by introducing additional therapy," said Benjamin Moeller, MD, PhD, chair of the guideline task force and a radiation oncologist at the Levine Cancer Institute in Charlotte, North Carolina.

"Patients in this setting typically receive two to three weeks of daily radiation, during which they might expect to have one to two weeks of clinically significant, treatment-related side effects—most commonly inflammation of the esophagus. Following treatment, however, these patients experience a more robust and durable stabilization of their quality of life, including less pain and fewer symptoms."

ASTRO Updates Guideline for Palliative Lung Cancer Radiation Therapy https://t.co/LobfbeISJD (https://t.co/LobfbeISJD) pic.twitter.com/HVWNXFiDYI (https://t.co/HVWNXFiDYI)

— JCP (@JournalofCP) April 5, 2018 (https://twitter.com/JournalofCP/status/981948842777169920?ref_src=twsrc%5Etfw)

YEAR-END 2017 FINANCIAL RESULTS

via GIPHY (https://giphy.com/gifs/illustration-up-arrow-t7sEnf5w7wJ1CEPyy7)

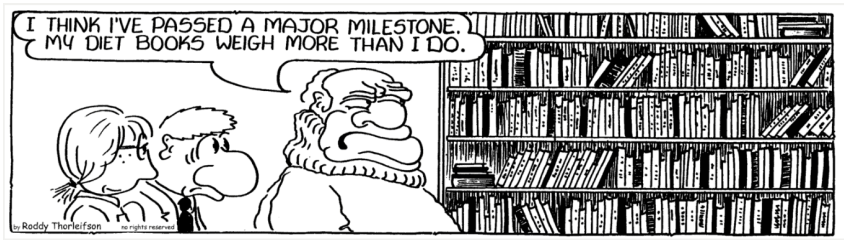
TapImmune reports 4th quarter and year-end 2017 financial results (https://tapimmune.com/2018/04/tapimmune-provides-fourth-quarter-and-year-end-2017-corporate-and-clinical-update/)

"Throughout 2017, we made significant advances toward achieving our goals and reaching our milestones," said Peter Hoang, President and CEO of TapImmune. "We recently announced the publication of new clinical data for our multi-epitope T-cell vaccine targeting folate receptor alpha, TPIV200, in patients with ovarian and breast cancer. In this publication we showed an encouraging potential progression-free survival benefit in women with ovarian

cancer in their first remission, which we are currently exploring further in an ongoing randomized Phase 2 study. Should we see a similar, prolonged PFS in this larger study, we believe that TPIV200 could have a viable pathway toward potential approval in this indication, for which it has FDA Fast Track designation. We remain on track to conduct an interim safety and futility analysis for the Phase 2 study by mid-2019."

> Updated TapImmune, Inc. #Investor (https://twitter.com/hashtag/Investor?src=hash&ref_src=twsrc%5Etfw) Kit now available – $TPIV (https://twitter.com/search?q=%24TPIV&src=ctag&ref_src=twsrc%5Etfw) #InvestorPresentation (https://twitter.com/hashtag/InvestorPresentation?src=hash&ref_src=twsrc%5Etfw) – Get Investment Info at https://t.co/CWCxyodejp (https://t.co/CWCxyodejp) pic.twitter.com/wTpbW94rsF (https://t.co/wTpbW94rsF)
>
> — The Investor Network (@investornetwork) March 30, 2018 (https://twitter.com/investornetwork/status/979757709963726848?ref_src=twsrc%5Etfw)

And now, some humor before we sign off....



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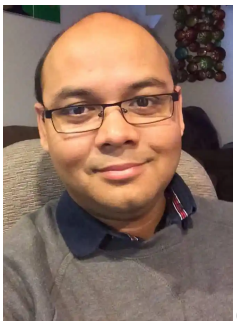
Source: Mooselakecartoons.com (https://mooselakecartoons.com/health/oksflvw12jarbzj8aybmmghfgrzori)

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: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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: Pixabay (https://pixabay.com/en/ecg-electrocardiogram-stethoscope-1953179/), Giphy, Wikipedia and Twitter

Cover image (https://upload.wikimedia.org/wikipedia/commons/1/1f/Vertical_circles_-_Aamir_Ahmed%2C_Michael_Millar_and_Jane_Pendjiky.jpg):In biology, normalcy and disease are two paradoxical states that occur in the same entity. QuiPCaMs are protein biomarkers discovered in my laboratory for diagnosis and prognosis of cancer. The nature of the two biological states, normal and cancer, is explored in this image by juxtaposing cores of normal and cancerous human tissue stained using antibodies against QuiPCaMs. Digital images were created by staining tissue sections for the expression of QuiPCaMs using fluorescence immunohistochemistry and confocal microscopy. The resulting images were then assembled into a montage in Photoshop. In the montage the tissue cores in the top circle are all benign, while the ones in the lower circle are cancerous. Credit for the image: Aamir Ahmed, Michael Millar and Jane Pendjiky., via Wikimedia Commons. By Jam Amp [CC BY-SA 4.0 (https://

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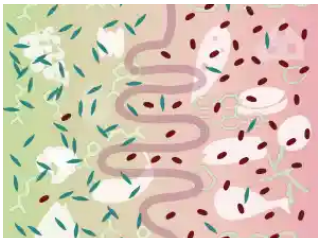

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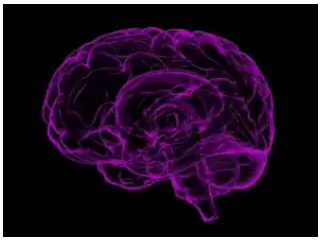

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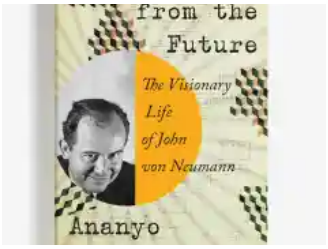

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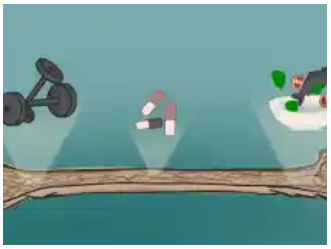

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