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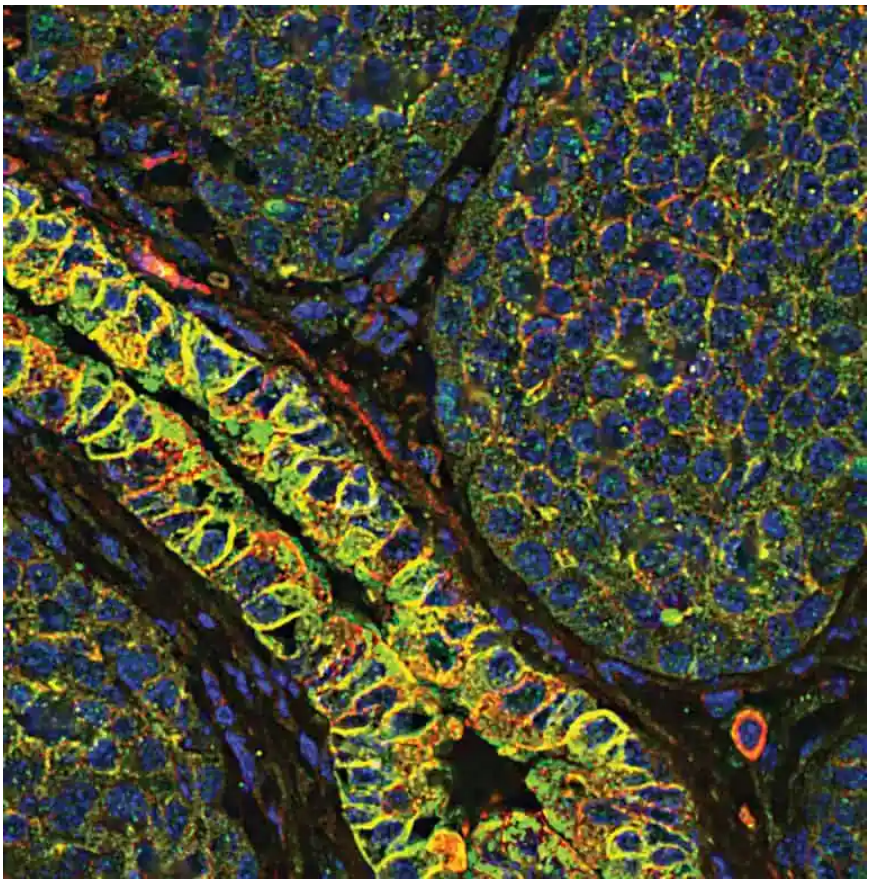
April 7, 2019(https://sciwri.club/archives/date/2019/04/07)



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AACR Annual Meeting, 2019 Coverage

> Digging wells and Building fires-Remarks from @NCIDirector (https://twitter.com/NCIDirector?ref_src=twsrc%5Etfw) Dr Norman Sharpless at #AACR2019 (https://twitter.com/hashtag/AACR2019?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/hTK934djZf (https://t.co/hTK934djZf)
>
> — Preety (@DrPreetyBajwa) March 31, 2019 (https://twitter.com/DrPreetyBajwa/status/1112349801423736832?ref_src=twsrc%5Etfw)

- Clinical benefit observed in Ph Ib/II trial of Sapacitabine in PARP inh-naive BRCA m+ breast cancer patients (https://investor.cyclacel.com/news-releases/news-release-details/cyclacel-announces-presentation-phase-1-data-sapacitabine)
- 85% ORR obtained in Ph I trial of telomelysin (OBP-301) in esophageal cancer patients (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1307)
- Case reports from Ph II trial of TEDOPI in CPI-refractory advanced NSCLC patients presented (https://ose-immuno.com/wp-content/uploads/2019/04/EN_190402_AACR-post-conference.pdf)
- Pharmacodynamic correlates and flat dosing strategy of PD-1 inh INCMGA00012 presented (http://ir.macrogenics.com/news-releases/news-release-details/macrogenics-reports-presentation-data-aacr-annual-meeting-2019)
- New data from Ph I trial of PD-1 KEY-Vaxx and HER-2 B-Vaxx cancer vaccines presented (https://static1.squarespace.com/static/5b63d41b3e2d09b1f56bf483/t/5ca28ef68165f55d1e9cd2f9/1554157306266/AACR+KEY+Vaxx+and+B+Vaxx+combined+2apr19.pdf)
- New data on the Ph Ib trial of HER-Vaxx cancer vaccine in gastric cancer patients presented (https://static1.squarespace.com/static/5b63d41b3e2d09b1f56bf483/t/5ca2878641920213e934975/1554155403078/AACR+HER+Vaxx+FINAL+2apr19.pdf)
- Safety and biomarker data for inhaled TLR9 agonist DV281 + Nivolumab in NSCLC patients presented (http://investors.dynavax.com/news-releases/news-release-details/dynavax-presents-phase-1b-data-inhaled-dv281-tlr9-agonist-2019)
- Rapid additive or synergistic anti-tumor activity observed with personalized immunotherapy, BriaCell + Pembrolizumab, in breast cancer patients (https://briacell.com/briacells-lead-candidate-combined-with-keytruda-strong-evidence-of-rapid-additive-or-synergistic-anti-tumor-activity/)
- Data on T-cell diversity and persistence from Ph II trial of TIL Therapy Lifileucel presented in metastatic melanoma patients (http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2392939)
- CXCL12 pathway identified as FTI inhibitor Tipifarnib's target; updates in several indications also presented (http://ir.kuraoncology.com/news-releases/news-release-details/kura-oncology-identifies-farnesylated-proteins-associated-cxcl12)
- Updated data from ongoing Ph Ib NT-001 trial of personal neoantigen vaccine NEO-PV-01 shows durable benefit in metastatic melanoma patients (https://ir.neontherapeutics.com/news-releases/news-release-details/neon-therapeutics-presents-updated-data-ongoing-phase-1b-nt-001)
- Updated results from Ph Ib Study 116/KEYNOTE-524 trial of Lenvatinib + pembrolizumab in HCC patients to be presented (https://www.prnewswire.com/news-releases/eisai-announces-presentations-of-latest-research-on-oncology-pipeline-at-the-110th-american-association-for-cancer-research-aacr-annual-meeting-300820803.html)
- Disease stabilization and extended survival observed with mitomycin-c lipidic prodrug, Promitil, in mCRC patients (http://www.globenewswire.com/news-release/2019/03/29/1789730/0/en/LipoMedix-to-Present-New-Clinical-Data-on-Promitil-at-American-Association-for-Cancer-Research-AACR-Annual-Meeting-2019.html?ev=1)
- Ph I trial shows mesothelin-targeted CAR T-cell therapy to be safe and efficacious in malignant pleural mesothelioma patients (http://investors.atarabio.com/news-releases/news-release-details/atara-biotherapeutics-announces-collaborator-presentation)
- Initial results from Ph I ALLCAR19 trial of AUTO1 in ALL patients presented (https://autolus.gcs-web.com/news-releases/news-release-details/initial-results-autolus-therapeutics-allcar19-phase-12-trial)
- mOS of 21.9 months observed in Ph Ib trial of autologous tumor cell vaccine, IGV-001, in 1L GBM patients (https://www.imvax.com/imvax-announces-positive-results-from-clinical-trial-of-novel-igv-001-autologous-cell-vaccine-in-treating-patients-with-newly-diagnosed-glioblastoma/)
- Encouraging safety results from Ph I trial of CIMAvax-EGF + Nivolumab in NSCLC patients presented (https://www.roswellpark.org/media/news/safety-analysis-now-complete-roswell-park-moves-forward-expanded-study-cimavax)
- Umbralisib shows early promise in Ph IIb UNITY-NHL trial in R/R MZL patients (http://ir.tgtherapeutics.com/news-releases/news-release-details/tg-therapeutics-reports-positive-interim-data-unity-nhl-phase-2b)
- Pooled analysis with longest follow up of Nivolumab in 2L NSCLC from CheckMate-017, -057, -063 and -003 trials presented (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-announces-long-term-survival-results-pool)
- Data from Ph Ib/II trial of Onvansertib in R/R AML patients showed safety, tolerability and relative durability (http://trovageneoncology.investorroom.com/2019-04-01-Phase-1b-2-Dose-Escalation-Trial-of-Onvansertib-in-Relapsed-Refractory-AML-Demonstrates-Safety-Tolerability-and-Relative-Durability-with-Complete-Responses-at-Highest-Dose-Levels)
- Gilteritinib significantly improves OS for FLT3 m+ R/R AML patients (https://newsroom.astellas.us/2019-04-01-Phase-3-ADMIRAL-Trial-Data-Show-XOSPATA-R-gilteritinib-Significantly-Prolongs-Overall-Survival-in-Adult-Patients-with-FLT3-Mutation-Positive-Relapsed-Refractory-Acute-Myeloid-Leukemia-Compared-with-Salvage-Chemothera)
- Latest findings from ASCO TAPUR trial presented (https://www.asco.org/about-asco/press-center/news-releases/latest-findings-asco-tapur-study-trial-presented-aacr-annual)
- Updated Ph II data from ENCORE 601 trial of Entinostat + pembrolizumab presented in Melanoma and NSCLC patients (http://www.syndax.com/wp-content/uploads/2019/04/SNDX_AACR-2019.pdf)
- Data from Ph Ib/II trial of CD40 inh APX005M + Nivolumab in metastatic Melanoma patients presented (https://www.apexigen.com/news/04-01-19/)
- Positive results from Ph Ib trial of HGF/c-Met inh Ficlatuzumab-Cytarabine in high risk R/R AML patients

presented (https://www.aveooncology.com/wp-content/uploads/2019/04/AVEO_AACR_AML_PR_2019.pdf)
- Encouraging results from Ph Ib ProSTAR trial of EZH2 inhibitor CPI-1205 in mCRPC patients presented (http://ir.constellationpharma.com/node/7211)
- Initial safety data from two patients with advanced HCC, from the first dose cohort of Ph I ADP-A2AFP trial presented (http://phx.corporate-ir.net/phoenix.zhtml?c=253991&p=irol-newsArticle&ID=2393177)
- Ph I ADXS-PSA data with Pembrolizumab combination in mCRPC patients presented (https://ir.advaxis.com/press-release/adxs-psa-combination-keytruda-prolonged-survival-metastatic-castration-resistant)
- Ph I ADXS-NEO data presented (https://ir.advaxis.com/press-release/preliminary-data-phase-1-study-evaluating-adxs-neo-suggest-rapid-immunogenicity-and)
- Updates from Ph II study of NLG207 presented (http://investors.linkp.com/news-releases/news-release-details/newlink-genetics-presents-encouraging-phase-2-results-nlg207)
- ICOS agonist Vopratelimab (JTX-2011) improves PFS and OS in solid tumor patients with ICOS high (hi) subset of CD4 T cells in Ph I/II ICONIC trial (https://ir.jouncetx.com/news-releases/news-release-details/jounce-therapeutics-reports-improved-pfs-and-os-associated)
- Data from Ph I ILLUMINATE-101 trial of TLR 9 agonist Tilsotolimod in solid tumors presented (http://ir.iderapharma.com/news-releases/news-release-details/idera-pharmaceuticals-presents-illuminate-101-data-demonstrating)
- Onvansertib Active in Prostate Cancer Patients With Initial Resistance to Anti-Androgen Therapy (http://trovageneoncology.investorroom.com/2019-04-02-Early-Data-from-Phase-2-Trial-Indicates-Activity-of-Onvansertib-in-Prostate-Cancer-Patients-Showing-Initial-Resistance-to-Anti-Androgen-Therapy)
- Clovis Oncology presented interim data from Ph II study of Rucaparib in pancreatic cancer, along with trial designs for ATHENA and ATLAS studies (https://ir.clovisoncology.com/investors-and-news/news-releases/press-release-details/2019/Clovis-Oncology-Announces-Interim-Results-from-Rubraca-rucaparib-Phase-2-Study-in-Advanced-Pancreatic-Cancer-and-Nonclinical-Data-in-Multiple-Solid-Tumor-Types-for-Ru)
- LOXO-195, 2nd gen TRKi, efficacious in 1st gen TRKi treated patients with acquired resistance (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1306)
- CD40 + PD-1 CPI + Chemo shows early promise in Pancreatic Cancer (https://www.parkerici.org/2019/03/31/for-advanced-pancreatic-cancer-combining-immunotherapies-with-chemotherapy-shows-early-promise-in-reducing-tumor-size/)
- TATTON trial – Addition of Savolitinib to Osimertinib was Beneficial for Certain Pretreated Lung Cancer Patients (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1294)
- Anti-CTLA-4 and Anti-PD-1 Blockade (Nivo + Ipi) – Combination Efficacious for patients with High-grade Neuroendocrine Carcinoma (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1293)
- HER2-targeted CAR T-cell therapy safe/promising antitumor activity in patients With Advanced Sarcoma (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1292)
- Mesothelin-targeted CAR T-cell therapy safe, shows early promise in patients with advanced Solid Tumors (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1291)
- Data from two KEYNOTE trials (KN-028 and KN-158) show Pembrolizumab benefited patients with advanced SCLC – retrospective, exploratory, pooled analysis (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1296)
- Roche's ipatasertib in combination with Tecentriq and chemotherapy shows promising anti-tumour activity in TNBC in early phase trial (https://www.roche.com/media/releases/med-cor-2019-04-01.htm)

DRUG APPROVALS

Radioenhancer NBTXR3 receives EMA approval for treatment of locally advanced soft tissue sarcoma (STS) based on Ph II/III Act.In.Sarc trial data (http://www.nanobiotix.com/download/news_en/2019/PR_Nanobiotix_marquage_CE_04042019_VF.pdf)

> Combination of first-in-class NBTXR3, radiotherapy, and anti-PD-1 immunotherapy demonstrate efficacy in treating resistant pre-clinical in vivo models of lung cancer #AACR19 (https://twitter.com/hashtag/AACR19?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #NBTXR3 (https://twitter.com/hashtag/NBTXR3?src=hash&ref_src=twsrc%5Etfw) #healthcare (https://twitter.com/hashtag/healthcare?src=hash&ref_src=twsrc%5Etfw) #immunooncology (https://twitter.com/hashtag/immunooncology?src=hash&ref_src=twsrc%5Etfw)
>
> More info: https://t.co/ZWxaA2B7IS (https://t.co/ZWxaA2B7IS) pic.twitter.com/l6G2aIMvTH (https://t.co/l6G2aIMvTH)
>
> — Nanobiotix (@Nanobiotix) April 2, 2019 (https://twitter.com/Nanobiotix/status/1113142936739430400?ref_src=twsrc%5Etfw)

Laurent Levy, CEO of Nanobiotix, commented, "We could not be more proud to receive market approval in Europe for Hensify®. This approval validates more than 15 years of hard work, cutting edge science, and a fierce commitment to changing the lives of patients. This is a significant achievement and represents just one more step in our mission to improve life for millions of people around the world."

Dacomitinib approved in Europe for 1L EGFR+ NSCLC patients based on data from Ph III ARCHER 1050 trial (https://www.pfizer.com/news/press-release/press-release-detail/vizimpro_dacomitinib_receives_marketing_authorization_in_european_union_eu_for_the_first_line_treatment_of_adult_patients_with_egfr_mutate

> Aprobación de dacomitinib como primera línea de tratamiento en cáncer de pulmón de células no pequeñas localmente avanzado https://t.co/QnYA5FFBlY (https://t.co/QnYA5FFBlY) pic.twitter.com/WJsVLMMgov (https://t.co/WJsVLMMgov)
>
> — Medscape ES (@MedscapeES) April 5, 2019 (https://twitter.com/MedscapeES/status/1114226195552395264?ref_src=twsrc%5Etfw)

"Lung cancer remains the leading cause of cancer-related death worldwide and despite advances in biomarker-driven therapies, overcoming resistance continues to be crucial in treating EGFR-mutated non-small cell lung cancer," said Andreas Penk, M.D., regional president, Oncology International Developed Markets at Pfizer. "The marketing authorization of VIZIMPRO, which has shown a more than five-month improvement in progression-free survival over an existing therapy in a Phase 3 clinical trial, provides a new option for patients with EGFR-mutated non-small cell lung cancer and reinforces Pfizer's ongoing commitment to addressing the remaining needs of the thousands of EU patients with this disease."

NMPA grants conditional approval to Pembrolizumab + Chemo in 1L EGFR WT/ALK WT non-sq mNSCLC patients based on Ph III KEYNOTE-189 data (https://www.mrknewsroom.com/news-release/research-and-development-news/mercks-keytruda-pembrolizumab-approved-china-first-line-t)

> Merck's Keytruda (pembrolizumab) + Chemotherapy Receive NMPA's (CFDA) Approval for 1L Metastatic Non-Squamous Non-Small Cell Lung Cancer (NSCLC) @Merck (https://twitter.com/Merck?ref_src=twsrc%5Etfw)https://t.co/8cLjHSp6Zh (https://t.co/8cLjHSp6Zh)
>
> — PharmaShots (@Pharmashot) April 3, 2019 (https://twitter.com/Pharmashot/status/1113350946950664192?ref_src=twsrc%5Etfw)

"Lung cancer is a deadly disease and the leading cause of cancer deaths in China, claiming the lives of more than 626,000 people in our country each year," said Prof. Yi-Long Wu, honorary director of the Guangdong Lung Cancer Research Institute, and tenured director of Guangdong Provincial People's Hospital. "The approval of KEYTRUDA in combination with standard chemotherapy for the first-line treatment of metastatic nonsquamous non-small cell lung cancer is an important milestone in the treatment of advanced lung cancer in China."

REGULATORY NEWS

FDA extends review period for Quizartinib in AML; new PDUFA: Aug 2019 (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006995.html)

> The FDA has added 3 months to the review period of an NDA seeking approval of quizartinib in these patients with AML: https://t.co/3lYFDhRRzC (https://t.co/3lYFDhRRzC) #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/QFsoJtQF3D (https://t.co/QFsoJtQF3D)
>
> — Targeted Oncology (@TargetedOnc) April 6, 2019 (https://twitter.com/TargetedOnc/status/1114498188680024064?ref_src=twsrc%5Etfw)

"We look forward to continued dialogue with the FDA throughout the review process of quizartinib," said Arnaud Lesegretain, Vice President, Oncology Research and Development and Head, AML Franchise, Daiichi Sankyo. "We remain confident in the data supporting our NDA submission and are committed to bringing quizartinib forward as a potential treatment for relapsed or refractory FLT3-ITD AML, a particularly aggressive and difficult-to-treat subtype of AML, where patients need additional targeted treatment options."

INDA approved for Ph I MUNDI-01 trial of CS-1-targeting allogenic CART, UCARTCS1, in multiple myeloma patients (https://www.cellectis.com/en/press/fda-clears-the-ind-for-ucartcs1-the-first-allogeneic-car-t-to-treat-multiple-myeloma-patients/)

> FDA Clears the IND for UCARTCS1, the First Allogeneic CAR-T to Treat Multiple Myeloma Patients https://t.co/1mwJAGlG8v (https://t.co/1mwJAGlG8v) pic.twitter.com/IRCQQPVjhp (https://t.co/IRCQQPVjhp)
>
> — PharmaMKTnet (@PharmaMKTnet) April 3, 2019 (https://twitter.com/PharmaMKTnet/status/1113402719551873024?ref_src=twsrc%5Etfw)

"The last quarters have been very productive for Cellectis' UCARTCS1 product candidate. We successfully manufactured and released GMP batches of UCARTCS1, filed an IND and secured approval from the FDA to start the MUNDI-01 Phase 1 clinical study," said Dr. André Choulika, Chairman and CEO of Cellectis. "This is the 4th time in 4 years that Cellectis demonstrates excellence with an allogeneic product candidate. It further demonstrates the strength of our innovation, our manufacturing process and our execution, as we are eager to bring the first allogeneic multiple myeloma CAR T-cell treatment to patients."

Positive CHMP opinions granted for both lenalidomide and pomalidomide-based triplet combination regimens in MM patients based on Ph III SWOG S0777 and OPTIMISMM trials, respectively (https://ir.celgene.com/press-releases/press-release-details/2019/Celgene-Receives-CHMP-Positive-Opinions-for-Both-REVLIMID-lenalidomide-and-IMNOVID-pomalidomide-Based-Triplet-Combination-Regimens-for-Patients-with-Multiple-Myeloma/

default.aspx)

> Celgene Receives CHMP Positive Opinions for Both REVLIMID® (lenalidomide) and IMNOVID® (pomalidomide)-Based Triplet Combination Regimens for Patients with Multiple #Myeloma (https://twitter.com/hashtag/Myeloma?src=hash&ref_src=twsrc%5Etfw). #AETOSWire (https://twitter.com/hashtag/AETOSWire?src=hash&ref_src=twsrc%5Etfw) @Celgene (https://twitter.com/Celgene?ref_src=twsrc%5Etfw) https://t.co/U6kYkQam2w (https://t.co/U6kYkQam2w) pic.twitter.com/BdPFb5WOc8 (https://t.co/BdPFb5WOc8)
>
> — AETOSWire (@AETOSWire) March 30, 2019 (https://twitter.com/AETOSWire/status/1111921209002917888?ref_src=twsrc%5Etfw)

"The CHMP positive opinions for our IMiD combinations, RVd and PVd represent very good news for patients with multiple myeloma in Europe," said Nadim Ahmed, President, Hematology/Oncology for Celgene. "We look forward to potential EMA approvals, which would make these new triplet regimens available to patients, as we aim to improve patient outcomes across multiple stages of their disease."

SPECIAL STATUSES

FDA grants Fast track designation to gp100-targeting therapy Tebentafusp (IMCgp100) in metastatic uveal melanoma patients (https://www.immunocore.com/news-hub/news/immunocores-lead-asset-tebentafusp-gains-fast-track-designation-metastatic-uveal-melanoma)

> Immunocore's Lead Asset Tebentafusp Gains Fast Track Designation for Metastatic Uveal Melanoma https://t.co/HuMfcv2eMo (https://t.co/HuMfcv2eMo) pic.twitter.com/g2XErtuZlo (https://t.co/g2XErtuZlo)
>
> — PharmaMKTnet (@PharmaMKTnet) April 3, 2019 (https://twitter.com/PharmaMKTnet/status/1113401799556259841?ref_src=twsrc%5Etfw)

"For patients with metastatic uveal melanoma, the prognosis is poor and has not meaningfully changed in decades. Our goal is to test whether tebentafusp can prolong survival for these patients." comments David Berman, Head of R&D of Immunocore. "We are delighted that tebentafusp has been granted Fast Track Designation."

EMA grants investigational CAR-T therapy JNJ-68284528 PRIME Designation (https://www.janssen.com/emea/sites/www_janssen_com_emea/files/car_t_prime_release_final_2019_04_03.pdf)

> Janssen Announces Investigational CAR-T Therapy JNJ-68284528 Granted PRIME Designation by the European Medicines Agency | Business Wire https://t.co/k6kix9mXmN (https://t.co/k6kix9mXmN)
>
> — Mohamad Mohty (@Mohty_EBMT) April 7, 2019 (https://twitter.com/Mohty_EBMT/status/1114706526034378752?ref_src=twsrc%5Etfw)

"The PRIME designation of this novel BCMA CAR-T therapy highlights the value of regulatory innovation in the European Union," said Sjaak Bot, Vice President, Head EMEA Regulatory Affairs at Janssen Biologics B.V. "We hope to bring this important advance to patients as quickly as possible and this PRIME designation, the first for Janssen, marks an important milestone towards potential market approval."

Alkylating deacetylase inhibitor tinostamustine granted FDA orphan drug designation for T-PLL (https://www.imbriumthera.com/news/imbrium-therapeutics-announces-u-s-fda-orphan-drug-designation-for-tinostamustine-for-the-treatment-of-t-cell-prolymphocytic-leukemia/)

> The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) granted orphan drug designation #ODD (https://twitter.com/hashtag/ODD?src=hash&ref_src=twsrc%5Etfw) to #tinostamustine (https://twitter.com/hashtag/tinostamustine?src=hash&ref_src=twsrc%5Etfw), a potentially first-in-class alkylating deacetylase inhibiting molecule being studied in early phase clinical trials, for the treatment of T-cell prolymphocytic #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) T-PLL @LLSusa (https://twitter.com/LLSusa?ref_src=twsrc%5Etfw) https://t.co/yqCF15Y02v (https://t.co/yqCF15Y02v)
>
> — CheckRare (@CheckRare) April 4, 2019 (https://twitter.com/CheckRare/status/1113859407216041990?ref_src=twsrc%5Etfw)

"This orphan drug designation represents an important step not just for Imbrium and the development of tinostamustine, but also for the patients suffering from T-PLL who do not currently have sufficient treatment options," said Richard Fanelli, PhD, head of Regulatory Affairs, Imbrium Therapeutics.

FDA grants Fast Track Designation to Ad-RTS-hIL-12 plus Veledimex in recurrent GBM (https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-announces-fda-fast-track-designation-ad-rts)

> The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw)) granted Fast Track Designation for Ad-RTS-hIL-12 plus veledimex for the treatment of recurrent or progressive #glioblastoma (https://twitter.com/hashtag/glioblastoma?src=hash&ref_src=twsrc%5Etfw) multiforme #rGBM (https://twitter.com/hashtag/rGBM?src=hash&ref_src=twsrc%5Etfw) in adults. @ziopharm (https://twitter.com/ziopharm?ref_src=twsrc%5Etfw) https://t.co/7ksAxy8Pgk (https://t.co/7ksAxy8Pgk)
>
> — CheckRare (@CheckRare) April 2, 2019 (https://twitter.com/CheckRare/status/1113102248807206912?ref_src=twsrc%5Etfw)

"Recurrent glioblastoma multiforme is an aggressive and life-threatening cancer of the central nervous system for which there are few treatment options and no cure," said Laurence Cooper, M.D., Ph.D., CEO of Ziopharm. "We are pleased the FDA has granted Fast Track designation and continue to believe this investigational drug has the potential to safely harness the power of interleukin-12, which in turn activates the patient's own immune system to attack this cancer and extend overall survival."

TRIAL RESULTS

Updated data following AACR presentation shows 50% CR and ~90% clinical benefit in Ph Ib/II trial of Onvansertib in R/R AML patients (http://trovageneoncology.investorroom.com/2019-04-05-Trovagene-Announces-Update-to-Phase-1b-2-AML-Trial-Data-Presented-at-AACR-Additional-Patients-Achieve-Complete-Response-at-Two-Highest-Dose-Levels-of-Onvansertib)

> Trovagene Announces Update to Phase 1b/2 AML Trial Data Presented at AACR – Additional Patients Achieve Complete Response at Two Highest Dose Levels of Onvansertib https://t.co/bK71E6nvtZ (https://t.co/bK71E6nvtZ)
>
> — RazzleTazzle (@RazzleTazzleMag) April 5, 2019 (https://twitter.com/RazzleTazzleMag/status/1114147180112240640?ref_src=twsrc%5Etfw)

"We are pleased with the response to treatment that we are seeing with onvansertib, as well as how safe and well tolerated it appears to be in this difficult-to-treat relapsed or refractory patient population," said Dr. Thomas Adams, Chief Executive Officer and Chairman of Trovagene. "As we continue advancing our AML trial to identify the maximum tolerated dose (MTD) and recommended Phase 2 dose (RP2D), we look forward to sharing additional readouts on the efficacy and safety of onvansertib and the potential opportunity to bring a much-needed new treatment option to relapsed or refractory AML patients."

Preliminary data from Ph II cohort of DECIDE trial of DPX-Survivac in low tumor burden ovarian cancer patients confirm Ph I trends (https://ir.imv-inc.com/news-releases/news-release-details/initial-phase-2-data-imv-clinical-study-continues-demonstrate)

> DPX-Survivac Treatment Continues to Show Promise in Women with Advanced Ovarian Cancer, Early Data Show https://t.co/nFByoq8Gqw (https://t.co/nFByoq8Gqw) pic.twitter.com/HuJMMIiWwm (https://t.co/HuJMMIiWwm)
>
> — BioNews Services (@bionewsservices) April 3, 2019 (https://twitter.com/bionewsservices/status/1113509785037627392?ref_src=twsrc%5Etfw)

"This initial phase 2 data confirms the earlier trends we saw in the phase 1b portion of the study," said Frederic Ors, Chief Executive Officer. "It supports the potential of DPX-Survivac as a monotherapy and the use of our patient selection strategy. We are encouraged by these early initial results and are committed to advancing this program quickly with the goal of providing an additional treatment option to patients with advanced ovarian cancer."

TRIAL/PROGRAM STATUSES

Merrimack discontinues development of MM-310 (http://investors.merrimack.com/node/11941)

> Merrimack Discontinues Development of its Investigational Solid Tumor Candidate MM310: CAMBRIDGE Mass. April 4 2019 PRNewswire &8212; Merrimack Pharmaceuticals Inc. Nasdaq MACK an oncology company focused on biomarkerdefined cancers today announced the... https://t.co/k7torYtW7M (https://t.co/k7torYtW7M)
>
> — Clinical Trials News (@ClinicalPhase) April 5, 2019 (https://twitter.com/ClinicalPhase/status/1114228977319596032?ref_src=twsrc%5Etfw)

"Due to our ongoing exploration of strategic alternatives and given these unfortunate challenges in identifying a clinically meaningful safety profile for MM-310, we have decided to halt further development of the program," said Richard Peters, M.D., Ph.D., President & Chief Executive Officer of Merrimack. "Additionally, as we have narrowed the scope of our pipeline to our two most promising preclinical programs, MM-401 and MM-201, we are initiating steps to close out remaining clinical activities in order to further preserve our resources. We continue to prudently advance these programs as we work expeditiously to bring our ongoing strategic process to conclusion."

HER2m+ mSalivary gland cancer and EGFR ex18m+ lung cancer cohorts to be added to Ph II SUMMIT trial (http://www.pumabiotechnology.com/pr20190404.html)

> Puma Biotechnology expands cohorts in phase II SUMMIT trial of Neratinib: The cohorts that have been expanded are i HER2 mutant patients with metastatic salivary gland cancer and ii patients with EGFR exon 18 mutationpositive lung cancer. The Phase The... https://t.co/ih3WaLoVxs (https://t.co/ih3WaLoVxs)
>
> — Clinical Trials News (@ClinicalPhase) April 5, 2019 (https://twitter.com/ClinicalPhase/status/1114093954289491969?ref_src=twsrc%5Etfw)

"We are pleased to expand our evaluation of neratinib in metastatic HER2 mutant salivary gland cancer and exon 18 mutated lung cancer from SUMMIT, as they both represent orphan and deadly diseases with few treatment options," said Alan H. Auerbach, Chief Executive Officer and President of Puma. "We believe this once again demonstrates the value of the basket study approach, in particular for developing targeted therapy for rare diseases with clinically-actionable mutations. We look forward to continuing enrollment into these expanded cohorts and presenting updated trial results."

Ph I trial of Galinpepimut-S (GPS) + Nivolumab in R/R malignant pleural mesothelioma to be initiated (https://www.sellaslifesciences.com/investors/news/News-Details/2019/SELLAS-Life-Sciences-Group-and-World-Renowned-Cancer-Center-to-Study-Galinpepimut-S-GPS-in-Combination-with-Nivolumab-in-Patients-with-Malignant-Pleural-Mesothelioma-MPM/default.aspx)

> $SLS (https://twitter.com/search?q=%24SLS&src=ctag&ref_src=twsrc%5Etfw) and World-Renowned Cancer Center to Study Galinpepimut-S (GPS), stock dives -8.70%, #SellasLifeSciences (https://twitter.com/hashtag/SellasLifeSciences?src=hash&ref_src=twsrc%5Etfw) https://t.co/NaD5GWhUNi (https://t.co/NaD5GWhUNi)
>
> — News Quantified (@NewsQuantified) April 4, 2019 (https://twitter.com/NewsQuantified/status/1113807140974501889?ref_src=twsrc%5Etfw)

"SELLAS is excited to embark upon this trial, as we look to expand the utility of GPS in combination with PD-1 inhibitors, and specifically nivolumab. The nivolumab/GPS immunotherapy combination is well positioned to exploit the unique features of each of these two agents through potential synergistic immune-based mechanisms of antitumor action. If positive, this clinical effort will allow us to consider advancing the clinical development of the combination of GPS and nivolumab in relapsed or refractory MPM as a potentially promising approach to treat patients with this recalcitrant thoracic malignancy," stated Dr. Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS.

Ph II trial of Telomelysin (OBP-301) – Pembrolizumab combination initiated in heavily-pretreated esophagogastric adenocarcinoma patients (https://www.oncolys.com/en/pdf/E_Press_Release_01072019.pdf)

> AACR 2019 Combo of virotherapy and radiotherapy shows early promise in patients with oesophageal cancer: he experimental oncolytic adenovirus telomelysin OBP301 in combination with radiotherapy was safe and showed early clinical efficacy in vulnerable... https://t.co/rK2ZoHOyty (https://t.co/rK2ZoHOyty)
>
> — Clinical Trials News (@ClinicalPhase) April 3, 2019 (https://twitter.com/ClinicalPhase/status/1113455515214831616?ref_src=twsrc%5Etfw)

"The Oncolys clinical development strategy for Telomelysin in esophageal cancer is designed to rationally exploit the compound's unique activity profile in combination with other therapies," said Mr. Yasuo Urata, president and chief executive officer of Oncolys BioPharma. One of the research concepts of Telomelysin is a "cure without surgery", and Oncolys is determined to continue to make a contribution to the development of effective cancer therapy by discovering the potential of Telomelysin combining it with another anti- tumor treatment".

Ph III MMY3021 trial to be initiated to evaluate SC Daratumumab in 1L post-transplant maintenance settings; primary endpoint: MRD conversion rate (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-phase-iii-study-exploring-daratumumab)

"We are pleased to see Janssen's continual commitment to evaluating the use of daratumumab in a wide array of settings and combinations. We are hopeful that the study will provide evidence of daratumumab's potential to provide a benefit to patients with multiple myeloma beyond current standard of care treatments in the maintenance phase of treatment," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

LN145 program updates – global IOV-COM-202 study to add Pembro combination arm for NSCLC patients; IOV-LUN-201 study to close (http://ir.lbio.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2393311)

> $IOVA (https://twitter.com/search?q=%24IOVA&src=ctag&ref_src=twsrc%5Etfw) to close IOV-LUN-201 study, add arm to IOV-COM-202 study, stock skyrockets +21.73% #IovanceBiotherapeutics (https://twitter.com/hashtag/IovanceBiotherapeutics?src=hash&ref_src=twsrc%5Etfw) https://t.co/Ec5MfQXxEE (https://t.co/Ec5MfQXxEE)
>
> — News Quantified (@NewsQuantified) April 3, 2019 (https://twitter.com/NewsQuantified/status/1113544558111936512?ref_src=twsrc%5Etfw)

"Based on the prior FDA interactions on lifileucel for melanoma, we amended the protocol for the ongoing Phase 2

study of LN-145 in cervical cancer to incorporate certain design elements that we believe are necessary for registration," commented Maria Fardis, Ph.D., president and chief executive officer of Iovance Biotherapeutics. "We believe these amendments will help to facilitate the discussion of the registration requirements necessary for this unmet medical need. We look forward to providing an update on the registrational path for LN-145 in cervical cancer later this year."

Patient dosing initiated in cohort 4 of Ph II pivotal InnovaTIL-01 trial of TIL therapy, Lifileucel, in metastatic Melanoma patients (http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2393137)

> Iovance Biotherapeutics Announces First Patient Dosed in Cohort 4 of Pivotal InnovaTIL-01 Study of Lifileucel in Metastatic #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw) https://t.co/ZuHbULDL25 (https://t.co/ZuHbULDL25) pic.twitter.com/j23Nc8pSAK (https://t.co/j23Nc8pSAK)
>
> — Ingentium Melanoma (@ingentium_mel) April 4, 2019 (https://twitter.com/ingentium_mel/status/1113641122809520134?ref_src=twsrc%5Etfw)

"Dosing of the first patient in Cohort 4, the pivotal arm of our melanoma program, is a significant step toward registration of TIL therapy," commented Maria Fardis, Ph.D., president and chief executive officer of Iovance. "Complete enrollment of this cohort is expected in early 2020 and we remain on track to file a Biologics License Application for regulatory approval of lifileucel in late 2020."

Ph II monotherapy trial of CD20-targeted ETB MT-3724 initiated in R/R DLBCL patients (http://ir.mtem.com/news-releases/news-release-details/molecular-templates-announces-initiation-phase-ii-monotherapy)

> Molecular Templates Presentations at the American Association of Cancer Research AACR Annual Meeting 2019 Highlight Evolution of ETB Platform: AUSTIN Texas April 02 2019 GLOBE NEWSWIRE Molecular Templates Inc. Nasdaq MTEM a clinical stage... https://t.co/bV039b1Iu2 (https://t.co/bV039b1Iu2) #diagnostics (https://twitter.com/hashtag/diagnostics?src=hash&ref_src=twsrc%5Etfw)
>
> — Molecular Diagnostics News & Research (@MolecularDia) April 2, 2019 (https://twitter.com/MolecularDia/status/1113041268345458688?ref_src=twsrc%5Etfw)

"We have been highly encouraged by the responses observed in the Phase I/Ib study of MT-3724 in heavily pretreated DLBCL patients," said Eric Poma, Ph.D., CEO and CSO of Molecular Templates. "This Phase II study largely replicates the Phase Ib expansion cohort, but with more clinical sites for enrollment, an independent data safety monitoring board, and independent central review for efficacy. Given the high level of unmet need in advanced DLBCL, we hope that this study will confirm that MT-3724 provides a meaningful benefit for this difficult to treat patient population."

Ph II CONTESSA TRIO trial of orally administered taxane Tesetaxel + IOs (Nivo/Pembro/Atezo) initiated in mTNBC patients; Tesetaxel monotherapy to be evaluated in elderly HER2neg mBC patients (https://ir.odonate.com/news-releases/news-release-details/odonate-therapeutics-initiates-contessa-trio)

> Tesetaxel Brain Concentrations Exceeded Concentrations Required for Tumor Killing for Sustained Period of Time in Preclinical Testing | Business Wire https://t.co/BH1M7f31OE (https://t.co/BH1M7f31OE) $ODT (https://twitter.com/search?q=%24ODT&src=ctag&ref_src=twsrc%5Etfw)
>
> — Joe Battaglia (@JBatta33) April 2, 2019 (https://twitter.com/JBatta33/status/1113061082946506752?ref_src=twsrc%5Etfw)

"Taxane-IO combinations hold great promise for patients living with TNBC," said Sara Tolaney, M.D., M.P.H., Associate Director, Susan F. Smith Center for Women's Cancers, Director, Clinical Trials, Breast Oncology at Dana-Farber Cancer Institute and Principal Investigator of CONTESSA TRIO. "This study will investigate the safety and antitumor activity of tesetaxel, an orally administered taxane with a distinct tolerability and pharmacokinetic profile, in combination with three approved PD-(L)1 inhibitors. CONTESSA TRIO also will investigate tesetaxel monotherapy in elderly patients with MBC, a patient population in need of easier-to-take and better tolerated therapies."

Patient enrolment completed in Ph I/II trial of T cell activating immunotherapy INO-5401 + PD-1 inh Cemiplimab-rwlc in 1L GBM patients (http://ir.inovio.com/news-and-media/news/press-release-details/2019/Inovio-Completes-Enrollment-Ahead-of-Schedule-In-Immuno-Oncology-Study-for-Glioblastoma-GBM-with-INO-5401-in-Combination-with-Regenerons-PD-1-Inhibitor/default.aspx)

> Inovio closes enrolment in Phase I/II glioblastoma trial https://t.co/kGma5WUX7C (https://t.co/kGma5WUX7C) via @PharmaTechFocus (https://twitter.com/PharmaTechFocus?ref_src=twsrc%5Etfw)
>
> — GuidantRx (@GuidantRx) April 3, 2019 (https://twitter.com/GuidantRx/status/1113481946603061248?ref_src=twsrc%5Etfw)

Dr. J. Joseph Kim, Inovio's President and Chief Executive Officer, said, "We sincerely thank the patients and their doctors for participating in our innovative combination trial. This is an important step for Inovio's cancer

combination strategy using our T cell-generating therapies in combination with PD-1/PD-L1 inhibitors for GBM and for multiple other cancers to improve overall efficacy of immunotherapy. We have previously shown in a Phase 1 head and neck cancer clinical study, combining Inovio's T cell-generating immunotherapy MEDI0457 along with checkpoint inhibitors have resulted in two complete responders who remain cancer free for over two years. In this GBM trial, our goal is to increase the overall survival of patients facing a disease where neither the standard of care, nor clinical outcomes have changed in a clinically significant way in more than a decade."

Seattle Genetics Completes Enrollment in Phase 2 Clinical Trial of Tisotumab Vedotin in Recurrent or Metastatic Cervical Cancer (http://investor.seattlegenetics.com/news-releases/news-release-details/seattle-genetics-completes-enrollment-phase-2-clinical-trial)

> Completing enrollment in this potentially pivotal phase 2 trial marks an important step forward in evaluating tisotumab vedotin for women with previously treated recurrent and/or metastatic cervical cancer. https://t.co/YPj81GX8e2 (https://t.co/YPj81GX8e2)
>
> — Connie Hampton (@BioRecruiter) March 31, 2019 (https://twitter.com/BioRecruiter/status/1112364974398152705?ref_src=twsrc%5Etfw)

"Cervical cancer is a devastating disease with a significant need to develop improved therapies for patients with metastatic disease who have progressed after treatment," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics. "Completing enrollment in this potentially pivotal phase 2 trial marks an important step forward in evaluating tisotumab vedotin for women with previously treated recurrent and/or metastatic cervical cancer."

COMPANION Dx

BRACAnalysis CDx® Test to identify gBRCA mutations in mCRPC patients (https://myriad.com/investors/news-release/news-release-detail/?newsItemId=20351)

> Myriad, Merck, And AstraZeneca Expand Collab On BRACAnalysis For Prostate Cancer Testhttps://t.co/41tkNQCcqI (https://t.co/41tkNQCcqI) #Medtech (https://twitter.com/hashtag/Medtech?src=hash&ref_src=twsrc%5Etfw)
>
> — Medtech Insight (@Medtech_Insight) April 4, 2019 (https://twitter.com/Medtech_Insight/status/1113864444315164673?ref_src=twsrc%5Etfw)

"Our companion diagnostic collaboration with AstraZeneca and Merck has led to significant advancements in precision treatment for patients with ovarian, breast cancer," said Nicole Lambert, president, Myriad Oncology. "However, there is a significant unmet medical need in men with metastatic castration-resistant prostate cancer and BRCA1/2 mutations, which is an area where the utility of PARP inhibitors is being explored. We look forward to this exciting opportunity to potentially expand the use of BRACAnalysis CDx in this setting."

COLLABORATIONS

BriaCell and Incyte to evaluate Bria-IMT with PD-1 inhibitor INCMGA0012 and IDO1 inhibitor epacadostat in advanced breast cancer patients (https://briacell.com/briacell-announces-clinical-trial-collaboration-agreement-with-incyte/)

"It is our belief that checkpoint inhibitors may significantly amplify the tumor-reducing effects of BriaCell's novel immunotherapy, Bria-IMT™, in advanced breast cancer patients. Incyte's portfolio has several candidates, including an anti-PD-1 monoclonal antibody and an IDO1 inhibitor, that we hope will improve the clinical benefits of Bria-IMT™," stated Dr. Bill Williams, BriaCell's President and Chief Executive Officer. "Incyte is a world-class biopharmaceutical company, we are aligned with the value that the team there places on innovation and we look forward to working with Incyte's scientists and clinical experts to develop novel therapeutics for advanced breast cancer patients."

Onco-this-Week Trivia

Snapshot of OCE Report 2018

The Oncology Center of Excellence of the FDA reports annually on its accomplishments and organization

In 2018, OCE & CDRH co-worked to achieve approval of 11 companion diagnostic products which include a new test for patients with acute myeloid leukemia (AML). This IDH1 genetic test assists to identify patients who are eligible for a new targeted therapy that can, in some cases, lead to remission.

Personalized Medicine

Diagnostics

In vitro diagnostic device or an imaging tool that provides essential information to the clinician

Therapeutic

Includes devices often used in combination with chemotherapy

Palliative

Relief of symptoms and improvement in quality of life.

https://www.fda.gov/downloads/Drugs/Guidances/ucm079543.pdf
https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/

About the Author:


(https://io.wp.com/www.sciwri.club/wp-content/uploads/2018/03/RT.jpg)

Richa (https://www.linkedin.com/in/richatewari/) earned her PhD at the National Brain Research Centre, India. For her thesis, she worked on the dreaded Glioblastoma multiforme. That was her first in-depth exposure to academic research in cancer biology. After her PhD, she expanded her research experience by working in the field of immunology at UCLA, USA. After her return to India, Richa switched to a corporate setting but continued her engagement with the cancer field. She is currently loving her work, which affords her the opportunity to continue developing her knowledge in the biomedical field of cancer. Outside of work, she enjoys watching, identifying and photographing birds.

Editor and Blog Design:

Abhi Dey (https://www.linkedin.com/in/abhinavdey/)

Abhi graduated from the Molecular Biophysics Unit of IISc (Bangalore, India) in 2011. As a Biomedical Scientist, he has worked with all three life-forms in his 13-year research career, viz., particulate, unicellular and multicellular. Currently, he is a Lead Scientist at MicroCures Inc. Previously, he served as 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 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: "This image, captured by Michele Balsamo of the Gertler Lab at the Koch Institute, shows metastatic breast tumors invading a lung." Source (https://ki-galleries.mit.edu/2011/balsamo)

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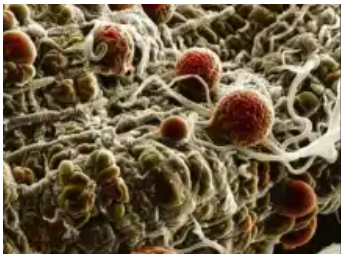

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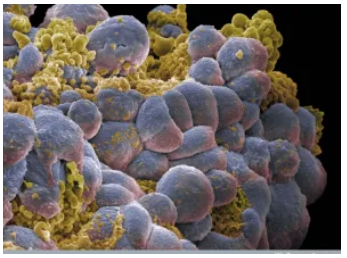

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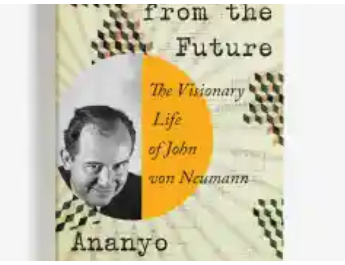

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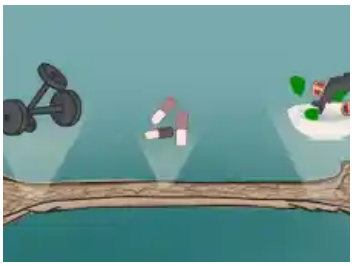

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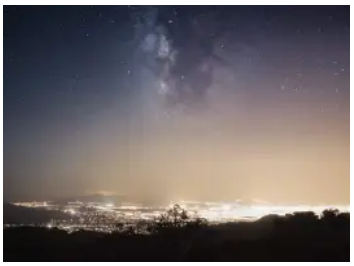

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