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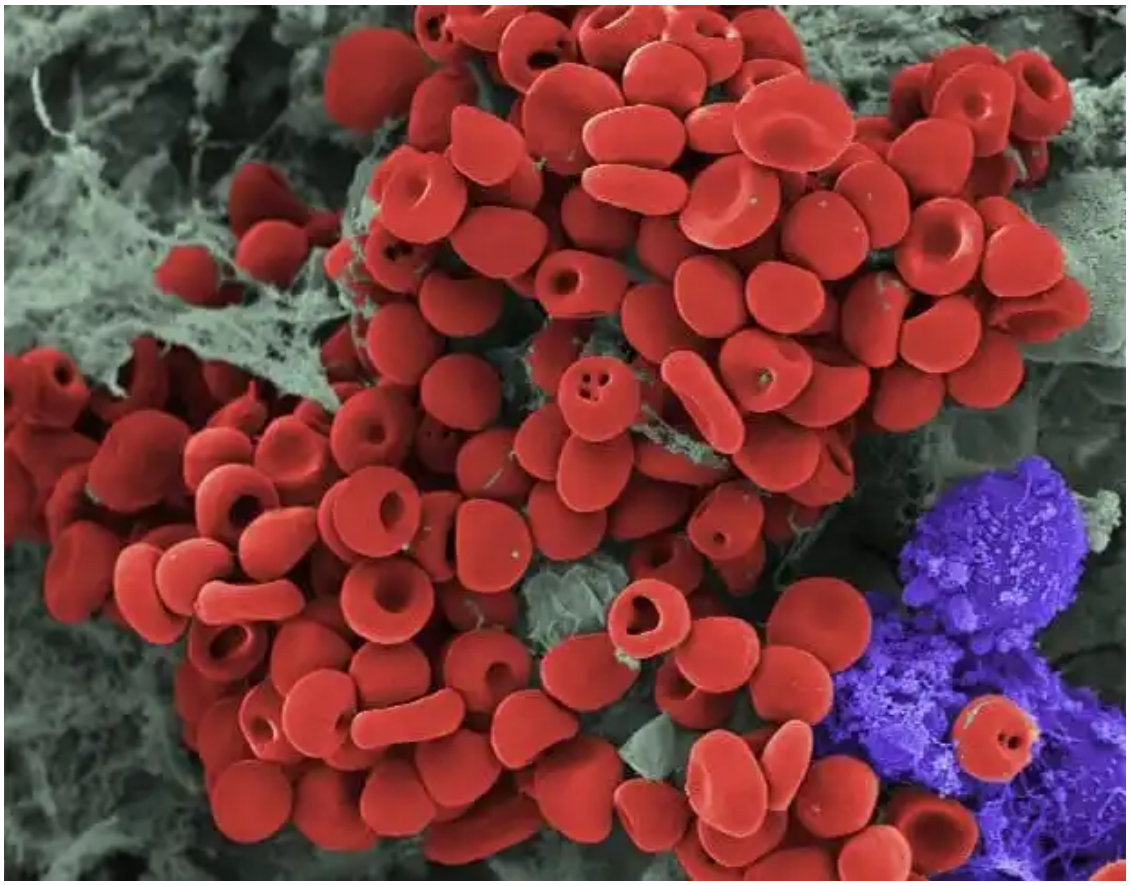
Onco-this-Week

August 4, 2018(https://sciwri.club/archives/date/2018/08/04)



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In the current edition of Onco-this-Week, Richa Tewari highlights Selumetinib's failure in Differentiated thyroid cancer (DTC) patients in Ph III ASTRA trial – AstraZeneca's drug thus completes a hattrick of failures. Also check out the news about a potential comeback of Buparlisib – Adlai Nortye gets global rights of this drug from Novartis. There is a flurry of activity in melanoma space in EU – approval of Nivolumab in adjuvant settings, and positive CHMP opinions to Encorafenib – Binimetinib and Dabrafenib – Trametinib combos in BRAF mutant melanoma patients.

The companies that we have covered this week include Merck, Bristol-Myers Squibb, Progenics, Pfizer, Genmab, Novartis, Trovagene, Daiichi Sankyo, Novocure, eFFECTOR, Surface

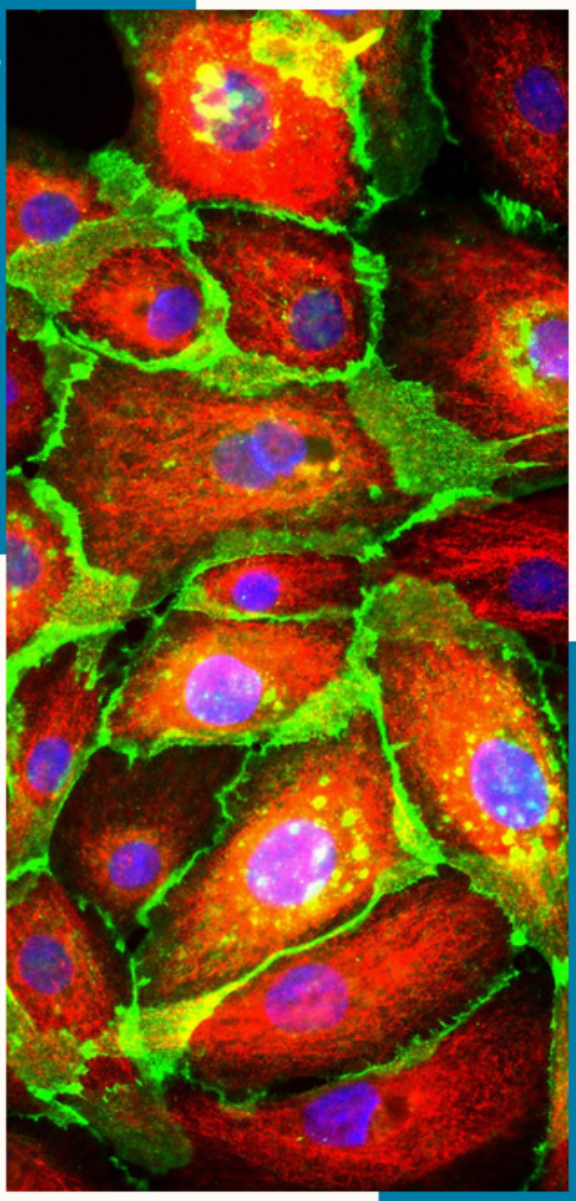
Oncology, Eisai, BioLineRx, Genprex, Medicenna & Genmab.

In the trivia section, we talk about the 4Rs of Cancer. Wondering what they are? Keep reading!

ONCO-THIS-WEEK TRIVIA

What are the 4Rs in Cancer?

RELAPSED, REFRACTORY, RESISTANT & RECURRENT



- **Relapsed** is defined as the development of disease progression following the achievement of stable disease (SD) or better to the most recent regimen

- **Refractory** is defined as experiencing cancer growth while on therapy

- **Resistant** is defined as experiencing cancer growth within some months after completion of the most recent regimen

- **Recurrent** is defined as cancer that has recurred (come back), usually after a period of time during which the cancer could not be detected. The cancer may come back to the same place as the original (primary) tumor or to another place in the body
  - o Local recurrence is defined as reappearance of cancer in the same place
  - o Regional recurrence denotes tumor involving the regional lymph nodes

(Source: https://www.cancer.gov/publications/dictionaries/cancer-terms?expand=R)
Image: Human mammary epithelial cells; Source: http://cellimagelibrary.org/images/48102

Biotechnologies

(https://goo.gl/XM63s6)

DRUG APPROVALS

EC approves Nivolumab in adjuvant settings in Melanoma patients based on CheckMate -238 trial results (https://news.bms.com/press-release/corporatefinancial-news/european-commission-approves-bristol-myers-squibbs-opdivo-ni-0)

"Stage III and IV melanoma patients are at high risk for disease recurrence after surgical removal and, therefore, in need of effective interventions to prevent recurrence," said James Larkin, M.D., Ph.D., Consultant Medical Oncologist, The Royal Marsden. "This is an important new treatment option, as the data support the benefit of nivolumab across a broad range of patients to address concerns around recurrence post-surgery."

> The European Commission approved adjuvant nivolumab as treatment for adult patients with completely resected melanoma with lymph node involvement or metastatic disease, regardless of BRAF mutation status... https://t.co/2xbfkHDsbj (https://t.co/2xbfkHDsbj) #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw) #melsm (https://twitter.com/hashtag/melsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/TwVgCoiRwR (https://t.co/TwVgCoiRwR)
>
> — Targeted Oncology (@TargetedOnc) August 2, 2018 (https://twitter.com/TargetedOnc/status/1024958097905909760?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are excited that *Opdivo* has become the first PD-1 agent to receive an approved indication from the EU in the adjuvant setting," said Fouad Namouni, M.D., head of oncology development, Bristol-Myers Squibb. "Today's approval helps strengthen patients' confidence in reducing the risk of recurrence and progression of melanoma after primary treatment and furthers our commitment to continuously explore new approaches that benefit more patients."

Iobenguane I 131 gets FDA approval in unresectable, locally advanced or metastatic Pheochromocytoma or Paraganglioma (https://progenicsgc.gcs-web.com/news-releases/news-release-details/progenics-pharmaceuticals-announces-fda-approval-azedrar)

"As the first FDA approved therapy for unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma who require systemic anticancer therapy, AZEDRA provides a new treatment option for physicians and their patients," said Mark Baker, Chief Executive Officer of Progenics. "AZEDRA has been shown to

decrease the need for blood pressure medication and reduce tumor size in some patients. We are extremely grateful to the patients, their families and the investigators who participated in AZEDRA's clinical development program. We also thank those who have contributed to the development of AZEDRA over many years."

> The U.S. Food and Drug Administration today approved Azedra (iobenguane I 131)
> Read More: https://t.co/J9JsJ9njLS (https://t.co/J9JsJ9njLS) pic.twitter.com/8IR1HsMyJX (https://t.co/8IR1HsMyJX)
>
> — VeedaCRO (Official) (@veedacr) August 1, 2018 (https://twitter.com/veedacr/status/1024550748682473472?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Emily Collins, President of the Pheo Para Alliance stated, "The FDA's approval of AZEDRA is welcome news to patients with pheochromocytoma and paraganglioma, who have an extremely limited number of treatment options available to them. The drug's Fast-Track status and Breakthrough Therapy designation by the FDA underscores the dire need for the development and expeditious review of diagnostic and therapeutic agents for pheo/para that, generally, don't get adequate prioritization despite the growing prevalence of these and other NET cancers globally."

TRASTUZUMAB biosimilar receives EU approval in HER2 overexpressing breast cancer and metastatic gastric or gastroesophageal junction adenocarcinoma (https://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_european_approval_for_oncology_biosimilar_trazimera_trastuzumab)

"TRAZIMERA has the potential to help many patients with HER2 overexpressing cancers, such as breast and gastric, which can correlate with poor outcomes and aggressive disease," said Professor Diana Lüftner, Charité Campus Benjamin Franklin and Member of the Presidency of the German Society of Hematology and Medical Oncology. "Today's approval will help enable greater access for patients and physicians across Europe, without compromising on quality, efficacy and safety."

> The European Union approved PF-05280014 (Trazimera), a biosimilar for trastuzumab for patients with HER2 overexpressing metastatic or early breast cancer and HER2 overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.
> Read more: https://t.co/6Rxc4k3e0O (https://t.co/6Rxc4k3e0O) pic.twitter.com/V8dMbWmM9V (https://t.co/V8dMbWmM9V)
>
> — Danielle Ternyila (@DaniTernyila) August 2, 2018 (https://twitter.com/DaniTernyila/status/1025100651632750594?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Richard Blackburn, Global President, Pfizer Essential Health Europe, Africa/Middle East and Biosimilars said "The approval of TRAZIMERA, Pfizer's first oncology biosimilar, is another significant step in our quest to introduce more treatment options for patients in Europe. Pfizer is investing in developing and launching a range of biosimilars which can help to reduce healthcare costs and increase patient access to important medicines."

REGULATORY NEWS

EMA adopts positive opinion for Pembrolizumab + Chemotherapy combination for 1L non-sq NSCLC and for 2L+ SCCHN (https://www.mrknewsroom.com/news-release/oncology/european-medicines-agency-adopts-positive-opinion-keytruda-pembrolizumab-combi)

“There is significant need for innovative therapies that can improve the overall survival of patients suffering from metastatic non-small cell lung cancer, as lung cancer is the leading cause of cancer deaths in Europe,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. “The KEYNOTE-189 trial demonstrated a significant survival benefit for the combination of KEYTRUDA with chemotherapy as compared with standard-of-care chemotherapy alone. We look forward to working with European regulatory authorities to bring this important treatment regimen to patients in Europe as quickly as possible.”

> EMA’s CHMP gives positive opinion to Merck’s pembrolizumab ... https://t.co/4ZOIoTm56i (https://t.co/4ZOIoTm56i) #Merck (https://twitter.com/hashtag/Merck?src=hash&ref_src=twsrc%5Etfw) #CHMP (https://twitter.com/hashtag/CHMP?src=hash&ref_src=twsrc%5Etfw) #pembrolizumab (https://twitter.com/hashtag/pembrolizumab?src=hash&ref_src=twsrc%5Etfw) #Keytruda (https://twitter.com/hashtag/Keytruda?src=hash&ref_src=twsrc%5Etfw) #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/56OE60KQNj (https://t.co/56OE60KQNj)
>
> — TRM Oncology (@TRMoncology) August 3, 2018 (https://twitter.com/TRMoncology/status/1025182528754331649?ref_src=twsrc%5Etfw)

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Daratumumab gets positive EU CHMP opinion in 1L MM patients based on Ph III ALCYONE study (http://ir.genmab.com/news-releases/news-release-details/chmp-issues-positive-opinion-recommending-darzalexr-1)

“We are very pleased to receive this positive opinion from the CHMP, as it is an important step towards potentially bringing daratumumab to an expanded number of patients throughout Europe,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

> UPDATE: CHMP of the European Medicines Agency (EMA) has recommended #daratumumab (https://twitter.com/hashtag/daratumumab?src=hash&ref_src=twsrc%5Etfw) as a frontline #MultipleMyeloma (https://twitter.com/hashtag/MultipleMyeloma?src=hash&ref_src=twsrc%5Etfw) treatment, following results of the ALCYONE study! 💊🇪🇺 👉 Check out @mvmateos (https://twitter.com/mvmateos?ref_src=twsrc%5Etfw) discussing the study here: https://t.co/KdrRqUfOGO (https://t.co/KdrRqUfOGO) #MMSM (https://twitter.com/hashtag/MMSM?src=hash&ref_src=twsrc%5Etfw) #Myeloma (https://twitter.com/hashtag/Myeloma?src=hash&ref_src=twsrc%5Etfw) #HemOnc (https://twitter.com/hashtag/HemOnc?src=hash&ref_src=twsrc%5Etfw) #hcsm (https://twitter.com/hashtag/hcsm?src=hash&ref_src=twsrc%5Etfw)
>
> — VJHemOnc (@VJHemOnc) August 3, 2018 (https://twitter.com/VJHemOnc/status/1025301510035578880?ref_src=twsrc%5Etfw)

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

Encorafenib + Binimetinib get positive EU CHMP opinion in advanced BRAFm+ Melanoma based on Ph III COLUMBUS trial (https://arraybiopharma.gcs-web.com/news-releases/news-release-details/braftovitm-encorafenib-mektovir-binimetinib-receives-positive)

“Following the recent U.S. FDA approval of BRAFTOVI + MEKTOVI for advanced *BRAF*-mutant melanoma, we are pleased to move one step closer to European approval,” said Ron Squarer, Chief Executive Officer. “We are proud that the combination of BRAFTOVI + MEKTOVI represents a new standard of care for *BRAF*-mutant melanoma patients in critical need of additional treatment options.”

> The #CHMP (https://twitter.com/hashtag/CHMP?src=hash&ref_src=twsrc%5Etfw) has been busy assessing #BRAF (https://twitter.com/hashtag/BRAF?src=hash&ref_src=twsrc%5Etfw) #MEK (https://twitter.com/hashtag/MEK?src=hash&ref_src=twsrc%5Etfw) inhibitors this month! #Braftovi (https://twitter.com/hashtag/Braftovi?src=hash&ref_src=twsrc%5Etfw) plus #Mektovi (https://twitter.com/hashtag/Mektovi?src=hash&ref_src=twsrc%5Etfw) is recommended for advanced #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw) and #Tafinlar (https://twitter.com/hashtag/Tafinlar?src=hash&ref_src=twsrc%5Etfw) plus #Mekinist (https://twitter.com/hashtag/Mekinist?src=hash&ref_src=twsrc%5Etfw) is recommended for adjuvant melanoma. Check out #DRGOncology (https://twitter.com/hashtag/DRGOncology?src=hash&ref_src=twsrc%5Etfw) for forecasts, data & insights! @DRGInsights (https://twitter.com/DRGinsights?ref_src=twsrc%5Etfw) pic.twitter.com/RoCTo8FSJC (https://t.co/RoCTo8FSJC)
>
> — Andrew Merron (@Amerron_DRG) July 27, 2018 (https://twitter.com/Amerron_DRG/status/1022867573459824642?ref_src=twsrc%5Etfw)

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Dabrafenib + Trametinib receive positive CHMP opinion for adjuvant treatment of BRAF V600m+ melanoma based on COMBI-AD trial data (https://www.novartis.com/news/media-releases/novartis-combination-tafinlarr-mekinistr-receives-positive-chmp-opinion-adjuvant-treatment-braf-v600-mutation-positive-melanoma)

“Melanoma is an aggressive, highly recurrent and often fatal disease. In advanced melanoma, we’ve demonstrated the ability to reduce the risk of death or recurrence by more than half,” said Liz Barrett, CEO, Novartis Oncology. “Today’s CHMP opinion brings us another step closer to reimagining earlier stage therapy for patients throughout Europe and making strides to bring improved outcomes for people living with melanoma.”

> CHMP gives positive opinion to Novartis’ dabrafenib + ... https://t.co/Vle150aab3 (https://t.co/Vle150aab3) #CHMP (https://twitter.com/hashtag/CHMP?src=hash&ref_src=twsrc%5Etfw) #Novartis (https://twitter.com/hashtag/Novartis?src=hash&ref_src=twsrc%5Etfw) #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw) #dabrafenib (https://twitter.com/hashtag/dabrafenib?src=hash&ref_src=twsrc%5Etfw) #trametinib (https://twitter.com/hashtag/trametinib?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/q0PoY1edu9 (https://t.co/q0PoY1edu9)
>
> — TRM Oncology (@TRMoncology) August 2, 2018 (https://twitter.com/TRMoncology/status/1025139707334877186?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“These relapse-free survival results are unprecedented,” said lead investigator Axel Hauschild, MD, PhD, Professor of Dermatology, University Hospital Schleswig-Holstein, in Kiel, Germany. “The overall survival improvements also demonstrated by Tafinlar in combination with Mekinist, among other key secondary endpoints, are encouraging in the treatment of stage III BRAF V600E/K mutation-positive melanoma. Adjuvant treatment options are critical for this patient community at risk for recurrence.”

Trovagene Receives Positive Opinion for Orphan Drug Designation in the European Union for PCM-075 (http://trovagene.investorroom.com/2018-08-01-Trovagene-Receives-Positive-Opinion-for-Orphan-Drug-Designation-in-the-European-Union-for-PCM-075-Trovagenes-Investigational-Cancer-Drug)

“The positive opinion from the EMAs Committee for Orphan Medicinal Products, based on our in vivo data supporting medical plausibility and the potential for significant benefit of PCM-075, marks another milestone in our efforts to improve the lives of patients suffering from AML,” said Dr. Thomas Adams, Chairman and Interim

Chief Executive Officer of Trovagene. “We believe that PCM-075, in combination with standard-of-care chemotherapies and targeted therapeutics, has the potential to provide significant clinical benefit with regard to efficacy and safety in patients with AML and we remain keenly focused on advancing our ongoing multi-center Phase 1b/2 clinical trial.”

> Trovagene Receives Positive Opinion for Orphan Drug Designation in the European Union for PCM-075, Trovagene’s Investigational Cancer Therapeutic for the Treatment of Patients with Acute Myeloid Leukemia https://t.co/Uac9USoLyX (https://t.co/Uac9USoLyX) pic.twitter.com/QNo5gcJyNx (https://t.co/QNo5gcJyNx)
>
> — Trovagene (@trovagene) August 1, 2018 (https://twitter.com/trovagene/status/1024626001270243333?ref_src=twsrc%5Etfw)

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SPECIAL STATUSES

Breakthrough Therapy Designation to FLT3 Inhibitor Quizartinib for R/R FLT3-ITD+ AML (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006896.html)

“There have been limited advances over the past several decades for the treatment of relapsed/refractory *FLT3*-ITD AML, a very aggressive form of the disease associated with poor prognosis. Quizartinib is the first FLT3 inhibitor to significantly improve overall survival as an oral, single agent compared to chemotherapy in patients with relapsed/refractory AML with *FLT3*-ITD, an underlying driver of this subtype of AML,” said Arnaud Lesegretain, Vice President, Oncology Research and Development and Head, AML Franchise, Daiichi Sankyo. “We are excited that quizartinib has received Breakthrough Therapy designation and we look forward to working closely with the FDA to bring this potential new treatment option to patients as quickly as possible.”

> A breakthrough therapy designation was granted to @DaiichiSankyo (https://twitter.com/DaiichiSankyo?ref_src=twsrc%5Etfw)’s quizartinib for the treatment of adult patients with relapsed/refractory FLT3-ITD acute myeloid #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) by the @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw).
>
> READ more: https://t.co/OHESoptCox (https://t.co/OHESoptCox) pic.twitter.com/sDhsLiyo8q (https://t.co/sDhsLiyo8q)
>
> — Rare Disease Report (@RareDR) August 3, 2018 (https://twitter.com/RareDR/status/1025486716365426689?ref_src=twsrc%5Etfw)

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Breakthrough Therapy Designation for Lenvatinib + Pembrolizumab in previously treated patients with advanced and/or metastatic non-MSI-H/pMMR Endometrial Carcinoma (https://www.mrknewsroom.com/news-release/oncology/eisai-and-merck-announce-fda-grants-breakthrough-therapy-designation-lenvima-l)

“This second Breakthrough Therapy designation for the LENVIMA/KEYTRUDA combination represents another step forward in our collaboration with Eisai and supports the continued evaluation of this combination in more than 11 types of cancer,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief

medical officer, Merck Research Laboratories. “We will continue to work closely with Eisai to build on the robust data for the LENVIMA/KEYTRUDA combination in advanced endometrial carcinoma in an effort to offer a new option for these patients and potentially help address a critical unmet need.”

> Eisai and Merck Announce FDA Grants Breakthrough Therapy Designation for LENVIMA® (lenvatinib) in Combination with KEYTRUDA® (pembrolizumab) as Therapy for Previously Treated Patients with Advanced and/or Metastatic non-MSI-H/pMMR Endometrial Carcinoma https://t.co/JK0T9HPBnH (https://t.co/JK0T9HPBnH) pic.twitter.com/UMRs07S215 (https://t.co/UMRs07S215)
>
> — Latest News from Business Wire (@NewsFromBW) July 31, 2018 (https://twitter.com/NewsFromBW/status/1024242338049056768?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“We designed Study 111 to learn as much as we could about the LENVIMA/KEYTRUDA combination as efficiently as possible, driven by a sense of urgency to bring forward a potential new treatment option for patients in need,” said Dr. Takashi Owa, Vice President and Chief Medicine Creation Officer, Oncology Business Group, Eisai. “We are encouraged by the continued activity seen in patients with endometrial carcinoma, and the latest Breakthrough Therapy designation for LENVIMA and KEYTRUDA has strengthened our commitment, as part of our *human health care* mission, to expedite the path to ultimately benefitting patients living with endometrial carcinoma as quickly as possible.”

Orphan Drug Designation to CD47 inhibitor SRF231 for the Treatment of Multiple Myeloma (https://investors.surfaceoncology.com/news-releases/news-release-details/fda-grants-orphan-drug-designation-surface-oncologys-srf231)

“While the potential applications for SRF231 in oncology are quite broad, we are particularly excited about the opportunity to provide benefit to patients with multiple myeloma. We have already demonstrated the ability of our antibody to increase phagocytosis of myeloma cells and to shrink tumors in preclinical models,” said Rob Ross, M.D., chief medical officer of Surface Oncology. “Receiving orphan designation for SRF231 represents an important milestone as we continue to progress the program in the clinic in multiple myeloma and other cancer types.”

> #MultipleMyeloma (https://twitter.com/hashtag/MultipleMyeloma?src=hash&ref_src=twsrc%5Etfw) treatment, #SRF231 (https://twitter.com/hashtag/SRF231?src=hash&ref_src=twsrc%5Etfw) of @SurfaceOncology (https://twitter.com/SurfaceOncology?ref_src=twsrc%5Etfw), was granted an orphan drug designation by the @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw).
>
> Read more: https://t.co/VvChHvnuDe (https://t.co/VvChHvnuDe) pic.twitter.com/N03RRwswIU (https://t.co/N03RRwswIU)
>
> — Rare Disease Report (@RareDR) July 31, 2018 (https://twitter.com/RareDR/status/1024399804150030343?ref_src=twsrc%5Etfw)

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RESULTS

Data published from biomarker analysis from BERIL-1, the Buparlisib study in HNSCC (https://www.prnewswire.com/news-releases/adlai-nortye-announces-the-publication-of-the-biomarker-analysis-from-beril-1-the-buparlisib-study-in-hnscc-300688244.html)

Mr. Yang Lu, the CEO of Adlai Nortye stated, “We are firmly committed to bringing Buparlisib to the market for the treatment of HNSCC and the findings in this study provide important direction for the future Buparlisib program (AN2025) in HNSCC. This is in line with Adlai Nortye’s strong commitment to developing unique therapeutic options for cancer patients.”

Dr. Denis Soulières, medical oncologist at Centre Hospitalier de l’Université de Montréal, Montréal, Canada, principal investigator on BERIL-1 and leading author of the publication, commented, “As investigators and treating physicians we are very excited to see the Buparlisib (AN2025) development moving forward in the HNSCC indication. HNSCC are the 6th most common cancers worldwide and 3rd most common cancers in the developing world. They account for about 5% of all malignancies worldwide and constitute a very important unmet medical need. Buparlisib (AN2025) showed strong results in a randomized trial in the second line setting of HNSCC and could become an important asset for the treatment of these patients.”

FAILED TRIAL: Guadecitabine did not meet the co-primary endpoints of CRR or OS in the ASTRAL-1 study (https://astx.com/astex-pharmaceuticals-and-otsuka-announce-results-of-the-phase-3-astral-1-study-of-guadecitabine-sgi-110-in-treatment-naive-aml-patients-ineligible-to-receive-intense-induction-chemotherapy/)

> Guadecitabine failed to improve complete response rate and overall survival in treatment-naïve adult patients with AML... Read on: https://t.co/WvpNTuOUXO (https://t.co/WvpNTuOUXO) Phase III endpoints in frontline AML missed.#leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/lK9VRAOKKP (https://t.co/lK9VRAOKKP)
>
> — Targeted Oncology (@TargetedOnc) August 3, 2018 (https://twitter.com/TargetedOnc/status/1025471466656223232?ref_src=twsrc%5Etfw)

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“We are disappointed in the outcome of the ASTRAL-1 study,” said Mohammad Azab, Astex’s president and chief medical officer. “The study used very strict criteria of ineligibility to receive intensive chemotherapy based on age (over 75 years) or poor performance status (ECOG PS of 2 or 3) or comorbidities, which made it a difficult population to show superior benefit of guadecitabine.” Dr. Azab also added, “ASTRAL-1 is the largest global prospective study ever conducted in this specific patient population with low intensity therapy, with 815 patients randomized, of whom about 90% were treated with hypomethylating agents or HMAs (guadecitabine, azacitidine, or decitabine). The large body of clinical and genetic data will still provide the medical community with very valuable insights into the role of several prognostic clinical and genetic markers that may influence outcome with HMA treatment. We are extremely grateful to all the patients, physicians and other healthcare professionals, and partner research and manufacturing organizations who contributed to this global effort. We are now looking forward to the completion of the ASTRAL-2 and ASTRAL-3 studies currently actively recruiting in two different indications.”

Results of Ph II INNOVATE trial of Tumor Treating Fields + Paclitaxel published; PFS doubles with TTFs (https://www.novocure.com/gynecologic-oncology-publishes-results-of-the-innovate-phase-2-pilot-study-demonstrating-combination-of-tumor-treating-fields-with-paclitaxel-may-improve-survival-of-patients-with-recurrent-ovarian-ca/)

“A clear unmet need remains for patients with recurrent ovarian cancer, particularly for those patients resistant to platinum-based chemotherapy, with median overall survival of about 13 months post recurrence,” said Dr. Ignace Vergote, Chairman of the Department of Obstetrics and Gynaecology and Gynaecologic Oncology at the Catholic University of Leuven, European Union, and an investigator in the trial. “These phase 2 pilot data show that Tumor Treating Fields combined with paclitaxel has the potential to increase survival without significantly

increasing side effects for recurrent ovarian cancer patients."

"These are encouraging results in a disease state that is very difficult to treat," said Dr. Eilon Kirson, Novocure's Chief Science Officer and Head of Research and Development. "We are now working to open INNOVATE-3, a phase 3 pivotal trial to further study Tumor Treating Fields for the treatment of recurrent ovarian cancer."

TRIAL STATUSES

Dosing of MNK1/2 inhibitor, tomivosertib, started as add-on therapy in NSCLC, urothelial, head and neck and HCC patients already receiving an PD/PD-L1 inhibitor (https://effector.com/2018/07/27/effector-initiates-dosing-of-eft508-tomivosertib-in-a-phase-2-add-on-cpi-a-trial-in-combination-with-checkpoint-inhibitors-to-treat-patients-with-insufficient-response-to-checkpoint-inhibitors-alo/)

"Despite the unprecedented activity of checkpoint inhibitors, the majority of patients fail to achieve a sufficient response to checkpoint inhibitor monotherapy, creating a critical need for combinations that improve outcomes," said Steve Worland, Ph.D., president and chief executive officer of eFFECTOR. "Because patients in this trial have already experienced an insufficient response to checkpoint inhibitors alone, it's an ideal environment to demonstrate a potential benefit of adding eFT508 to continued checkpoint inhibitor treatment. In preclinical studies, eFT508 demonstrated synergies with immune checkpoint blockade, so we believe there is great potential for this trial design, which allows us to broadly combine eFT508 with any approved checkpoint inhibitor in multiple indications."

> eFFECTOR Initiates Dosing of eFT508 (tomivosertib) in a Phase 2 Add-on (CPI-A) Trial in Combination with Checkpoint Inhibitors to Treat Patients with Insufficient Response to Checkpoint Inhibitors Alone https://t.co/D3HxLikLbR (https://t.co/D3HxLikLbR)
>
> — SPI News (@NewsFromSPI) July 27, 2018 (https://twitter.com/NewsFromSPI/status/1022808699134529536?ref_src=twsrc%5Etfw)

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Ph I/IIa trial for Glycolipid drug AGI-134 initiated in solid tumors (http://www.biolinerx.com/default.asp?pageid=16&itemid=617)

Prof. Mark Middleton of the University of Oxford, the study's principal investigator, stated, "We are very excited to be launching a first-in-human clinical trial assessing AGI-134 for the treatment of solid tumors. AGI-134 represents a new mechanistic class of cancer immunotherapies, with a unique and highly differentiated mode of action, harnessing pre-existing immune machinery to trigger a systemic anti-tumor response and create a pro-inflammatory tumor microenvironment. More treatment options are urgently needed for cancer patients and we are optimistic that AGI-134's encouraging pre-clinical results are going to translate to an efficacious and safe treatment for humans."

> BioLineRx Initiates Phase 1/2a Clinical Study for AGI-134, a Novel Immunotherapy for Treatment of Solid Tumors https://t.co/s9LSre8TSM (https://t.co/s9LSre8TSM)
>
> — NGT Consulting (@natGeneTherapy) August 2, 2018 (https://twitter.com/natGeneTherapy/status/1024984419168382976?ref_src=twsrc%5Etfw)

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"We are pleased to enter the clinic with our second lead oncology project," said Philip Serlin, Chief Executive Officer of BioLineRx. "Numerous pre-clinical studies to date have demonstrated that treatment with AGI-134 leads to regression of established primary tumors, prevents growth of untreated distal secondary tumors, and triggers a vaccine effect that may prevent the development of future metastases. Furthermore, a combination of

AGI-134 and an anti-PD-1 immune checkpoint inhibitor has demonstrated synergistic effect in protection from secondary tumor growth. We look forward to the first results of the Phase 1/2a study expected by the end of 2020. ”

Patient enrollment resumes in Ph I/II trial of Oncoprex/Erlotinib in NSCLC (http://ir.genprex.com/news-releases/news-release-details/genprex-updates-agreement-university-texas-md-anderson-cancer)

“We look forward to completing the Oncoprex/erlotinib trial and expanding the study of Oncoprex in combination with other targeted and immunotherapies in the future,” said Rodney Varner, Chairman and Chief Executive Officer of Genprex. “We believe the data from the more than 50 late-stage NSCLC patients treated to date provide persuasive evidence of Oncoprex’s anti-tumor effects and favorable safety profile.”

> $GNPX (https://twitter.com/search?q=%24GNPX&src=ctag&ref_src=twsrc%5Etfw) Genprex to enroll patients in study to evaluate anti-cancer agent #Oncoprex (https://twitter.com/hashtag/Oncoprex?src=hash&ref_src=twsrc%5Etfw) with FDA-approved Erlotinib @genprex (https://twitter.com/genprex?ref_src=twsrc%5Etfw) https://t.co/0AF3U8PNP5 (https://t.co/0AF3U8PNP5)
>
> — Proactiveinvestors (@proactive_NA) August 2, 2018 (https://twitter.com/proactive_NA/status/1025045426989359105?ref_src=twsrc%5Etfw)

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Medicenna provides development update on MDNA109 IL-2 superkine program (https://ir.medicenna.com/2018-08-02-Medicenna-Provides-Development-Update-on-MDNA109-IL-2-Superkine-Program)

“We believe that MDNA109 is the best in class IL-2 cytokine in development due to its highly selective CD122 targeting, ease of manufacture, superior safety, efficacy and remarkable versatility due to its synergy with check-point inhibitors and ability to develop novel immunocytokines, armed CAR-T cells or oncolytic viruses,” stated Dr. Fahar Merchant, Chairman, President and CEO of Medicenna. “Furthermore, recent pre-clinical data shows that fusions of MDNA109 with inactive protein scaffolds are long-acting and provide the convenience of easier dosing for the patient without sacrificing the safety and efficacy of MDNA109. We look forward to presenting our progress and results at upcoming conferences.”

> Medicenna Therapeutics Corp. updates its IL-2 Superkine program MDNA109, the only IL-2 in development that selectively targets CD122 due to its enhanced affinity. #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) #health (https://twitter.com/hashtag/health?src=hash&ref_src=twsrc%5Etfw) https://t.co/W9JoDjJKuh (https://t.co/W9JoDjJKuh) pic.twitter.com/lQ72Got24u (https://t.co/lQ72Got24u)
>
> — Biotechnology Focus (@BiotechFocus) August 2, 2018 (https://twitter.com/BiotechFocus/status/1025045357292646401?ref_src=twsrc%5Etfw)

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COLLABORATIONS AND LICENSING

Daiichi Sankyo to develop and commercialize TA-MUC1 antibody gatipotuzumab as an ADC (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006890.html)

“With the licensing of gatipotuzumab with the intention of developing an ADC, we now have seven novel ADCs in development, which demonstrate our commitment to maximizing the potential of our proprietary ADC payload and linker technology to help address the unmet needs of patients with cancer worldwide,” said Tom Held, Vice President, Head, Antibody Drug Conjugate Task Force, Oncology Research and Development, Daiichi Sankyo.

“We are excited by the rapid progress we have made in our collaboration with Glycotope and look forward to the continued clinical development of this potentially first-in-class TA-MUC1-targeting ADC.”

> #biotechnology (https://twitter.com/hashtag/biotechnology?src=hash&ref_src=twsrc%5Etfw) #biotechnology (https://twitter.com/hashtag/biotechnology?src=hash&ref_src=twsrc%5Etfw) Daiichi Sankyo and Glycotope reach agreement for firstinclass ADC: Daiichi Sankyo and Glycotope have signed a licensing agreement to develop an antibodydrug conjugate that enables tumorspecific binding to TAMUC1. https://t.co/DF4a2ScJ1H (https://t.co/DF4a2ScJ1H)
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> — BioPortfolio News Portal (@BioPortfolio) August 3, 2018 (https://twitter.com/BioPortfolio/status/1025421590413148160?ref_src=twsrc%5Etfw)

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“This agreement with Daiichi Sankyo highlights the potential and wide applicability of gatipotuzumab,” said Henner Kollenberg, Managing Director of Glycotope. “Our world-leading glyco-biology expertise has allowed us to create a novel anti-TA-MUC1 monoclonal antibody with carbohydrate mediated tumor-specificity and high affinity binding. We look forward to continuing to work with Daiichi Sankyo on this ADC program and on the further development of gatipotuzumab in other formats.”

Adlai Nortye Announce Global License Agreement for Buparlisib (BKM120) (http://www.adlainortye.com/en_newsdetail.php?cid=69&id=90)

“Combination of buparlisib and paclitaxel demonstrated improved clinical efficacy with a manageable safety profile in patients with HNSCC compared to paclitaxel alone,” said Dr. Lars Birgerson, Chief Development Officer of Adlai Nortye and President & CEO of Adlai Nortye USA Inc. “We believe that buparlisib will be another key component in furthering development of our oncology pipeline, and it has great potential for future application in cancer treatment.”

“Buparlisib has been extensively profiled in breast cancer and other tumor types. Buparlisib when combined with other therapies has shown impressive anti-cancer efficacy in HNSCC,” said Carsten Lu, CEO of Adlai Nortye, “It has very good market prospects when combined with paclitaxel, and we are planning to carry out clinical trials of combination of buparlisib and immune check point inhibitor treatment.”

BioLineRx and Merck expand IO collaboration in Pancreatic Cancer (http://www.biolinerx.com/default.asp?pageid=16&itemid=616)

“We are very excited to report the expansion of our immuno-oncology collaboration with Merck and the inclusion of an additional arm in the COMBAT/KEYNOTE-202 study. The decision to investigate the combination of BL-8040 and KEYTRUDA, together with chemotherapy, stems from the encouraging results we have seen in the trial,” stated Philip Serlin, Chief Executive Officer of BioLineRx. “These results continue to demonstrate the safety and tolerability of BL-8040, as well as validate its mechanism of action, namely that BL-8040 mobilizes immune cells into the peripheral blood, promotes T-cell infiltration into tumors, and has an effect on immuno-suppressive cells.”

> BioLineRx and Merck Expand Their Prostate Cancer Collaboration https://t.co/wwOWLdiMTd (https://t.co/wwOWLdiMTd) pic.twitter.com/JuX19LeYNf (https://t.co/JuX19LeYNf)
>
> — HealthIT and Biotech (@UCCharting) August 3, 2018 (https://twitter.com/UCCharting/status/1025505358406721537?ref_src=twsrc%5Etfw)

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“In light of this,” continued Mr. Serlin, “the addition of cytotoxic chemotherapy may be synergistic with the existing combination, due to the fact that besides helping to reduce the overall tumor burden, chemotherapy induces immunogenic cell death, thus leading to activation and expansion of new tumor-reactive T cells. Based on its demonstrated mechanism of action, BL-8040 should facilitate the infiltration of these T cells into the tumor core, alongside the restoration of T-cell activity within the tumor by KEYTRUDA. We look forward to presenting results from the dual combination arm of BL-8040 and KEYTRUDA in the COMBAT/KEYNOTE-202 study later this year, and expect to present results from the new triple combination arm of the study in the second half of next year.”

Laekna acquires rights of oral pan-AKT kinase inhibitors afuresertib (ASB183) and uprosertib (UPB795) from Novartis (https://www.prnewswire.com/news-releases/laekna-acquires-exclusive-worldwide-rights-to-two-clinical-stage-oncology-assets-300689735.html)

“Novartis is a global leader in oncology drug innovation. This is the second licensing agreement between Laekna and Novartis, adding to the previous licensing of CFG920 less than a year ago”, says Dr. Chris Lu, founder and CEO of Laekna. “We have demonstrated to Novartis that Laekna is a valuable collaborator with our strong commitment, experienced team and financing support from the top investment partners.”

> The Chinese pharma market gets a further boost, as Novartis licenses out global rights to two of its cancer drugs – afuresertib and uprosertib – to Laekna Therapeutics. https://t.co/vUNXeYpMZW (https://t.co/vUNXeYpMZW)#PharmaNews (https://twitter.com/hashtag/PharmaNews?src=hash&ref_src=twsrc%5Etfw) | #China (https://twitter.com/hashtag/China?src=hash&ref_src=twsrc%5Etfw) | #Oncology (https://twitter.com/hashtag/Oncology?src=hash&ref_src=twsrc%5Etfw)
>
> — Fraser Dove International (@FraserDoveInt) August 2, 2018 (https://twitter.com/FraserDoveInt/status/1025018716990447616?ref_src=twsrc%5Etfw)

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“We are dedicated to developing these products rapidly through the regulatory process and into commercialization, with the goal of ultimately benefitting patients around the world,” added Amy Xie, VP Operations at Laekna.

About the Author:


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

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

Editor and Blog Design:


(https://i1.wp.com/www.sciwri.club/wp-content/uploads/2016/06/Self2015.jpg)

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

Abhi graduated from the Molecular Biophysics Unit of IISc (Bangalore, India) in 2011. As a Biomedical Scientist, he has worked with all three life-forms in his 13-year research career, viz., particulate, unicellular and multicellular. He is currently an Assistant Scientist at Emory University (Atlanta, GA) studying mechanisms of tumor recurrence in kids with brain tumors. As a postdoctoral fellow, he was the recipient of two Young Investigator Awards from Alex Lemonade Stand Foundation (Philadelphia, PA) and Rockland Immunochemicals. His current research has been funded by Northwestern Mutual Foundation (Milwaukee, WI), CURE Childhood Cancer Foundation (Atlanta, GA) and American Association for Cancer Research (AACR). When he is not on the bench you will find him spending time with his family or exploring the world through traveling and blogging.

Image Sources: Wikipedia and Twitter

Cover image: (Cell Image Library) Description-Scanning electron micrograph of a hamster oocyte cumulus complex. Cumulus cells (purple) and matrix (gray) are shown. Small blood clots (red) also often appear in oocyte cumulus complexes. The red blood cells are 6-8 microns in diameter."- Source (http://cellimagelibrary.org/images/18042)

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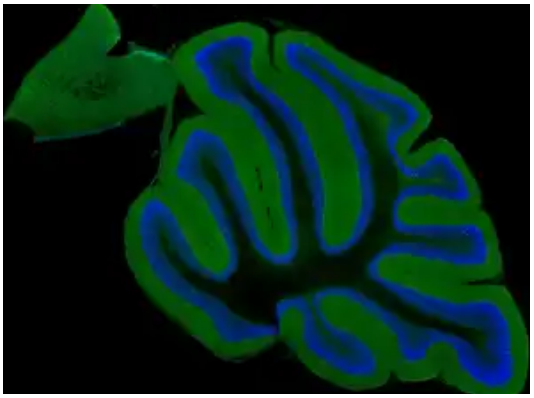

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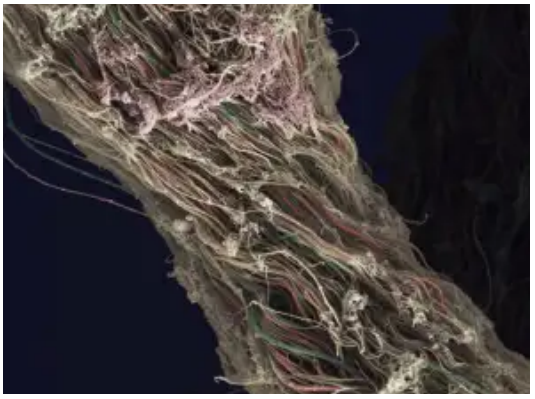

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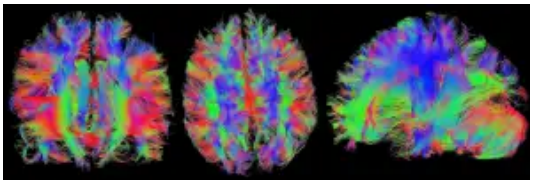

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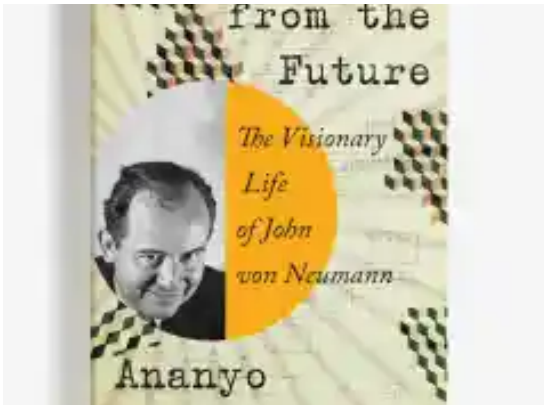

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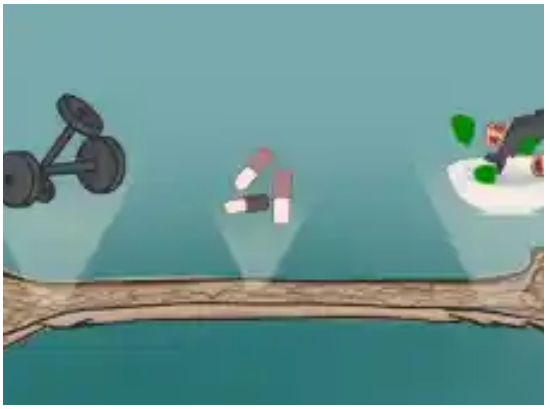

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