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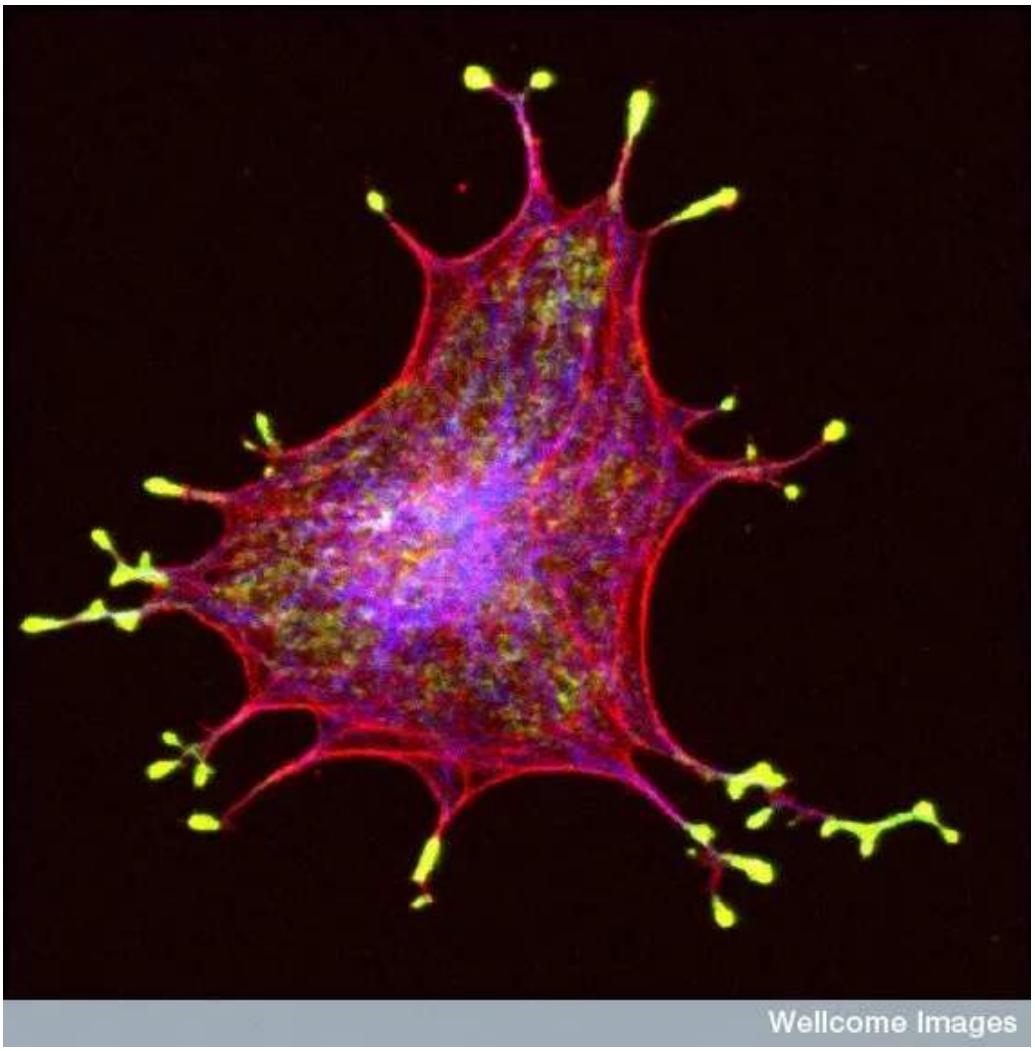
Onco-this-Week

October 14, 2018(https://sciwri.club/archives/date/2018/10/14)



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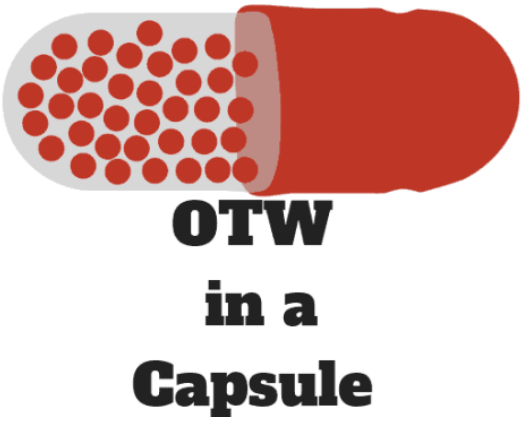
This Edition Of Onco-This-Week Highlights The Failure Of Nivolumab In Small Cell Lung Cancer, FDA's Priority Review Granted To Selinexor In Penta-Refractory Multiple Myeloma, And Iovance's Lifileucel Recieving Regenerative Medicine Advanced Therapy (RMAT) Designation For In Advanced Melanoma. If You Are Wondering What Is RMAT,

Then Check Out Our Trivia Section To Get A Comprehensive View. A Special Feature That We Have This Week Is A List Of Major Companies Who Are Attending European Society For Medical Oncology Congress-ESMO 2018- With The Links To Their Abstracts To Be Presented. If You Are Going To Be In Munich For ESMO 2018, Make Sure You Have Your Networking Plans In Place. -Abhi Dey



1. **Failure of Nivolumab in SCLC.** Nivolumab failed to meet primary endpoint of OS improvement in previously-treated SCLC patients in CheckMate-331 trial, dampening the hopes of a finding a viable therapeutic option in this aggressive tumor. It is important to note that BMS was evaluating several Nivolumab trials in SCLC in different settings with or without a combination with chemotherapy. Nivolumab even got accelerated approval in heavily pre-treated SCLC patients based on ORR results from CheckMate-032 trial! Would the failure of CheckMate-331 extend to CheckMate-032, revoking its approval or not in this tumor type with high unmet need?
2. **Priority review granted to Selinexor in penta-refractory Multiple Myeloma.** Penta-refractory multiple myeloma patients are those who would have previously received at least two IMiDs, two PIs, one alkylating agent, glucocorticoids, and daratumumab, thus essentially exhausting every therapeutic option in this disease area. In this niche area of heavily pre-treated patients, Selinexor is demonstrating good efficiency by more than doubling the overall survival obtained with historical controls. PDUFA is April 6, 2019 and it would be great to have a therapy option which is achieving great disease control rate.
3. **End of Phase 2 meeting of Iovance Biotherapeutics with FDA.** Iovance Biotherapeutics was not only granted a Regenerative Medicine Advanced Therapy (RMAT) designation for lifileucel in advanced melanoma based on data from the company's C-144-01 study, FDA also acknowledged the potential acceptability of a single-arm cohort for registration – something not very commonly seen in a area where randomized trials are considered the decisive ones. Even more surprising was FDA's opinion that conducting a randomized Ph III trial may not be feasible. Was it due to the specific patient population being enrolled (consisting of patients treated with at least one systemic therapy including a PD-1 inhibitor AND a BRAF inhibitor +/- MEK inhibitor if BRAF V600 mutation positive)?

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REGULATORY NEWS

Priority review granted to Selinexor in penta-refractory Multiple Myeloma; PDUFA: Apr 6, 2019 (http://investors.karyopharm.com/news-releases/news-release-details/us-food-and-drug-administration-accepts-karyopharms-new-drug)

> After a recent fast track designation approval in April, selinexor is now granted FDA priority review https://t.co/fzBLOLgHlU (https://t.co/fzBLOLgHlU) @MM_Hub (https://twitter.com/MM_Hub?ref_src=twsrc%5Etfw) #MYELOMA (https://twitter.com/hashtag/MYELOMA?src=hash&ref_src=twsrc%5Etfw) #mmsm (https://twitter.com/hashtag/mmsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/Gc1dSTWpgh (https://t.co/Gc1dSTWpgh)
>
> — Multiple Myeloma Hub (@MM_Hub) October 9, 2018 (https://twitter.com/MM_Hub/status/1049650343687151617?ref_src=twsrc%5Etfw)

"As a potential new therapy with a novel mechanism and compelling clinical profile, we believe oral selinexor, if approved, will provide a meaningful therapeutic option for patients battling highly resistant, penta-refractory myeloma," said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm. "The acceptance of this NDA for review and grant of Priority Review mark significant milestones for the selinexor program, and further underscores the high level of unmet need in this patient population. We look forward to working with the FDA during the review process."

Duvelisib added to NCCN guidelines for Follicular lymphoma based on data from Ph II DYNAMO trial; secures cat 2A recommendation (http://investor.verastem.com/phoenix.zhtml?c=250749&p=irol-newsArticle&ID=2370557\)

> Duvelisib delayed progression in CLL/SLL: study. https://t.co/dlw6aYoUkB (https://t.co/dlw6aYoUkB) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw)
>
> — CancerTherapyAdvisor (@CancerTherAdvsr) October 12, 2018 (https://twitter.com/CancerTherAdvsr/status/1050837930607038465?ref_src=twsrc%5Etfw)

"We are pleased that the NCCN has added COPIKTRA to their updated guidelines, which are recognized as an important resource for clinicians and other healthcare decision makers", said Robert Forrester, President and Chief Executive Officer of Verastem Oncology. "We believe COPIKTRA's inclusion illustrates its importance as an additional therapy option for relapsed or refractory patients suffering from FL."

IND application submitted to evaluate Tedopi®+ Nivolumab in Ph II TEDOPaM trial in HLA-A2 positive Pancreatic Cancer patients as 1L maintenance therapy (http://ose-immuno.com/site/wp-content/uploads/EN_181010_TEDOPAM_Accord-Reg.pdf)

"This new step marks the expansion of the development of Tedopi, already under evaluation in a Phase 3 study in advanced lung cancer, to an additional oncology indication, a particularly aggressive cancer for which new therapeutic options are strongly needed. With this new clinical development program evaluating Tedopi in combination with the PD-1 inhibitor nivolumab, a checkpoint inhibitor, in advanced pancreatic cancer, we are broadening our exploration of new pathways in immuno-oncology," commented Alexis Peyroles, chief executive officer of OSE Immunotherapeutics.

> We are pleased to announce the submission of an IND to initiate a Phase 2 #ClinicalTrial (https://twitter.com/hashtag/ClinicalTrial?src=hash&ref_src=twsrc%5Etfw) of Tedopi in combination with checkpoint inhibitor nivolumab in pancreatic cancer in partnership with GERCOR. https://t.co/4sZZoRbfHz (https://t.co/4sZZoRbfHz) $OSE (https://twitter.com/search?q=%24OSE&src=ctag&ref_src=twsrc%5Etfw) pic.twitter.com/M3vgSqTUpd (https://t.co/M3vgSqTUpd)
>
> — OSE_IMMUNO (@OSEIMMUNO) October 10, 2018 (https://twitter.com/OSEIMMUNO/status/1050056127600320514?ref_src=twsrc%5Etfw)

"The study's rationale is based on the interest of a combination of immunotherapies that stimulate cytotoxic T-cells with Tedopi, whose antigens are overexpressed in pancreatic tumor, and a PD-1 checkpoint inhibitor nivolumab, whose preclinical data available to date in this cancer plead in favor of a combination with a neoepitope-type immunotherapy, likely to potentiate its activity. Our network of clinicians is now mobilizing to start this Phase 2 trial," concluded Professor Christophe Louvet, president of GERCOR.

OncBioMune advancing ProscaVax towards second Ph II trial for Prostate Cancer with protocol submission to FDA (https://www.nasdaq.com/press-release/oncbiomune-advancing-proscavax-towards-second-phase-2-clinical-trial-for-prostate-cancer-with-20181011-00693)

> New Post: OncBioMune Readies for Enrollment in Phase 2 Trial of ProscaVax Vaccine https://t.co/utUp6YNAFw (https://t.co/utUp6YNAFw) pic.twitter.com/jaBwDTJLAw (https://t.co/jaBwDTJLAw)
>
> — Prostate Cancer News (@NewsProstate) October 11, 2018 (https://twitter.com/NewsProstate/status/1050520686626787328?ref_src=twsrc%5Etfw)

"We are thrilled to be working with the esteemed prostate cancer experts at UCNT and to have completed all necessary negotiations and protocol finalizations to move towards a second clinical trial of ProscaVax in late-stage patients. We believe that ProscaVax will again be able to deliver a meaningful therapeutic benefit to these patients with advanced disease that currently are presented with almost no safe and effective options," commented Dr. Jonathan Head, Chief Executive Officer at OncBioMune. "Combined with the initiation of the world's first ever study of a vaccine in early-stage prostate cancer patients in 'active surveillance' at a teaching hospital of Harvard University, we are steadily building our position as a leader in immunotherapy with a novel approach to prostate cancer. As we grow this footprint, we believe that there will be an increase in our market valuation followed by potential partnering opportunities."

Iovance Biotherapeutics reports results from FDA end of Ph II meeting (http://phx.corporate-ir.net/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2371343)

> Iovance released preliminary results of Ph2 TIL trial in melanoma: 37% ORR (1 CR, 16 PR of 46 total) in patients, progressed on CPI (PD-1) and BRAF-inhibitor https://t.co/JrSY5GyhSH (https://t.co/JrSY5GyhSH) Is first line CPI eliminating the possibility for post-TIL CR?
>
> — Alexey Bersenev (@cells_nnm) October 11, 2018 (https://twitter.com/cells_nnm/status/1050484780209463297?ref_src=twsrc%5Etfw)

"We are very excited with the progress made at Iovance during 2018. Specifically, we are pleased to have alignment with FDA regarding acceptability of a single-arm cohort to support registration of our lead product. In addition, we have greatly optimized our manufacturing process with Gen 2, leading to a scalable, commercial manufacturing process. We now have a global footprint with our clinical sites resulting in increased clinical enrollment and have produced sufficient data to discuss our registration path with FDA. As part of the recent interactions, we have also received an RMAT designation allowing for more frequent interactions with the FDA, benefiting from the agency's guidance during development of lifileucel," said Dr. Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics.

Orphan Drug Designation granted to Sutro's CD74-Targeting ADC "STRO-001" for treatment of Multiple Myeloma (https://www.sutrobio.com/sutros-stro-001-receives-u-s-fda-orphan-drug-designation-for-treatment-of-multiple-myeloma/)

"There is a growing need for new treatment options for patients with multiple myeloma," commented Bill Newell, Sutro's Chief Executive Officer. "This Orphan Drug Designation is a great step towards advancing our uniquely designed STRO-001 that could bring new treatment options to patients in need."

Exciting new class of ADCs (immunotherapy) for #multiplemyeloma (https://twitter.com/hashtag/multiplemyeloma?src=hash&ref_src=twsrc%5Etfw) patients. https://t.co/tWVJZX70KY (https://t.co/tWVJZX70KY) #mmsm (https://twitter.com/hashtag/mmsm?src=hash&ref_src=twsrc%5Etfw) #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw)

— Kathy Giusti (@KathyGiusti) October 12, 2018 (https://twitter.com/KathyGiusti/status/1050738489275367424?ref_src=twsrc%5Etfw)

"STRO-001 was designed to directly target cancer cells to deliver a cytotoxic payload. Building upon our XpressCF+TMplatform we plan to develop better options to treat tumors with greater precision," Bill Newell added.

TRIAL RESULTS

Ph III CheckMate-331 trial of Nivolumab failed to meet primary endpoint of OS improvement in SCLC patients (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-announces-phase-3-checkmate-331-study-doe)

Sabine Maier, M.D., development lead, thoracic cancers, Bristol-Myers Squibb, commented, "Small cell lung cancer is a highly aggressive disease in which significant unmet need remains. We are focused on researching innovative oncology therapies to improve outcomes for patients with lung cancer. We thank the patients, their families, and the physicians involved in the CheckMate -331 study."

Bristol's Checkmate-331 Failure Not Likely To Endanger SCLC Labeling For Opdivohttps://t.co/4Qz9qkslRi (https://t.co/4Qz9qkslRi) #PharmaScrip (https://twitter.com/hashtag/PharmaScrip?src=hash&ref_src=twsrc%5Etfw)

— Scrip (@PharmaScrip) October 13, 2018 (https://twitter.com/PharmaScrip/status/1051020314078052353?ref_src=twsrc%5Etfw)

Neoadjuvant Nivolumab + Ipilimumab combination trial yields high response rates for patients with high-risk stage 3 melanoma (https://www.mdanderson.org/newsroom/2018/10/neoadjuvant-combination-checkpoint-blockade-trial-yields-high-response-rates-for-melanoma-patients.html)

"In this trial, treatment with single-agent anti-PD-1 was associated with modest response rates, and we were concerned that two patients on that arm progressed and could not go to surgery," said co-first author Rodabe Amaria, M.D., assistant professor of Melanoma Medical Oncology. "Treatment with combined checkpoint blockade was much more effective, but at the expense of significant toxicity. It is clear from this trial that we need to further optimize this treatment approach."

Ipilimumab alone or in combination with nivolumab after progression on anti-PD-1 therapy in a... https://t.co/fPwU5OP1VR (https://t.co/fPwU5OP1VR) pic.twitter.com/kecvgDdWEj (https://t.co/kecvgDdWEj)

— Ingentium Melanoma (@ingentium_mel) October 13, 2018 (https://twitter.com/ingentium_mel/status/1051126808492560384?ref_src=twsrc%5Etfw)

“The advantage of a neoadjuvant approach in this setting is that it enables an interval evaluation of the tumor cells after therapy to determine the extent to which those tumor cells responded to the therapy in real time and predict which patients are likely to experience durable responses going forward. It also provides us the tissue resources to determine why tumors may not respond to therapy and thus tailor therapies going forward as we learn more about resistance,” said co-senior author on the study, Michael Tetzlaff, M.D. Ph.D., associate professor of Pathology and Translational and Molecular Pathology.

ET inhibitor BLU-667 shows broad, durable activity in advanced RET-altered Medullary and Papillary Thyroid Cancers (http://ir.blueprintmedicines.com/news-releases/news-release-details/blueprint-medicines-announces-updated-data-phase-1-arrow)

> Blueprint Medicines Announces Updated Data from Phase 1 ARROW Clinical Trial Showing Broad, Durable Activity of BLU-667 in Advanced RET-Altered Medullary and Papillary Thyroid Cancers https://t.co/a3x2GIfQBQ (https://t.co/a3x2GIfQBQ) #realestate (https://twitter.com/hashtag/realestate?src=hash&ref_src=twsrc%5Etfw) #CRE (https://twitter.com/hashtag/CRE?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/FrQCxegnew (https://t.co/FrQCxegnew)
>
> — CRE Demographics (@credemographics) October 6, 2018 (https://twitter.com/credemographics/status/1048559017386229760?ref_src=twsrc%5Etfw)

“Existing treatment of medullary and papillary thyroid cancer with multi-kinase inhibitors is limited by frequent dose modifications or interruptions due to off-target toxicities, reducing the opportunity for a meaningful or sustained response,” said Andy Boral, M.D., Ph.D., Chief Medical Officer of Blueprint Medicines. “These new data showed selectively targeting RET alterations with BLU-667 was well-tolerated and enabled durable responses. Importantly, response rates were high for patients with prolonged time on therapy at higher dose levels, demonstrating that potent and sustained target inhibition leads to improved patient outcomes. We believe these results begin to reveal the potential of BLU-667 to transform the care of patients with RET-altered thyroid cancer, and we look forward to seeing the data continue to mature as additional patients are treated at the recommended phase 2 dose for longer durations.”

92% ORR observed with BTK inhibitor Zanubrutinib in Waldenström’s Macroglobulinemia patients in Ph I trial (http://ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2371428)

> We’re proud to announce our new clinical collaboration with @BeiGeneUSA (https://twitter.com/BeiGeneUSA?ref_src=twsrc%5Etfw) to evaluate the combo of their BTK inhibitor, Zanubrutinib, with ME-401, our novel PI3K inhibitor. Read more on today’s news: https://t.co/Zj2e8nel8E (https://t.co/Zj2e8nel8E) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/oeCEqxTiXl (https://t.co/oeCEqxTiXl)
>
> — MEI Pharma (@MEI_Pharma) October 11, 2018 (https://twitter.com/MEI_Pharma/status/1050371201971838980?ref_src=twsrc%5Etfw)

“As we prepare our first U.S. New Drug Application (NDA) filing for zanubrutinib, which we expect to file in the first half of 2019 in patients with Waldenström’s Macroglobulinemia (WM), we are pleased to update data in patients with WM from the Phase 1 trial that will support our filing. With more than 70 patients with WM now

treated, we continue to see a high rate of deep and durable responses across genotypes, including high rates of overall, major, and very good partial responses (VGPRs)," commented Jane Huang, M.D., Chief Medical Officer, Hematology, at BeiGene. "We believe that the maturing data across B-cell malignancies continue to support a multi-regional approval strategy for zanubrutinib, including the ongoing NDA review in China for zanubrutinib in patients with relapsed/refractory mantle cell lymphoma by The National Medical Products Administration. We are hopeful that zanubrutinib, if approved, will represent a valuable treatment option across the globe for patients with several forms of B-cell malignancy."

TRIAL/PROGRAM STATUSES

Ph III pivotal trial (COSMIC-311) of Cabozantinib in radioiodine-refractory DTC patients initiated (http://ir.exelixis.com/phoenix.zhtml?c=120923&p=RssLanding&cat=news&id=2370576)

"Cabozantinib has demonstrated encouraging clinical activity in patients with radioiodine-refractory differentiated thyroid cancer in phase 1 and 2 studies, suggesting it may be a promising treatment option for patients who have progressed after prior VEGFR-targeting therapy," said Gisela Schwab, M.D., President, Product Development and Medical Affairs and Chief Medical Officer, Exelixis. "We look forward to enrolling patients in this global trial to learn more about the potential of cabozantinib for this intractable form of thyroid cancer."

> Cabozantinib active in RAI-refractory thyroid cancer: https://t.co/KjIZJn1rfy (https://t.co/KjIZJn1rfy)
>
> — Medscape Oncology (@MedscapeOnc) February 15, 2018 (https://twitter.com/MedscapeOnc/status/964228704816779264?ref_src=twsrc%5Etfw)

"With the incidence of thyroid cancer increasing more rapidly than any other type of cancer in the U.S., and limited options available to patients whose disease has progressed following anti-VEGFR therapy, there is an urgent need for new treatments," said Marcia Brose, M.D., Ph.D., Associate Professor of Otorhinolaryngology: Head and Neck Surgery and Director of the Center for Rare Cancers and Personalized Therapy at the Abramson Cancer Center of the University of Pennsylvania, and principal investigator of the trial. "Given the positive results from earlier stage trials, we are eager to learn more from this phase 3 study about cabozantinib's potential benefit in this patient population."

Patient dosing started in Ph I/IIa trial of Bria-IMT™ + Pembrolizumab or ipilimumab in advanced breast cancer (http://briacell.com/2018/10/09/briacell-initiates-dosing-in-phase-iiia-combination-study-with-keytruda-or-yervoy/)

"We believe that combination of Bria-IMT™ with immune checkpoint inhibitors should create even more potent anti-cancer immune responses, leading to our strategy of combination studies of Bria-IMT™ with KEYTRUDA® or YERVOY®," stated BriaCell's President and CEO, Dr. Bill Williams. "BriaCell is committed to exploring additional ways to address the unmet needs of the advanced breast cancer community. We are very excited to test this novel combination treatment approach which we believe will offer significant clinical benefit to patients with advanced breast cancer."

> Briacell Therapeutics Bria-IMT Mechanism of Action https://t.co/jNxzJnBbFL (https://t.co/jNxzJnBbFL) pic.twitter.com/L9e2uxqiRE (https://t.co/L9e2uxqiRE)
>
> — Krishan Maggon (@kkmaggon) May 4, 2018 (https://twitter.com/kkmaggon/status/992297522600148992?ref_src=twsrc%5Etfw)

Ph II trial to evaluate non-steroidal SERM drug oral Lasofoxifene in ESR1 mutation positive women with ER+/HER2- metastatic Breast Cancer (https://www.morningstar.com/news/globe-news-wire/GNW_7399310/sermonix-launches-phase-2-trial-to-evaluate-investigational-oral-lasofoxifene-as-a-targeted-precision-treatment-for-women-with-esr1-mutations-in-metastatic-breast-cancer.html)

"Clinical data have shown a significant reduction in the incidence of ER+ breast cancer in postmenopausal women with osteoporosis who were treated with lasofoxifene," said Paul Plourde, MD, Sermonix vice president of clinical development. "Additional non-clinical and clinical study results provide further impetus for undertaking a Phase 2 trial in a targeted way that compares lasofoxifene to fulvestrant, a current, widely used injectable medication for advanced metastatic breast cancer."

> Sermonix launches their Phase 2 Trial for Lasofoxifene as a targeted precision treatment for women with ESR1 mutations in metastatic breast cancer: https://t.co/H6g9Oey1dt (https://t.co/H6g9Oey1dt) pic.twitter.com/Uvj9NAQiu4 (https://t.co/Uvj9NAQiu4)
>
> — LinicalAccelovanceGroup (@Accelovance) October 9, 2018 (https://twitter.com/Accelovance/status/1049709944025563136?ref_src=twsrc%5Etfw)

"Sermonix selected Linical Accelovance to be our clinical research development partner for this program because we are impressed with the organization's integrated clinical trial services, as well as its operational capabilities in the development of oncology drugs," said Sermonix Chief Operating Officer Dr. Miriam Portman.

Ph Ib/II trial to evaluate the safety and efficacy of LB-100 in R/R low or intermediate-1 Risk Myelodysplastic Syndrome patients (https://globenewswire.com/news-release/2018/08/21/1554629/0/en/Lixte-Biotechnology-Announces-a-Clinical-Trial-Agreement-with-Moffitt-Cancer-Center-to-Initiate-Phase-1b-2-Trial-Evaluating-the-Safety-and-Efficacy-of-LB-100-in-Treatment-of-Patien.html)

Dr. John S. Kovach, founder and CEO of Lixte, said, "Certain cancers possessing unique genetic changes are vulnerable to inhibition of an enzyme, protein phosphatase 2A (PP2A), by LB-100. Among these is myelodysplastic syndrome (MDS), an increasingly common family of neoplastic diseases, especially in persons aged 65 and older. MDS is characterized by failure of the bone marrow often causing significant anemia and requiring frequent blood transfusions. In preclinical models of MDS, treatment with LB-100 inhibits the growth and/or induces the death of the abnormal blood cells. Cells of one variant of MDS, termed del(5q) MDS, are missing 50% of their PP2A activity rendering them sensitive to PP2A inhibition."

"We are excited to embark on the clinical investigation of LB-100 in lower-risk MDS patients. If LB-100 proves to be effective in the clinic, it could be an important addition to the limited treatment options for patients failing standard treatment," said David Sallman, M.D., assistant member of Moffitt's Malignant Hematology Department.

Ph II MANIFEST trial of BET inhibitor CPI-0610 in Myelofibrosis patients enhanced and expanded (http://ir.constellationpharma.com/news-releases/news-release-details/constellation-pharmaceuticals-enhances-and-expands-phase-2)

> Constellation Pharmaceuticals Enhances and Expands Phase 2 MANIFEST Study of CPI-0610 in Myelofibrosis $CNST (https://twitter.com/search?q=%24CNST&src=ctag&ref_src=twsrc%5Etfw) https://t.co/mLog2uFPGl (https://t.co/mLog2uFPGl)
>
> — GNWLive (@GNWLive) October 10, 2018 (https://twitter.com/GNWLive/status/1050121802272378880?ref_src=twsrc%5Etfw)

"We are encouraged by the preliminary data from MANIFEST, which may indicate synergistic and disease-modifying effects of CPI-0610 in myelofibrosis," said Adrian Senderowicz, Senior Vice President and Chief Medical Officer of Constellation Pharmaceuticals. "We are enhancing the study's design to better measure these potential effects. Among the key goals of MANIFEST are identifying the most appropriate endpoints and patient populations for future pivotal studies. We continue to look forward to determining proof of concept for CPI-0610 in MF by mid-2019."

Ph II study planned with PSMA-targeted drug I-131 1095 + Enzalutamide in chemo-naïve patients with mCRPC (https://progenicsgc.gcs-web.com/news-releases/news-release-details/progenics-advances-1095-psma-targeted-therapeutic-candidate)

"We are pleased, following our discussions with FDA, to move this important therapeutic agent into a phase 2 study in combination with enzalutamide in chemo-naïve patients with mCRPC," stated Vivien Wong, Ph.D., Executive Vice President Development at Progenics. "1095 delivers a targeted radiation dose to prostate cancer cells utilizing iodine-131 as the payload. Iodine 131 is an attractive agent to use because its physical properties of longer range and higher energy could potentially improve efficacy for bulky lesions and lesions that have lower PSMA expression. Iodine has been used widely in other cancer therapeutics, is broadly available with a ready supply and known safety profile. We look forward to evaluating the safety and efficacy of 1095 in this Phase 2 study."

COLLABORATIONS

Ph IIa trial to check efficacy of TLR3 agonist Ampligen + Checkpoint Inhibitors in Urothelial Carcinoma, RCC and Melanoma patients (http://ir.hemispherx.net/profiles/investor/ResLibraryView.asp?ResLibraryID=88924&BzID=2265&g=980&Nav=0&LangID=1&s=0)

> Hemispherx Biopharma Signs Clinical Trial Agreement with Roswell Park Comprehensive Cancer Center: Hemispherx Biopharma NYSEHEBÂannounces the signing of a clinical trial agreement with Roswell Park Comprehensive Cancer Center to evaluate Ampligen in... https://t.co/nR9rjqq73z (https://t.co/nR9rjqq73z)
>
> — Bio-Alliances News (@BioAlliances) October 10, 2018 (https://twitter.com/BioAlliances/status/1050073016170758144?ref_src=twsrc%5Etfw)

"This event marks an important milestone for Hemispherx as we evaluate Ampligen in combination with CPIs in difficult-to-treat solid tumors and among a patient population that is largely relapsed and/or refractory to treatment," said Thomas K. Equels, Chief Executive Officer of Hemispherx. "Our expanded collaboration with Roswell Park offers an ideal setting for these early stage trials. We have developed a productive working

relationship with this world-class team and look forward to beginning these important clinical trials."

Safety and tolerability of anti-PVRIG antibody COM701 and Nivolumab to be tested in advanced solid tumors (https://news.bms.com/press-release/rd-news/bristol-myers-squibb-and-compugen-announce-clinical-collaboration-evaluate-the)

"We are excited to have Bristol-Myers Squibb, the global leader in immuno-oncology, as a collaborator and strategic investor in Compugen," said Anat Cohen-Dayag, Ph.D., President and CEO of Compugen Ltd. "This collaboration gives Compugen access to Bristol-Myers Squibb's Opdivo, enabling the evaluation of COM701 plus a PD-1 inhibitor and potentially accelerating the timeline for clinical testing of COM701 as part of other novel combinations."

> BMS, Compugen to trial COM701 Opdivo combo in advanced solid tumors https://t.co/VaoFFA1cS1 (https://t.co/VaoFFA1cS1) pic.twitter.com/OwvMnInP5E (https://t.co/OwvMnInP5E)
>
> — OyeCricket.com (@cricket_fundas) October 13, 2018 (https://twitter.com/cricket_fundas/status/1050924674132176901?ref_src=twsrc%5Etfw)

"Our goal is to evaluate whether the innovative combination of COM701 with Opdivo is safe and active in various tumor types," said Fouad Namouni, M.D., Head of Development, Oncology, Bristol-Myers Squibb. "We look forward to building a strong collaboration with Compugen and addressing significant unmet needs."

Efficacy of PI3K delta inhibitor ME-401 + BTK inhibitor Zanubrutinib to be evaluated in patients with B-cell malignancies (http://investor.meipharma.com/2018-10-11-MEI-Pharma-and-BeiGene-Announce-Clinical-Collaboration-to-Evaluate-ME-401-in-Combination-with-Zanubrutinib-in-Patients-with-B-Cell-Malignancies)

"We are excited to be working with BeiGene to explore the potential of ME-401 in combination with zanubrutinib," said Robert Mass, M.D., chief medical officer of MEI Pharma. "Combinatorial approaches to fighting difficult to treat cancers historically have proven to be important in the delivery of better treatments to patients, and we believe that the data observed to date for ME-401, with its unique pharmaceutical properties, and for zanubrutinib support the evaluation of the combination for the treatment of patients with various B-cell malignancies."

> MEI, BeiGene to evaluate ME-401-Zanubrutinib combo in B-cell malignancies https://t.co/RI5mdXbfPs (https://t.co/RI5mdXbfPs)
>
> — pharmabr (@PharmaBR) October 12, 2018 (https://twitter.com/PharmaBR/status/1050679302956568581?ref_src=twsrc%5Etfw)

"Zanubrutinib is a potentially differentiated BTK inhibitor that is being globally developed in a number of B-cell malignancies both as a monotherapy and in combination. We look forward to exploring this interesting combination in patients with B-cell malignancies," commented Jane Huang, M.D., chief medical officer, hematology, at BeiGene.

RESULTS ALERT: ESMO 2018

1. Roche to present new positive data from its broad cancer immunotherapy programme and across a wide range of cancers (http://hugin.info/174806/R/2219681/868305.pdf)
2. Merck Data at ESMO 2018 Congress Highlight Multiple Therapeutics with Potential to Transform Cancer Care (https://www.merckgroup.com/en/news/esmo-curtain-raiser-09-10-2018.html?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)
3. AstraZeneca presents advances in improving treatment options for ovarian and lung cancer patients at ESMO 2018 (https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2018/astrazeneca-presents-advances-in-improving-treatment-options-for-ovarian-and-lung-cancer-patients-at-esmo-2018-09102018.html)
4. Bayer to Showcase Latest Oncology Research at ESMO 2018 Congress (https://www.bayer.us/en/newsroom/press-releases/article/?id=123245)
5. AVEO Oncology to Present Updated Interim Results from the Phase 2 Portion of the TiNivo Study of Tivozanib and Nivolumab (OPDIVO®) in RCC at the ESMO 2018 Annual Congress (https://investor.aveooncology.com/news-releases/news-release-details/aveo-oncology-present-updated-interim-results-phase-2-portion)
6. Lilly to Present New Data from Oncology Portfolio at ESMO 2018 Congress, Showcasing Patient-Centric Advances in Cancer Care (https://investor.lilly.com/news-releases/news-release-details/lilly-present-new-data-oncology-portfolio-esmo-2018-congress)
7. Incyte Announces Data for Pemigatinib, its Selective FGFR Inhibitor, to be Featured at the ESMO 2018 Congress (https://investor.incyte.com/news-releases/news-release-details/incyte-announces-data-pemigatinib-its-selective-fgfr-inhibitor)
8. Libtayo® (cemiplimab-rwlc) Data at ESMO 2018 Congress Provide New Insights in Six Tumor Types Under Investigation (https://investor.regeneron.com/news-releases/news-release-details/libtayor-cemiplimab-rwlc-data-esmo-2018-congress-provide-new)
9. Loxo Oncology Announces Details for Data Presentations at the European Society for Medical Oncology 2018 Congress (https://ir.loxooncology.com/press-releases/2370733-Loxo-oncology-announces-details-for-data-presentations-at-the-european-society-for-medical-oncology-2018-congress)
10. Cabozantinib to Be Featured in 13 Presentations at ESMO 2018 Congress (http://ir.exelixis.com/phoenix.zhtml?c=120923&p=RssLanding&cat=news&id=2370700)
11. TESARO Announces Data Presentations at the ESMO 2018 Congress (http://ir.tesarobio.com/news-releases/news-release-details/tesaro-announces-data-presentations-esmo-2018-congress)
12. NuCana to Present New Data from its ProTide Portfolio at the European Society for Medical Oncology (ESMO) 2018 Congress (http://www.nucana.com/downloads/NuCana9October2018.pdf)
13. EISAI TO PRESENT ABSTRACTS ON ONCOLOGY PRODUCTS AND PIPELINE AT ESMO 2018 CONGRESS (https://www.eisai.com/news/2018/news201881.html)
14. Janssen to showcase robust oncology portfolio at ESMO 2018 (https://www.businesswire.com/news/home/20181010005357/en/)
15. Clovis Oncology to Highlight Results from Rubraca® (rucaparib) TRITON Prostate Program at ESMO 2018 Congress (https://ir.clovisoncology.com/investors-and-news/news-releases/press-release-details/2018/Clovis-Oncology-to-Highlight-Results-from-Rubraca-rucaparib-TRITON-Prostate-Program-at-ESMO-2018-Congress/default.aspx)
16. Corvus Pharmaceuticals to Present Data on Lead Programs at the European Society for Medical Oncology (ESMO) 2018 Congress (http://investor.corvuspharma.com/news-releases/news-release-details/corvus-pharmaceuticals-present-data-lead-programs-european')

OTW Trivia

Q: **What is Regenerative Medicine Advanced Therapy (RMAT) designation?**

A: *Regenerative Medicine Advanced Therapy (RMAT) Designation Is A Special Status That Can Be Given By FDA To A Drug, Which Is Defined As A Cell Therapy, Human Cell And Tissue Product, Therapeutic Tissue Engineering Product, Or Any Combination Product Using Such Therapies Or Products.*

Q: **What is the eligibility criteria of Regenerative Medicine Advanced Therapy (RMAT) designation?**

A: *A Drug Is Eligible For Regenerative Medicine Advanced Therapy (RMAT) Designation If:*

1. *The Drug Is A Regenerative Medicine Therapy, Which Is Defined As A Cell Therapy, Therapeutic Tissue Engineering Product, Human Cell And Tissue Product, Or Any Combination Product Using Such Therapies Or Products, Except For Those Regulated Solely Under Section 361 Of The Public Health Service Act And Part 1271 Of Title 21, Code Of Federal Regulations;*
2. *The Drug Is Intended To Treat, Modify, Reverse, Or Cure A Serious Or Life-Threatening Disease Or Condition; And*
3. *Preliminary Clinical Evidence Indicates That The Drug Has The Potential To Address Unmet Medical Needs For Such Disease Or Condition*

Q: **When can a request for RMAT designation be made?**

A: *The Request For RMAT Designation Must Be Made Either Concurrently With Submission Of An Investigational New Drug Application (IND) Or As An Amendment To An Existing IND. FDA Doesnot Grant A RMAT Designation If An IND Is On Hold Or Is Placed On Hold During The Designation Review.*

Q: **Which oncology drug recently got RMAT designation?**

A: *Lifileucel (LN-144), A TUMOR INFILTRATING LYMPHOCYTES (TIL) Therapy From Iovance Therapeutics, Was Granted RMAT Designation In Advanced Melanoma Based On C-144-01 Study.*

Source: https://www.fda.gov/biologicsbloodvaccines/cellulargenetherapyproducts/ucm537670.htm (https://www.fda.gov/biologicsbloodvaccines/cellulargenetherapyproducts/ucm537670.htm)

About the Author:


(https://i0.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: (CellImageLibrary)Confocal micrograph of an isolated melanin-producing cell (a melanocyte) showing the melanosomes (vesicles that hold the melanin granules) in yellow, the actin in red and the microtubules in blue. The melanin gets transferred from the melanocytes to the epidermal cells, giving colour to

the skin and hair.– Source (http://cellimagelibrary.org/images/38956)

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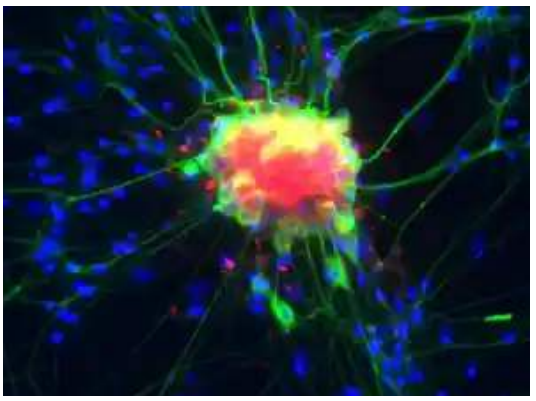

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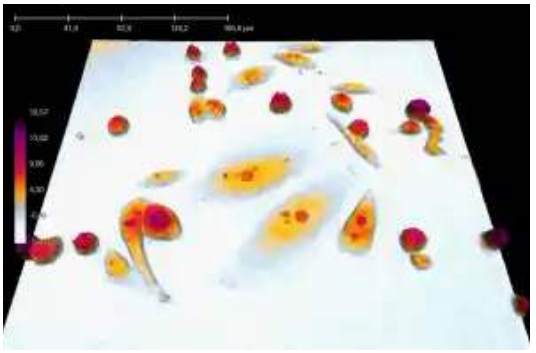

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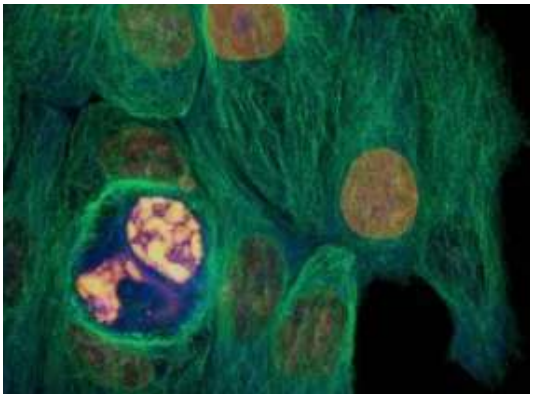

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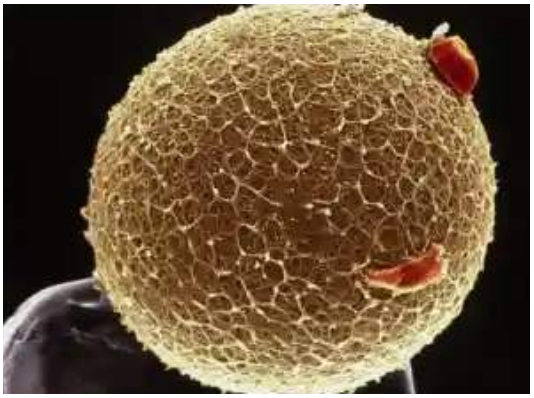

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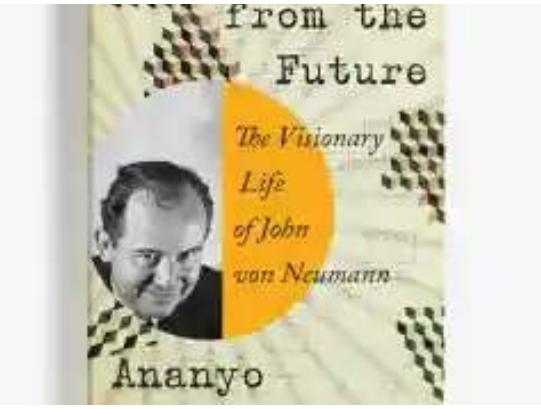

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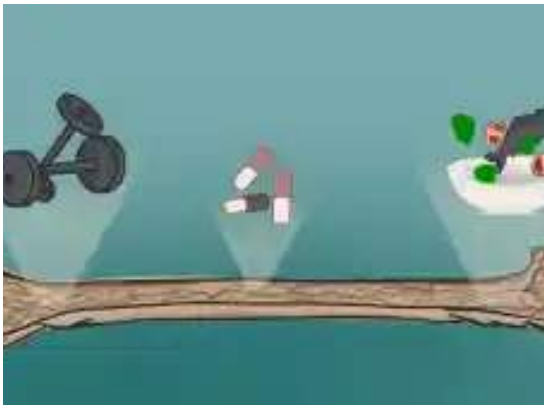

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