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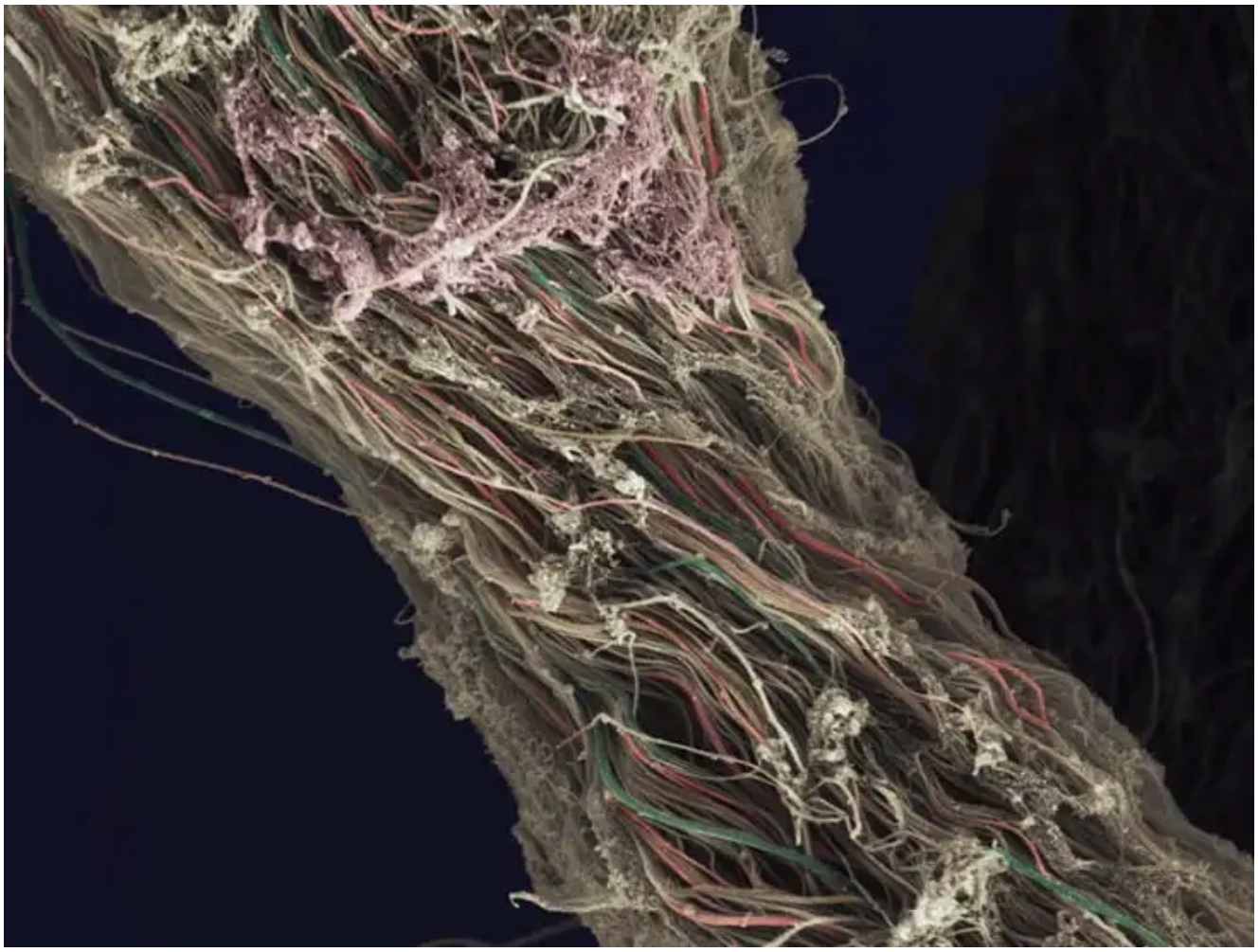
Onco-this-Week

September 1, 2018(https://sciwri.club/archives/date/2018/09/01)



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Editor's Summary: In the current edition of Onco-this-week, Richa Tewari presents FDA-accelerated approval of single-agent nivolumab for the treatment of patients with SCLC and Bristol-Myers Squibb's Application for Sprycel (dasatinib) in Pediatric Patients with Newly Diagnosed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia. Check out FDA's Fast Track Designation to Aravive's AVB-S6-500 for ovarian cancer and Breakthrough status to Y-mAbs' naxitamab + GM-CSF in pediatric R/R high-risk neuroblastoma Immunotherapy that targets GD2-expressing tumors. In other news, Unum Therapeutics files IND for its

antibody-coupled T cell receptor (ACTR) program.

In international news, AstraZeneca's Tagrisso gets a green light to be the first-line treatment in Japan for subset of lung cancers. European Commission Approves BLINCYTO® (blinatumomab) for use In Pediatric Patients and Jazz Pharma's Vyxeos for AML treatment. Novartis wins EU approval for blood cancer therapy Kymriah and European Commission grants Orphan Drug Designation to Onvansertib (PCM-075) for Treatment of acute myeloid leukemia.

We also begin a new section which showcases the highlights and analysis of this comprehensive news report and our regular Onco-this-Week Trivia features infographics on Black-Box Labeling of drugs.

Hope you enjoy reading this edition and staying updated on the latest in Oncology news!- Abhi Dey (https://www.linkedin.com/in/abhinavdey/)

HIGHLIGHTS AND ANALYSIS

1. EU approval of Amgen's leukemia drug, Vyxeos (an advanced liposomal formulation delivering a synergistic molar ratio of daunorubicin and cytarabine), coming after almost an year after its FDA approval. Vyxeos is the first chemotherapy to demonstrate an OS advantage versus the standard of care in a Phase III trial of older adult patients with newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC).

2. Back-to-back EU approvals of Yescarta (Axicabtagene Ciloleucel) in R/R DLBCL and PMBCL and Kymriah (tisagenlecleucel) in R/R B-ALL and DLBCL after EMA's CHMP recommended approval of both therapies in June. However, the long-term and late toxic effects of both still remain unknown. The physicians too will have to find the balance between life-saving versus QoL (quality of life)-preserving aspects of these two therapies.

3. Nivolumab's accelerated approval in R/R SCLC patients by FDA, which is the first in nearly 20 years, comes from results of ph I/II CheckMate-032 trial and is contingent on findings from a confirmatory study. While there have been several immunotherapy approvals in the past few years for NSCLC patients, there was hardly any progress in treatments—of any type—for advanced SCLC. The approval thus brings new hope for physicians and patients.

DRUG APPROVALS

Daratumumab approved in EU in 1L Multiple myeloma based on Ph III ALCYONE study results (http://ir.genmab.com/news-releases/news-release-details/genmab-announces-european-marketing-authorization-darzalexr-0)

"Approved in this indication in the U.S. since early May, DARZALEX in combination with bortezomib, melphalan and prednisone will now become an option for newly diagnosed multiple myeloma patients in Europe," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab. "We are very pleased that many more patients in need will have the opportunity for treatment with this regimen and we look forward to seeing this combination launched in Europe."

> Daratumumab is an effective agent in multiple myeloma. Its binding of CD38 on red cells causes false positive results on Coombs' blood-compatibility testing. F(ab')2 fragments of daratumumab block this binding and restore the accuracy of the test.
>
> — NEJM (@NEJM) July 7, 2018 (https://twitter.com/NEJM/status/1015664243016851456?ref_src=twsrc%5Etfw)

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

Blinatumomab approved in pediatric patients with Philadelphia chromosome-negative R/R B-ALL based on results from the Ph I/II '205 study (https://www.amgen.com/media/news-releases/2018/08/european-commission-approves-blincyto-blinatumomab-for-use-in-pediatric-patients-with-philadelphia-chromosomenegative-relapsed-or-refractory-bcell-precursor-acute-lymphoblastic-leukemia/)

“Historically, children with relapsed or refractory ALL have had limited pharmacologic options beyond chemotherapy, resulting in poor outcomes,” said David M. Reese, M.D., executive vice president of Research and Development at Amgen. “This approval for BLINCYTO provides physicians across Europe with an important new immunotherapy option for these young, heavily pretreated patients, delivering on Amgen’s commitment to making a difference in the lives of cancer patients.”

> European Commission Approves BLINCYTO® (blinatumomab) For Use In Pediatric Patients https://t.co/GR3JAMrotZ (https://t.co/GR3JAMrotZ) pic.twitter.com/qSolrIoLKN (https://t.co/qSolrIoLKN)
>
> — PICANTE Media (@Picante_Media) August 29, 2018 (https://twitter.com/Picante_Media/status/1034838793482731520?ref_src=twsrc%5Etfw)

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

EU approves Vyxeos for adults with some types of poor prognosis newly diagnosed, therapy-related acute myeloid leukaemia (t-AML) or AML with myelodysplasia-related changes (AML-MRC) (http://investor.jazzpharma.com/phoenix.zhtml?c=210227&p=irol-newsArticle&ID=2364833)

“*Vyxeos* is the first chemotherapy to demonstrate an overall survival advantage versus the standard of care in a Phase 3 study of older adult patients with newly diagnosed therapy- related AML or AML with myelodysplasia-related changes,” said Daniel Swisher, president and chief operating officer at Jazz Pharmaceuticals. “Jazz is committed to making *Vyxeos* available to patients in the EU and we will now pursue rolling launches of *Vyxeos* across the European Union on a country-by-country basis as pricing and reimbursement decisions are made.”

> EU approval for Jazz Pharma’s AML treatment Vyxeos https://t.co/iG5q46dabm (https://t.co/iG5q46dabm) pic.twitter.com/oZBbAMIoMe (https://t.co/oZBbAMIoMe)
>
> — Pharma Business Int (@PBIForum) August 28, 2018 (https://twitter.com/PBIForum/status/1034446032543703042?ref_src=twsrc%5Etfw)

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“AML is a rare cancer in Europe and patients with therapy-related AML or AML with myelodysplasia-related changes have a particularly poor prognosis compared to people with other forms of leukaemia,” said Professor Charles Craddock CBE, Academic Director, Centre for Clinical Haematology at University Hospitals Birmingham NHS Foundation Trust. “*Vyxeos* is a new and clinically meaningful treatment option that provides a welcome advance for patients and health care professionals across the European Union.”

Dabrafenib + trametinibfor approved in EU for adjuvant treatment of BRAF V600 mutation-positive melanoma based on Ph III COMBI-AD study results (https://www.novartis.com/news/media-releases/european-commission-approves-novartis-combination-therapy-tafinlar-mekinist-adjuvant-treatment-braf-v600-mutation-positive-melanoma)

“Novartis’ deep therapeutic knowledge and our ability to apply novel approaches to the development of new medicines has resulted again in a new treatment advance for melanoma patients,” said Liz Barrett, CEO, Novartis Oncology. “The European approval of the Tafinlar and Mekinist combination illustrates Novartis’ continued efforts to reimagine cancer by providing a highly effective, targeted therapy for earlier-stage melanoma patients.”

> Factors predictive of response, disease progression, and overall survival after dabrafenib and trametinib combination treatment: a pooled analysis of individual patient data from randomised trials https://t.co/1k5SIO5VMt (https://t.co/1k5SIO5VMt) pic.twitter.com/oLfkr3WZHs (https://t.co/oLfkr3WZHs)
>
> — Krishan Maggon (@kkmaggon) August 17, 2018 (https://twitter.com/kkmaggon/status/1030367597185912832?ref_src=twsrc%5Etfw)

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

Yescarta (Axicabtagene Ciloleucel) gets EU approval for R/R DLBCL and PMBCL, after two or more lines of systemic therapy (http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle&ID=2364850)

"Axicabtagene ciloleucel is a new and exciting way of treating cancer that offers a new option to patients with DLBCL and PMBCL in Europe," said Professor Gilles Salles, Head of Hematology, South Lyon Hospital Complex. "Many patients with these aggressive forms of non-Hodgkin lymphoma who have not responded to or failed commonly available treatment options have a very poor prognosis and there is an urgent need for new therapies."

> Just one day after the European Commission greenlighted Yescarta, a UK committee says the treatment is too expensive. https://t.co/pSa7at82zI (https://t.co/pSa7at82zI)
>
> — The Scientist (@TheScientistLLC) September 1, 2018 (https://twitter.com/TheScientistLLC/status/1035731471322017792?ref_src=twsrc%5Etfw)

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"We are proud to be leading this frontier of cancer innovation that is bringing novel, personalized therapy to people living with these blood cancers," said Alessandro Riva, MD, Gilead's Executive Vice President, Oncology Therapeutics & Head, Cell Therapy. "Our vision is for cell therapy to serve as the foundation for treating all cancer types. Today's milestone is another step on this exciting and important journey."

Kymriah® (tisagenlecleucel) scores EU approval in R/R B-ALL and DLBCL (https://www.novartis.com/news/media-releases/novartis-receives-european-commission-approval-its-car-t-cell-therapy-kymriah-tisagenlecleucel)

"The Kymriah approval is a transformational milestone for patients in Europe in need of new treatment options," said Liz Barrett, CEO, Novartis Oncology. "Novartis will continue to build a global infrastructure for delivering CAR-T cell therapies where none existed before remaining steadfast in our goal of reimagining cancer."

> Novartis wins EU approval for #bloodcancer (https://twitter.com/hashtag/bloodcancer?src=hash&ref_src=twsrc%5Etfw) therapy Kymriahhttps://t.co/y1vcE6povd (https://t.co/y1vcE6povd)
>
> — Xtalks Webinars (@Xtalks) August 31, 2018 (https://twitter.com/Xtalks/status/1035671134480551936?ref_src=twsrc%5Etfw)

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

"When the University of Pennsylvania and Novartis agreed to work together to develop CAR-T therapy, our main goal was clear and ambitious to address unmet needs for patients and to extend, improve and save lives," said Carl June, MD, the Richard W. Vague Professor in Immunotherapy in the Department of Pathology and Laboratory Medicine at Penn and Director of the Center for Cellular Immunotherapies in the Abramson Cancer Center. "We are proud that our efforts in CAR-T now offer the European blood cancer community a breakthrough that brings new hope."

Ibrutinib + Rituximab approved by FDA as First Chemotherapy-Free Combination Treatment in Adults with Waldenström's Macroglobulinemia based on Ph III iNNOVATE (PCYC-1127) trial results (https://news.abbvie.com/news/abbvie-announces-imbruvica-ibrutinib-plus-rituximab-approval-by-us-fda-as-first-chemotherapy-free-combination-treatment-in-adults-with-waldenstrms-macroglobulinemia-rare-type-blood-cancer.htm)

"We are pleased to have IMBRUVICA approved, both as a single agent and combination therapy with rituximab, to provide an additional efficacious treatment option for people living with Waldenström's macroglobulinemia," said Thorsten Graef, M.D., Ph.D., Head of Clinical Development at Pharmacyclics LLC, an AbbVie company. "We are proud of our robust clinical development program, and this new approval reflects our continuous commitment to exploring the full potential of IMBRUVICA's mechanism of action for treating patients with diseases that have great unmet medical need."

> Exciting new therapy for Waldenstr�m�s macroglobulinemia: ibrutinib plus rituximab https://t.co/WYMpK6ZHUO (https://t.co/WYMpK6ZHUO) pic.twitter.com/lAsH8mCnvA (https://t.co/lAsH8mCnvA)
>
> — Oncology Tube (@oncologytube) August 29, 2018 (https://twitter.com/oncologytube/status/1034938547734642688?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The iNNOVATE study demonstrated persuasive clinical evidence supporting the efficacy of IMBRUVICA plus rituximab in Waldenström's macroglobulinemia," said Dr. Meletios A. Dimopoulos, Professor and Chairman of the Department of Clinical Therapeutics, National and Kapodistrian University of Athens School of Medicine, Athens, Greece, and lead iNNOVATE study investigator.* "This approval is a significant milestone for the WM community who have limited treatment options."

"Ibrutinib has significantly advanced the treatment of Waldenström's macroglobulinemia. The approval of ibrutinib and rituximab has added a new option for many Waldenström's patients," said Steven P. Treon, M.D., Ph.D., Director of the Bing Center for Waldenström's Macroglobulinemia at the Dana-Farber Cancer Institute, Associate Professor at Harvard Medical School, and lead investigator of the IMBRUVICA Phase 2 clinical trial which served as the basis for its January 2015 FDA approval.*

EU approves Lenvatinib in 1L HCC patients based on Ph III REFLECT trial data (https://www.mrknewsroom.com/news-release/prescription-medicine-news/eisai-and-merck-announce-european-commission-grants-marketin)

"Patients with hepatocellular carcinoma are faced with a cancer that is difficult to treat and has a particularly poor prognosis, with only one systemic first-line treatment option currently available," said Gary Hendler, Chairman and CEO, Eisai EMEA. "LENVIMA is the first new treatment option to be made available in this first-line systemic treatment setting in over a decade and represents an important new therapeutic option for patients. Eisai and Merck are therefore committed to working together to ensure that patients have rapid access to LENVIMA across Europe."

#Merck (https://twitter.com/hashtag/Merck?src=hash&ref_src=twsrc%5Etfw), #Eisai (https://twitter.com/hashtag/Eisai?src=hash&ref_src=twsrc%5Etfw) Get #EU (https://twitter.com/hashtag/EU?src=hash&ref_src=twsrc%5Etfw) Approval for #Lenvima (https://twitter.com/hashtag/Lenvima?src=hash&ref_src=twsrc%5Etfw) #LabelExpansion (https://twitter.com/hashtag/LabelExpansion?src=hash&ref_src=twsrc%5Etfw) https://t.co/ZXOOHv9r1l (https://t.co/ZXOOHv9r1l) @MSN_Money (https://twitter.com/MSN_Money?ref_src=twsrc%5Etfw) @Merck (https://twitter.com/Merck?ref_src=twsrc%5Etfw) #tyrosinekinase (https://twitter.com/hashtag/tyrosinekinase?src=hash&ref_src=twsrc%5Etfw) #lenvatinib (https://twitter.com/hashtag/lenvatinib?src=hash&ref_src=twsrc%5Etfw) #hepatocellularcarcinoma (https://twitter.com/hashtag/hepatocellularcarcinoma?src=hash&ref_src=twsrc%5Etfw) #HCC (https://twitter.com/hashtag/HCC?src=hash&ref_src=twsrc%5Etfw) #livercancer (https://twitter.com/hashtag/livercancer?src=hash&ref_src=twsrc%5Etfw)

— Plexus Ventures (@PlexusVentures) August 27, 2018 (https://twitter.com/PlexusVentures/status/1034108409883369475?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“Today’s approval brings an important new first-line treatment option to patients with hepatocellular carcinoma in Europe,” said Dr. Jonathan Cheng, vice president, oncology clinical research, Merck Research Laboratories. “As a result of our efforts with Eisai on LENVIMA, we continue to make significant progress in gaining regulatory approval in countries around the world, as we strive together to make this medicine available to patients in need as quickly as possible.”

Priority review granted to elotuzumab+ pomalidomide + Low-Dose Dexamethasone in R/R MM patients based on Ph II ELOQUENT-3 trial data; PDUFA: Dec 27, 2018 (https://news.bms.com/press-release/bristolmyers/us-food-and-drug-administration-accepts-priority-review-bristol-myers-squ)

“This file acceptance is an important step in BMS’s ongoing efforts to advance treatment options for patients with relapsed/refractory multiple myeloma,” said Jeffrey Jackson, Ph.D., hematology development lead, Bristol-Myers Squibb. “Given the need for new, effective treatment options in this patient population, we look forward to working with the FDA with the hope of bringing this combination to patients with RRMM whose disease progressed on previous therapies as quickly as possible.”

FDA accepts BMS’ sBLA for elotuzumab + pomalidomide and LD ... https://t.co/JxLEtUbtdv (https://t.co/JxLEtUbtdv) #BMS (https://twitter.com/hashtag/BMS?src=hash&ref_src=twsrc%5Etfw) #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) #multiplemyeloma (https://twitter.com/hashtag/multiplemyeloma?src=hash&ref_src=twsrc%5Etfw) #elotuzumab (https://twitter.com/hashtag/elotuzumab?src=hash&ref_src=twsrc%5Etfw) #Empliciti (https://twitter.com/hashtag/Empliciti?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/QtIPi1vdiK (https://t.co/QtIPi1vdiK)

— TRM Oncology (@TRMoncology) August 30, 2018 (https://twitter.com/TRMoncology/status/1035293415452409856?ref_src=twsrc%5Etfw)

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Tagrisso approved in Japan in 1L EGFR-mutated NSCLC patients based on Ph III FLAURA trial data (https://www.astrazeneca.com/media-centre/press-releases/2018/tagrisso-approved-in-japan-for-1st-line-treatment-of-egfr-mutated-non-small-cell-lung-cancer-21082018.html)

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit, said: “Tagrisso is already

approved in Japan for the treatment of patients with EGFR T790M mutation-positive inoperable or recurrent NSCLC that is resistant to existing 1st-line EGFR-inhibitor medicines. Today's approval moves the use of Tagrisso to the 1st-line setting, replacing older medicines which, given the high prevalence of the EGFR mutation in Japan, offers an important new treatment option for these patients."

> AstraZeneca's #Tagrisso (https://twitter.com/hashtag/Tagrisso?src=hash&ref_src=twsrc%5Etfw) gets green light to be first-line treatment in #Japan (https://twitter.com/hashtag/Japan?src=hash&ref_src=twsrc%5Etfw) https://t.co/26I8yx31O2 (https://t.co/26I8yx31O2) @AstraZeneca (https://twitter.com/AstraZeneca?ref_src=twsrc%5Etfw) @EPM_Magazine (https://twitter.com/EPM_Magazine?ref_src=twsrc%5Etfw) #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/wokVc87qUw (https://t.co/wokVc87qUw)
>
> — Euro Pharma Mag (@EPM_Magazine) August 26, 2018 (https://twitter.com/EPM_Magazine/status/1033696871208955904?ref_src=twsrc%5Etfw)

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Nivolumab secures FDA approval in 2L+ Small Cell Lung Cancer (https://news.bms.com/press-release/corporatefinancial-news/us-food-and-drug-administration-approves-opdivo-nivolumab-firs)

"At Bristol-Myers Squibb, we recognize the critical need to provide patients with cancer therapies that may offer more durable responses – particularly for those living with hard-to-treat, aggressive diseases like small cell lung cancer," said Sabine Maier, M.D., development lead, thoracic cancers, Bristol-Myers Squibb. "This approval builds on our heritage of bringing Immuno-Oncology therapies to patients with other types of thoracic cancers. It also reinforces our commitment to bringing transformative treatments to patients in urgent need of effective new options."

> Josephine L. Feliciano, MD, comments on the data that led to the accelerated approval of single-agent nivolumab for the treatment of patients with SCLC #lcsm (https://twitter.com/hashtag/lcsm?src=hash&ref_src=twsrc%5Etfw) https://t.co/7ezC9FxRPs (https://t.co/7ezC9FxRPs)
>
> — OncLive SOSS (@OncLiveSOSS) August 29, 2018 (https://twitter.com/OncLiveSOSS/status/1034651901659361281?ref_src=twsrc%5Etfw)

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"While Immuno-Oncology innovations have dramatically changed how oncologists approach certain cancers, we have had limited progress for patients with small cell lung cancer," said Leora Horn, M.D., M.Sc., associate professor of medicine, Ingram associate professor of cancer research, director of the thoracic oncology program and assistant vice chairman for faculty development, Vanderbilt University Medical Center. "Today's approval of nivolumab is particularly exciting considering it is the first checkpoint inhibitor approved for these specific patients, and now we can finally treat this devastating disease from a different angle."

"Small cell lung cancer can be a very challenging disease, particularly for those who have already been through multiple types of treatment, as most patients relapse within a year of diagnosis,"7 said Andrea Ferris, president and chairman of LUNGevity Foundation. "This approval marks a major milestone for the patients touched by this unrelenting disease and may motivate them to pursue further treatment where there previously were no other approved options."

REGULATORY NEWS

sBLA accepted for Dasatinib in pediatric patients with 1L Philadelphia Chromosome-positive ALL based on

results from Ph II CA180-372 study; action date: Dec 29, 2018 (https://news.bms.com/press-release/corporatefinancial-news/us-food-and-drug-administration-accepts-bristol-myers-squibb-0)

"*Sprycel* was first established as an important treatment option for appropriate pediatric patients last year, when it was approved for the treatment of children with Ph+ chronic myeloid leukemia," said Jeffrey Jackson, Ph.D., development lead, hematology, Bristol-Myers Squibb. "This latest milestone in Ph+ ALL reinforces our commitment to researching the potential of *Sprycel* in different types of pediatric leukemia and to providing this vulnerable population with access to potential new therapies."

> U.S. Food and Drug Administration Accepts Bristol-Myers Squibb's Application for Sprycel (dasatinib) in Pediatric Patients with Newly Diagnosed Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia https://t.co/SHmafzxKON (https://t.co/SHmafzxKON) pic.twitter.com/3ZIbaV1xHI (https://t.co/3ZIbaV1xHI)
>
> — Latest News from Business Wire (@NewsFromBW) August 30, 2018 (https://twitter.com/NewsFromBW/status/1035121722767290368?ref_src=twsrc%5Etfw)

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

Loxo Oncology announces submission of European Marketing Authorization application for Larotrectinib (https://ir.loxooncology.com/press-releases/2364834-Loxo-oncology-announces-submission-of-european-marketing-authorization-application-for-larotrectinib)

"Larotrectinib has demonstrated exciting clinical responses in patients with TRK fusion cancer across various tumor types in both children and adults," said Ulrik Lassen, M.D., Ph.D., Department of Oncology, Rigshospitalet, Copenhagen. "The regulatory submission of larotrectinib in Europe moves us closer to being able to provide a targeted treatment option to these patients for which there is currently no approved therapy."

> Loxo Oncology submits European MAA for larotrectinib https://t.co/nnuLlJZFGX (https://t.co/nnuLlJZFGX) $LOXO (https://twitter.com/search?q=%24LOXO&src=ctag&ref_src=twsrc%5Etfw)
>
> — Breaking News (@MarketCurrents) August 27, 2018 (https://twitter.com/MarketCurrents/status/1034016313641906176?ref_src=twsrc%5Etfw)

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sNDA submitted for Carfilzomib QW 70 mg/m2 + Dexamethasone based on Ph III A.R.R.O.W. trial (https://www.amgen.com/media/news-releases/2018/08/amgen-submits-supplemental-new-drug-application-for-kyprolis-carfilzomib-onceweekly-70-mgm2-in-combination-with-dexamethasone/)

"I'm proud of our continued dedication to the KYPROLIS clinical program, with a focus on generating additional data to reduce the dosing and administration burden on patients with relapsed or refractory multiple myeloma," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Data from the Phase 3 A.R.R.O.W. study illustrates KYPROLIS' potential to extend the time patients live without their disease progressing while also providing a more convenient once-weekly dosing option for this frequently relapsing and difficult-to-treat cancer. We look forward to working with the Agency to bring this more streamlined dosing regimen to patients."

> @Amgen (https://twitter.com/Amgen?ref_src=twsrc%5Etfw) files #sNDA (https://twitter.com/hashtag/sNDA?src=hash&ref_src=twsrc%5Etfw) for #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw) combo regimen carfilzomib, dexamethasone https://t.co/Gl7FRfHfwa (https://t.co/Gl7FRfHfwa) pic.twitter.com/oRDfdI1yco (https://t.co/oRDfdI1yco)
>
> — Iowa Biotech Assoc. (@IowaBio) August 31, 2018 (https://twitter.com/IowaBio/status/1035542408312905733?ref_src=twsrc%5Etfw)

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Fast Track Designation granted to GAS6-AXL signaling pathway inhibitor AVB-S6-500 for platinum-resistant recurrent ovarian cancer (http://aravive.com/press-releases/u-s-fda-grants-fast-track-designation-to-aravive-biologics-avb-s6-500/)

"Gaining Fast Track Designation is an important recognition of the potential that AVB-S6-500 has to offer to meet a critical unmet medical need for patients with recurrent ovarian cancer," said Ray Tabibiazar, M.D., Executive Chairman of Aravive Biologics. "We look forward to initiating the Phase 1b portion of our planned Phase 1b/2 study combining AVB-S6-500 with standard-of care therapies in patients with platinum-resistant ovarian cancer before the end of the year."

> FDA grants Fast Track Designation to Aravive's AVB-S6-500 for ... https://t.co/Xq8Inx03fu (https://t.co/Xq8Inx03fu) #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) #Aravive (https://twitter.com/hashtag/Aravive?src=hash&ref_src=twsrc%5Etfw) #ovariancancer (https://twitter.com/hashtag/ovariancancer?src=hash&ref_src=twsrc%5Etfw) #AVBS6500 (https://twitter.com/hashtag/AVBS6500?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/p9ku2PIYoe (https://t.co/p9ku2PIYoe)
>
> — TRM Oncology (@TRMoncology) August 23, 2018 (https://twitter.com/TRMoncology/status/1032760000119271425?ref_src=twsrc%5Etfw)

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"We are very pleased that the FDA has granted Fast Track status to AVB-S6-500," said Gail McIntyre Ph.D., DABT, Senior Vice President of R&D at Aravive. "This important designation is based on the promising safety and activity observed to-date with AVB-S6-500, and we look forward to working closely with the FDA as we advance its development in ovarian cancer."

IND application for Antibody-Coupled T Cell Receptor (ACTR) platform in combination with Trastuzumab in HER2+ patients (http://globenewswire.com/news-release/2018/08/13/1551128/0/en/Unum-Therapeutics-Announces-Active-Investigational-New-Drug-IND-Application-for-Antibody-Coupled-T-Cell-Receptor-ACTR-platform-in-Combination-with-Trastuzumab-in-Patients-with-HER2.html?ev=1)

"We are very happy to reach this important milestone for patients and for Unum," said Chuck Wilson, Chief Executive Officer of Unum. "ACTR represents a promising novel technology that can be used to target different tumor types and it's exciting to expand its application to target solid tumors. We are committed to developing ACTR for patients with HER2+ advanced cancers who need better treatment options."

> Unum Therapeutics files IND for its #antibody (https://twitter.com/hashtag/antibody?src=hash&ref_src=twsrc%5Etfw)-coupled T cell receptor (ACTR) program
>
> Expects to initiate Ph1 #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) of #trastuzumab (https://twitter.com/hashtag/trastuzumab?src=hash&ref_src=twsrc%5Etfw)/ACTR combo vs advanced HER2+ #cancers (https://twitter.com/hashtag/cancers?src=hash&ref_src=twsrc%5Etfw) by end of 2018https://t.co/U6xnNsybkG (https://t.co/U6xnNsybkG)#immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) #biopharma (https://twitter.com/hashtag/biopharma?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/8N9JQ7Jn1p (https://t.co/8N9JQ7Jn1p)
>
> — DDNews Online (@DDNewsOnline) August 13, 2018 (https://twitter.com/DDNewsOnline/status/1029125282765000704?ref_src=twsrc%5Etfw)

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Priority review granted to ELZONRIS (tagraxofusp; SL-401) for the treatment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN); PDUFA: February 21, 2019 (https://www.stemline.com/newsArticleDetails.asp?id=197)

> #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) has accepted the Biologics License Application for #ELZONRIS (https://twitter.com/hashtag/ELZONRIS?src=hash&ref_src=twsrc%5Etfw) (tagraxofusp; SL-401) with 77% ORR and 54% CR in 13 blastic plasmacytoid dendritic cell neoplasm patients.#EHA (https://twitter.com/hashtag/EHA?src=hash&ref_src=twsrc%5Etfw) #immunotoxins (https://twitter.com/hashtag/immunotoxins?src=hash&ref_src=twsrc%5Etfw) #payload (https://twitter.com/hashtag/payload?src=hash&ref_src=twsrc%5Etfw) #toxins (https://twitter.com/hashtag/toxins?src=hash&ref_src=twsrc%5Etfw) #drugconjugate (https://twitter.com/hashtag/drugconjugate?src=hash&ref_src=twsrc%5Etfw) #targetedtherapies (https://twitter.com/hashtag/targetedtherapies?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/SndqLvwSDe (https://t.co/SndqLvwSDe)
>
> — Beacon Intelligence (@BeaconIntel) August 22, 2018 (https://twitter.com/BeaconIntel/status/1032288786552709123?ref_src=twsrc%5Etfw)

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

Ivan Bergstein, M.D., Stemline's CEO, commented, "The acceptance of our BLA for filing and grant of Priority Review represent tremendous milestones for Stemline and the BPDCN patient community. We would like to thank the patients and their families who participated in our clinical trials, as well as recognize the tireless work of our investigators and entire Stemline team. Given both Priority and Breakthrough status, our commercial organization is positioning itself to rapidly launch ELZONRIS, if approved, to ensure this important new treatment reaches patients as quickly as possible."

SPECIAL STATUSES

Orphan drug designation to PLK1 inh Onvansertib (PCM-075) for treatment of Acute Myeloid Leukemia in Europe (http://trovagene.investorroom.com/2018-08-29-Trovagene-Announces-European-Commission-Grants-Orphan-Drug-Designation-to-Onvansertib-PCM-075-for-Treatment-of-Acute-Myeloid-Leukemia-in-Europe)

"The European Commission's decision to grant orphan drug designation to Onvanersertib for the treatment of AML is a key regulatory milestone that will further facilitate our clinical development program," said Dr. Thomas

Adams, Executive Chairman of Trovagene. “We believe that Onvansertib, which previously received orphan drug designation for the treatment of AML from the FDA in the U.S., has the potential to provide a much-needed new therapeutic option for patients who are ineligible for induction therapy or who have relapsed/refractory disease.”

> European Commission grants Orphan Drug Designation to Onvansertib (PCM-075) for Treatment of acute myeloid leukemia https://t.co/0x7OJm98D1 (https://t.co/0x7OJm98D1) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/gLoqpzs875 (https://t.co/gLoqpzs875)
>
> — AML Global Portal (@AGP_hematology) September 3, 2018 (https://twitter.com/AGP_hematology/status/1036736103942971393?ref_src=twsrc%5Etfw)

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Y-mAbs Receives Breakthrough Therapy Designation for Naxitamab for the Treatment of High Risk Neuroblastoma (https://www.ymabs.com/page/release/y-mabs-receives-breakthrough-therapy-designation-for-naxitamab-for-the-treatment-of-high-risk-neuroblastoma/)

YmAbs Founder, President and Head of Business Development and Strategy, Thomas Gad said, “We are very pleased that the FDA has granted the Breakthrough Therapy designation to naxitamab and we look forward to continuing to work with the FDA to make this therapy potentially available to children facing an unmet medical need. We believe that Naxitamab provides a new opportunity for pediatric patients otherwise faced with little or no options. This is an important milestone achievement for YmAbs, and we continue to work with the regulatory authorities to advance naxitamab to patients suffering from high risk neuroblastoma as quickly as possible.”

> FDA grants Breakthrough status to Y-mAbs’ naxitamab + GM-CSF in paediatric R/R high-risk #neuroblastoma (https://twitter.com/hashtag/neuroblastoma?src=hash&ref_src=twsrc%5Etfw)#Immunotherapy (https://twitter.com/hashtag/Immunotherapy?src=hash&ref_src=twsrc%5Etfw) that targets GD2-expressing #tumors (https://twitter.com/hashtag/tumors?src=hash&ref_src=twsrc%5Etfw) is in Ph2 #clnicaltrails (https://twitter.com/hashtag/clnicaltrails?src=hash&ref_src=twsrc%5Etfw) (NCT03363373)https://t.co/FF5qrAy1Et (https://t.co/FF5qrAy1Et) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #biopharma (https://twitter.com/hashtag/biopharma?src=hash&ref_src=twsrc%5Etfw) #antibody (https://twitter.com/hashtag/antibody?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/voG6SkETw8 (https://t.co/voG6SkETw8)
>
> — DDNews Online (@DDNewsOnline) August 22, 2018 (https://twitter.com/DDNewsOnline/status/1032353333313327104?ref_src=twsrc%5Etfw)

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Dr. Claus Møller, Chief Executive Officer, further notes, “This is the first time naxitamab has earned the distinction of a Breakthrough Therapy Designation. We are pleased that the FDA continues to recognize the potential of naxitamab to help patients with high risk neuroblastoma.”

Orphan drug designation grated to Altered Energy Metabolism Directed (AEMD) drug CPI-613 for Treatment of Peripheral T-Cell Lymphoma (PTCL) (http://www.globenewswire.com/news-release/2018/08/16/1553115/0/en/Rafael-Pharmaceuticals-Receives-FDA-Orphan-Drug-Designation-of-CPI-613-for-the-Treatment-of-Peripheral-T-Cell-Lymphoma-PTCL.html)

Zanetta Lamar, MD, the Principal Investigator of this trial at Wake Forest Baptist commented: “This study of CPI-613 in combination with bendamustine in patients with relapsed or refractory T-Cell Lymphoma showed a good safety profile and encouraging efficacy. The orphan drug designation in this case provides hope to the poor-risk patient population, and inspires us to continue our tireless effort to bring these patients a legitimate treatment option.”

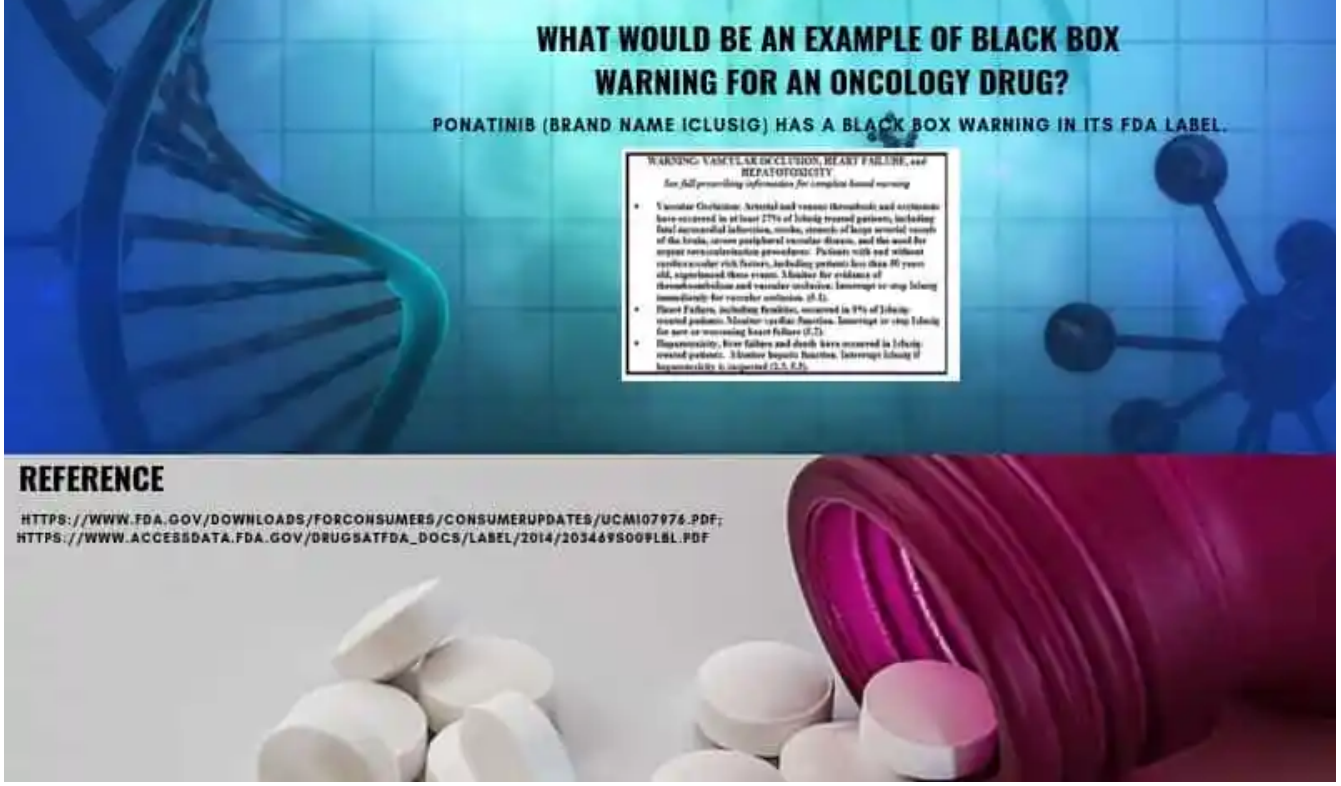
> Penn’s Abramson Cancer Center Added as Second Clinical Trial Site for CPI-613 in T-cell Lymphoma https://t.co/boIdFAptXT (https://t.co/boIdFAptXT) pic.twitter.com/07chrahcsE (https://t.co/07chrahcsE)
>
> — BioNews Services (@bionewsservices) September 4, 2018 (https://twitter.com/bionewsservices/status/1037047128189816832?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Sanjeev Luther, Rafael Pharmaceutical’s President and Chief Executive Officer, said, “Rafael is now the only oncology company in the U.S. with five orphan drug designations. These orphan drug designations include: Acute Myeloid Leukemia, Myelodysplastic Syndrome, Pancreatic Cancer, Burkitt’s Lymphoma, and now Peripheral T-cell Lymphoma, another patient population with severe unmet clinical need.”

CLR 131 receives FDA Rare Pediatric Disease Designation for treatment of Ewing’s Sarcoma (https://www.cellectar.com/news-media/press-releases/detail/186/cellectars-clr-131-receives-fda-rare-pediatric-disease)

> Ewings Sarcoma Treatment, CLR 131, Granted Rare Pediatric Disease Designation https://t.co/HM5gSqWVIz (https://t.co/HM5gSqWVIz) via @raredr (https://twitter.com/RareDR?ref_src=twsrc%5Etfw) pic.twitter.com/u3nyWfQSf2 (https://t.co/u3nyWfQSf2)
>
> — CURE ChildhoodCancer (@CUREchildcancer) August 14, 2018 (https://twitter.com/CUREchildcancer/status/1029511497343492096?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“We are delighted to announce receipt of our third RPDD from the FDA, which underscores Cellectar’s commitment to rare pediatric cancers. There is a critical need to develop new therapies to fight deadly childhood cancers such as Ewing’s sarcoma, and CLR 131 has shown early promise in this arena,” said John Friend, M.D., chief medical officer of Cellectar Biosciences. “This designation, combined with our receipt of FDA Orphan Drug Designation for Ewing’s sarcoma last month, will help support our efforts to optimize the drug development path in this indication and, if successful, enable this new therapeutic candidate is made available to patients as rapidly as possible.”



About the Author: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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)Colorized scanning electron micrograph of collagen/connective tissue removed from a human knee during arthroscopic surgery. The horizontal field width of the image is 16 microns. Wellcome Image Award 2012.B0008288. 2011 Collection: Wellcome Images Copyrighted work available under Creative Commons by-nc-nd 2.0 UK: England & Wales, see http://images.wellcome.ac.uk/indexplus/page/Prices.html- Source (http://cellimagelibrary.org/images/41738)

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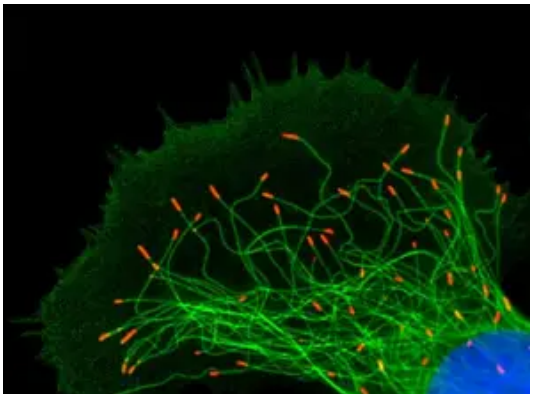

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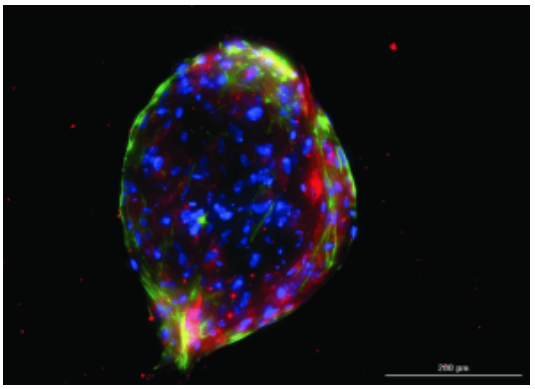

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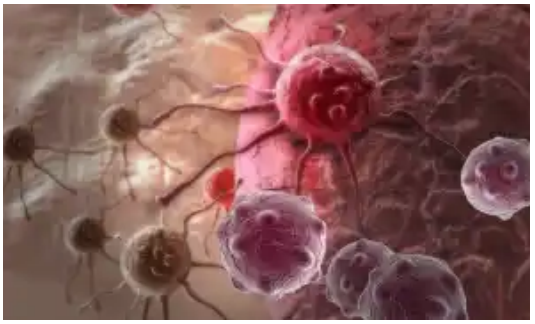

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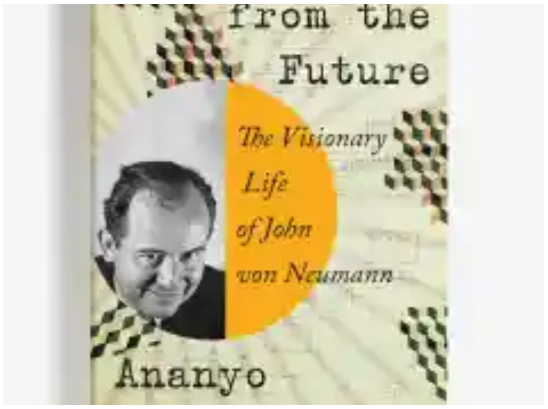

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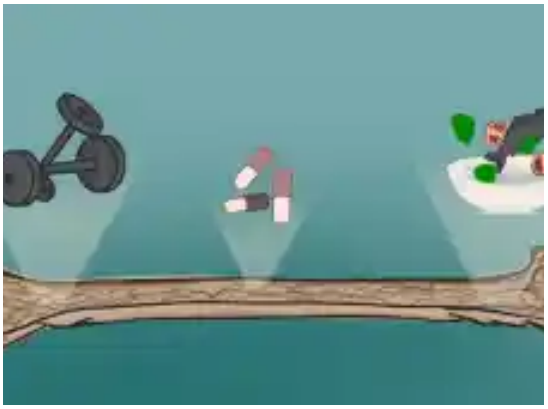

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