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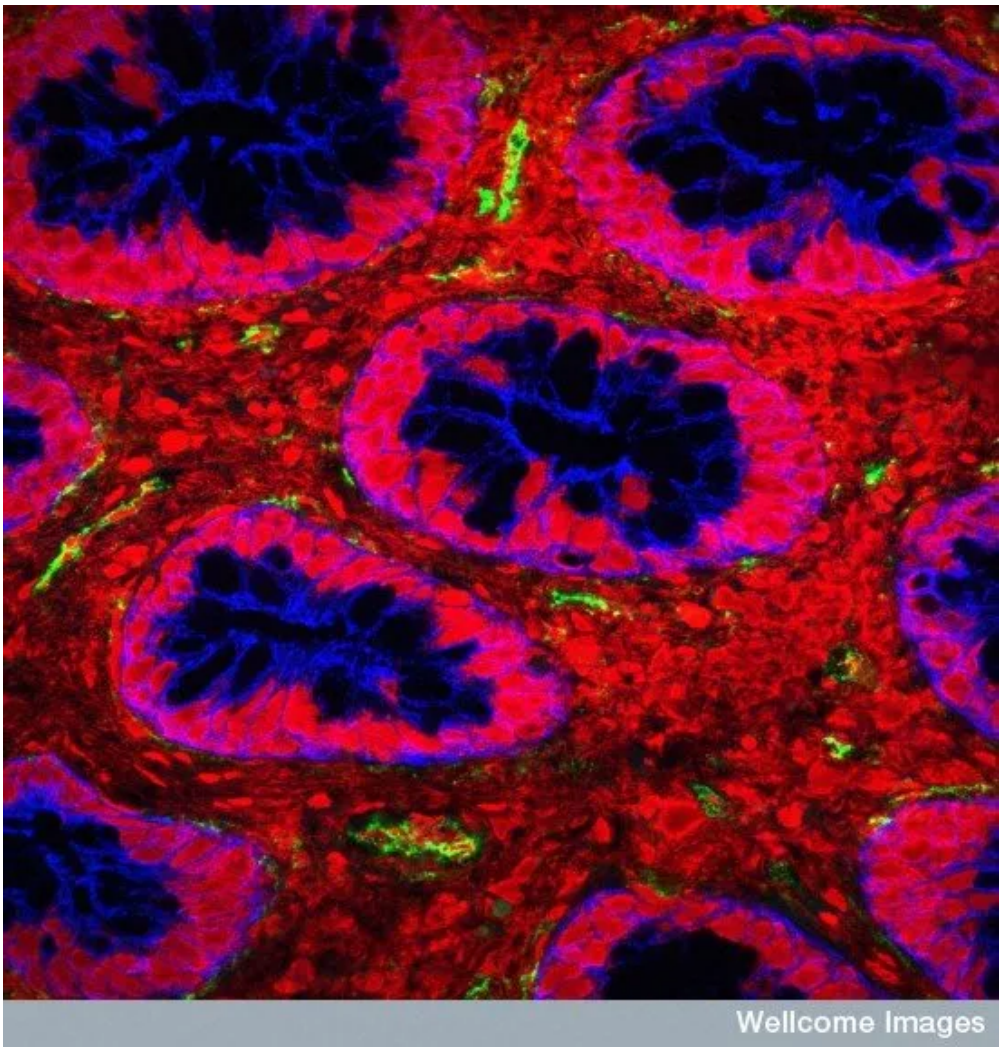
Onco-this-Week

March 17, 2019(https://sciwri.club/archives/date/2019/03/17)



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OTW in a Capsule

HIGHLIGHTS

1. **Approval of Atezolizumab in PD-L1+ TNBC patients.** FDA approval of Atezolizumab in combination with nab-paclitaxel garnered all the attention for two very strong reasons – the evident one is filling the unmet need in a therapy area which is very difficult to treat owing to the lack of any targets (unlike its HER2+ or HR+ counterparts). The second one is that this approval marks the entry of immunotherapies in treatment algorithm of breast cancer. With Atezolizumab snapping up the first ever IO approval in breast cancer, all the eyes would be on upcoming IO results in this patient segment.
2. **Ph III RELAY trial of Ramucirumab meeting primary endpoint of PFS improvement in 1L EGFR+ NSCLC patients.** Though lung cancer is always a lucrative market for pharma companies owing to the big patient population, it is also known to be very saturated with plenty of options available in different lines of therapy. The battle then comes down to maximum efficacy with least safety concerns. Keeping these in mind, it was exciting to see Ramucirumab showing positive improvement in EGFR mutated frontline NSCLC patients, a segment which is dominated by several EGFR inhibitors. There would be a lot of excitement around the announcement of efficacy data, which is expected in an upcoming medical conference.
3. **Failure of Ph III APACT trial of nab-Paclitaxel + gemcitabine combination in adjuvant pancreatic cancer.** Curiously, the secondary endpoint of OS showed minimal significant improvement over gemcitabine alone, the study is deemed failed as it could not reach the primary endpoint of improvement in DFS. The idea of testing the combination may have stemmed from success of nab-paclitaxel in frontline patients; it was still a stiff challenge due to a strong comparator (gemcitabine) and presence of a better alternative (mFOLFOX) in adjuvant settings. Hopefully the sting of this failure fades away in the recent success of Atezolizumab – abraxane combination in TNBC patients.

(https://goo.gl/XM63s6)

DRUG APPROVALS

Atezolizumab + Abraxane combination approved in PD-L1+ mTNBC patients based on Ph III IMpassion130 data (https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm633065.htm?utm_campaign=Oncology%20March%208%202019&utm_medium=email&utm_source=Eloqua)

"Tecentriq in combination with nab-paclitaxel has the potential to meaningfully advance treatment for people with PD-L1-positive, metastatic triple-negative breast cancer. People need more options for this type of breast cancer, which is particularly difficult to treat," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We are working closely with the FDA to bring this Tecentriq combination to people with PD-L1-positive metastatic triple-negative breast cancer as soon as possible."

> On March 8, 2019, the #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) approved #Tecentriq (https://twitter.com/hashtag/Tecentriq?src=hash&ref_src=twsrc%5Etfw) (#atezolizumab (https://twitter.com/hashtag/atezolizumab?src=hash&ref_src=twsrc%5Etfw)) in combination with #Abraxane (https://twitter.com/hashtag/Abraxane?src=hash&ref_src=twsrc%5Etfw) (#paclitaxel (https://twitter.com/hashtag/paclitaxel?src=hash&ref_src=twsrc%5Etfw) #proteinbound (https://twitter.com/hashtag/proteinbound?src=hash&ref_src=twsrc%5Etfw)) for PD-L1 positive unresectable locally advanced or metastatic triple-negative #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) (#TNBC (https://twitter.com/hashtag/TNBC?src=hash&ref_src=twsrc%5Etfw)) pic.twitter.com/DoW1hddwVP (https://t.co/DoW1hddwVP)
>
> — Bichoy Gabra, R.Ph., Ph.D. (@bichoy_g) March 8, 2019 (https://twitter.com/bichoy_g/status/1104150796986433536?ref_src=twsrc%5Etfw)

Pembrolizumab + chemotherapy combo approved in EU in 1L squamous mNSCLC patients based on Ph III KEYNOTE-407 data (https://www.mrknewsroom.com/news-release/research-and-development-news/european-commission-approves-mercks-keytruda-pembrolizu-0)

"In KEYNOTE-407, first-line treatment with KEYTRUDA in combination with chemotherapy resulted in significant improvements in overall survival for patients with metastatic squamous non-small cell lung cancer, regardless of PD-L1 expression," said Dr. Luis Paz-Ares, chair of the medical oncology department, Hospital Universitario Doce de Octubre, Madrid, Spain. "Lung cancer is the leading cause of cancer death in Europe, so this approval marks an important milestone for the patients and families facing this difficult-to-treat type of lung cancer."

MSD's Keytrudachemo combo nabs EU approval in firstline metastatic squamous lung cancer: MSDs antiPDL1 therapy Keytruda pembrolizumab has been awarded marketing authorisation in Europe for the firstline treatment of adult patients with metastatic... https://t.co/ZfejrnjlxS (https://t.co/ZfejrnjlxS) pic.twitter.com/vwiyjpPKOb (https://t.co/vwiyjpPKOb)

— Clinical Trials News (@ClinicalPhase) March 15, 2019 (https://twitter.com/ClinicalPhase/status/1106539823869812736?ref_src=twsrc%5Etfw)

REGULATORY NEWS

PDUFA extended for Selinexor NDA; additional data requested by FDA (https://investors.karyopharm.com/news-releases/news-release-details/karyopharm-announces-fda-extension-review-period-selinexor-new)

"We look forward to the continued collaboration with FDA in trying to meet the needs of patients with relapsed refractory multiple myeloma," said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm.

The Daily Biotech Pulse: KaryoPharm's Selinexor Review Delayed, FDA Accepts Adamas Opioid Overdose Drug NDA $CDNA (https://twitter.com/search?q=%24CDNA&src=ctag&ref_src=twsrc%5Etfw) https://t.co/RXqrAEnoHC (https://t.co/RXqrAEnoHC)

— SmallCap Network (@SmallCapNetwork) March 15, 2019 (https://twitter.com/SmallCapNetwork/status/1106537842933727232?ref_src=twsrc%5Etfw)

Request for Fast track designation submitted for next-gen anthracycline drug, Annamycin, in R/R AML patients (https://ir.moleculin.com/press-releases/detail/117/moleculin-files-with-fda-for-expedited-approval-pathway-for)

"Now that we have some traction in our clinical trials of Annamycin for the treatment of relapsed or refractory AML," commented Walter Klemp, Moleculin's Chairman and CEO, "we believe it is appropriate to request Fast Track designation for Annamycin. Importantly, this is a valuable first step in ultimately qualifying for Accelerated Approval and Priority Review."

Moleculin Files with FDA for Expedited Approval Pathway for Annamycin https://t.co/F2xJBSRnqv (https://t.co/F2xJBSRnqv)

— Stocks News Feed (@feed_stocks) March 13, 2019 (https://twitter.com/feed_stocks/status/1105819061101879296?ref_src=twsrc%5Etfw)

sBLA filed for Daratumumab + Len-Dex in 1L transplant-ineligible MM patients based on Ph III MAIA data; being reviewed under the FDA RTOR pilot program (https://www.janssen.com/janssen-submits-application-us-fda-seeking-approval-darzalex-daratumumab-combination-therapy)

"We are pleased to complete the latest DARZALEX submission based upon the Phase 3 MAIA study, which evaluated the efficacy and safety of this anti-CD38 monoclonal antibody as a combination regimen for newly diagnosed patients with multiple myeloma who are transplant ineligible," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Vice President, Hematologic Malignancies Disease Area Leader, Janssen Research & Development, LLC. "We look forward to closely collaborating with the Agency throughout the expedited Real-Time Oncology Review process

in support of this newly diagnosed, transplant ineligible multiple myeloma patient population for whom a combination treatment regimen with DARZALEX may be useful."

> @JanssenUS (https://twitter.com/JanssenUS?ref_src=twsrc%5Etfw) Submits sBLA for Daratumumab Combo Therapy in Certain Patients with #MultipleMyeloma (https://twitter.com/hashtag/MultipleMyeloma?src=hash&ref_src=twsrc%5Etfw)
> More: https://t.co/f9BseiEZhJ (https://t.co/f9BseiEZhJ) pic.twitter.com/nvYhQAKxcJ (https://t.co/nvYhQAKxcJ)
>
> — SpecialtyPTimes (@SpecialtyPTimes) March 14, 2019 (https://twitter.com/SpecialtyPTimes/status/1106283862680895489?ref_src=twsrc%5Etfw)

ESMO GUIDELINES: Tivozanib added as a recommendation for 1L ccRCC patients based on Ph III trial TiVO-1 trial data (https://apnews.com/Business%20Wire/bodea4f93d5e41afbac225bb6daf6d84)

Dr Bernard Escudier, Medical Oncologist and member of the Genitourinary Tumour Board of Gustave Roussy, France, commented "This is excellent news for patients with metastatic RCC. Outcomes in this disease have greatly improved with the introduction of targeted therapies, meaning that patients are living for longer, although currently available therapies can be associated with burdensome toxicities. We are still in need of effective and well tolerated new treatments in metastatic RCC and thus, tivozanib is a welcomed addition. We also look forward to continuing our investigations of potential combination approaches with other therapeutic agents."

> Brian I. Rini, MD, on Renal Cell Carcinoma: Results From the TIVO-3 Trial on Tivozanib vs Sorafenib https://t.co/eBYaB9Xt9z (https://t.co/eBYaB9Xt9z) #kcsm (https://twitter.com/hashtag/kcsm?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #GU19 (https://twitter.com/hashtag/GU19?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/RR7MSVETbT (https://t.co/RR7MSVETbT)
>
> — The ASCO Post (@ASCOPost) March 9, 2019 (https://twitter.com/ASCOPost/status/1104450024820240384?ref_src=twsrc%5Etfw)

Positive DSMB reviews of UNITY-CLL and UNITY-NHL trials announced; trials to continue without modification in absence of any safety concerns (http://ir.tgtherapeutics.com/news-releases/news-release-details/tg-therapeutics-announces-positive-data-safety-monitoring-board)

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are highly encouraged that based on the progression-free survival data accumulated to date, the UNITY-CLL DSMB determined that the study was not futile and supported continuation of the trial as planned. We are also extremely pleased that the DSMBs, which collectively evaluated safety data from over 750 patients treated with umbralisib, did not raise any safety concerns and recommended that both the UNITY-CLL and the UNITY-NHL trials continue unmodified." Mr. Weiss continued, "We look forward to presenting interim safety and efficacy data from the MZL cohort of the UNITY-NHL trial in an oral presentation next month at the AACR conference."

TG Therapeutics Announces Positive Data Safety Monitoring Board Reviews of UNITYCLL and UNITYNHL Clinical Trials: UNITYCLL DSMB conducted a preplanned futility analysis of progressionfree survival and determined that the study was not futile and should... https://t.co/QzDvNHuibS (https://t.co/QzDvNHuibS)

— Drug Discovery News (@DiscoveryDrug) March 8, 2019 (https://twitter.com/DiscoveryDrug/status/1103999691572707328?ref_src=twsrc%5Etfw)

Updates on L-MIND and B-MIND trials of Fc-enhanced anti-CD19 antibody MOR208 in R/R unfit DLBCL patients provided (https://www.morphosys.com/media-investors/media-center/morphosys-ag-morphosys-provides-updates-on-l-mind-and-b-mind-clinical)

"Our L-MIND trial continues as planned and we are on track to completing our regulatory submission to the FDA this year", commented Dr. Malte Peters, Chief Development Officer of Morphosys AG. "Further, we are having early conversations with European regulators about the possibility of using L-MIND as the basis for a filing in Europe. We hope to have a clearer picture of the regulatory path in Europe within the next several months. Following discussions with the FDA, we have introduced a co-primary endpoint into the B-MIND trial based on pre-clinical data that suggest the involvement of a certain biomarker. The amended B-MIND trial enables us to test the hypothesis that MOR208 shows enhanced activity in patients who can be identified using the biomarker, while in addition allowing us to test efficacy in the unselected patient population as originally planned."

MorphoSys AG MorphoSys Provides Updates on LMIND and BMIND Clinical Trials of MOR208 in RelapsedRefractory DLBCL news with additional features: DGAPNews MorphoSys AG Key words Study07.03.2019 2201 The issuer is solely responsible for the content of this... https://t.co/SZ5dlCVTBR (https://t.co/SZ5dlCVTBR)

— Renal Cell Carcinoma (@Renal_Bio) March 7, 2019 (https://twitter.com/Renal_Bio/status/1103778370322554882?ref_src=twsrc%5Etfw)

TRIAL RESULTS

Ph III trial NRG-RTOG 0521 data suggests benefit of addition of chemotherapy to androgen suppression in high-risk non-metastatic prostate cancer (https://www.nrgoncology.org/News/Research-Results/NRG-Oncology-Trial-Suggests-Adding-Docetaxel-based-Chemotherapy-to-Standard-Treatment-Should-be-Considered-for-Men-with-High-Risk-Prostate-Cancer)

"The addition of cytotoxic chemotherapy to androgen suppression and radiotherapy improved overall survival from 89% to 93% at 4 years following randomization. There was also improvement in disease-free survival and reduced rates of distant metastases," stated Seth A. Rosenthal, MD, FACR, FASTRO, of Sutter Medical Group and Sutter Cancer Centers, Sacramento, California, and corresponding author for NRG-RTOG 0521. "These are promising results. The trial results suggest that the addition of docetaxel chemotherapy to standard treatment with long-term androgen suppression therapy and RT, is a viable treatment option for men with high-risk non-metastatic prostate cancer. Physicians should be considering the discussion of this option with selected patients who are fit for chemotherapy"

FAILED TRIAL: Nab-paclitaxel + Gemcitabine misses DFS endpoint in Pancreatic Cancer in Ph III APACT trial (https://ir.celgene.com/press-releases/press-release-details/2019/Celgene-Provides-Update-on-ABRAXANE-

Combination-Therapy-in-the-Treatment-of-Metastatic-Triple-Negative-Breast-Cancer-and-Pancreatic-Cancer/default.aspx)

The adjuvant combination of nab-paclitaxel and gemcitabine did not improve the primary endpoint disease-free survival (DFS) compared with gemcitabine alone, as per independent radiological review (IRR), in pancreatic cancer patients enrolled in Ph III APACT trial (NCT01964430).

> Nab-Paclitaxel Plus Gemcitabine Misses DFS Endpoint in Pancreatic Cancer https://t.co/FmMhv7Ufvw (https://t.co/FmMhv7Ufvw)
>
> — Immuno-Oncology (@immuno_onc) March 13, 2019 (https://twitter.com/immuno_onc/status/1105827360622944261?ref_src=twsrc%5Etfw)

Ph III RELAY trial of Ramucirumab meets primary EP of PFS improvement in 1L EGFR+ NSCLC patients (https://investor.lilly.com/news-releases/news-release-details/lillys-cyramzar-ramucirumab-phase-3-relay-trial-met-primary)

"We are excited about these results, which show CYRAMZA plus erlotinib significantly delayed disease progression in this patient population. The RELAY trial is another example of Lilly's deep commitment to providing new treatment options to patients with lung cancer," said Dr. Dickler. "We would like to thank the patients, investigators and clinical trial sites that are participating in the RELAY study, and we look forward to working with regulatory authorities globally on our submissions."

> PFS was significantly improved with frontline combination ramucirumab plus erlotinib compared to placebo plus erlotinib in patients with metastatic EGFR-mutant non–small cell lung cancer in this phase III.https://t.co/gjg6gL8aPe (https://t.co/gjg6gL8aPe)#lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) #nsclc (https://twitter.com/hashtag/nsclc?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/69EkWoqsPB (https://t.co/69EkWoqsPB)
>
> — Targeted Oncology (@TargetedOnc) March 12, 2019 (https://twitter.com/TargetedOnc/status/1105589530046935041?ref_src=twsrc%5Etfw)

RESULTS // ICHM 2019: Updated Duvelisib data from Ph III DUO crossover extension trial in R/R CLL/SLL patients presented (http://investor.verastem.com/phoenix.zhtml?c=250749&p=irol-newsArticle&ID=2390596)

"The subset of 46 patients who received duvelisib monotherapy for greater than 2 years achieved an overall response rate (ORR) of 89% and a median progression-free survival (PFS) of 40 months," commented Ian Flinn, MD, PhD, Director, Lymphoma/CLL Program at Sarah Cannon Research Institute and lead author of the abstract. "In this study, we were able to manage most adverse events through dose reductions and dosing holds, which allowed these patients to remain on treatment. These data support duvelisib's potential as a long-term treatment in patients with relapsed or refractory CLL/SLL and we are excited to share them with the medical community at ICHM 2019."

> Verastem Oncology Reports Results of Copiktra (Duvelisib) in P-III DUO Study in Patients with R/R CLL/SLL @VerastemOncolog (https://twitter.com/VerastemOncolog?ref_src=twsrc%5Etfw) https://t.co/NlJiRN6AM8 (https://t.co/NlJiRN6AM8) pic.twitter.com/sfPJI9yvxa (https://t.co/sfPJI9yvxa)
>
> — PharmaShots (@Pharmashot) March 6, 2019 (https://twitter.com/Pharmashot/status/1103158959685304320?ref_src=twsrc%5Etfw)

TRIAL STATUSES

Ph II MARIO-3 trial of PI3K inhibitor IPI-549 + Atezolizumab in 1L TNBC and RCC to be initiated (http://investors.infi.com/news-releases/news-release-details/infinity-initiate-mario-3-phase-2-multi-arm-study-evaluating-ipi)

"We are very pleased to have entered into this agreement with Roche to evaluate combinations including IPI-549 and Tecentriq in front-line solid tumor settings," said Sam Agresta, M.D., M.P.H., Chief Medical Officer at Infinity. "MARIO-3 is a key part of our strategy to expand the breadth and depth of the development of IPI-549 into earlier lines of therapy and in combination with potentially transformative new treatment regimens for patients. We look forward to initiating MARIO-3 later this year."

> Infinity To Initiate MARIO-3, A Phase 2 Multi-Arm Study Evaluating IPI-549 In Front-Line Triple Negative Breast Cancer And Renal Cell Cancer https://t.co/R9RQbTiRRy (https://t.co/R9RQbTiRRy)
>
> — RazzleTazzle (@RazzleTazzleMag) March 14, 2019 (https://twitter.com/RazzleTazzleMag/status/1106152895249072128?ref_src=twsrc%5Etfw)

Ph I trial of PD-L1 inhibitor IMC-001 (also known as STI-3031) in locally-advanced or metastatic solid tumors completed (http://investors.sorrentotherapeutics.com/news-releases/news-release-details/correcting-and-replacing-yuhan-corp-and-sorrento-therapeutics)

"Based on the results of the Phase 1 trial of IMC-001, we are planning on conducting a Phase 2 trial to evaluate its efficacy in rare cancers in the second half of this year," stated Yun Jeong Song, CEO of ImmuneOncia. "Moreover, we greatly appreciate those who supported us and for their contributions as the company successfully completed a Phase 1 trial of IMC-001. In collaboration with various institutions, we will continue our research and development of IMC-001 as well as the additional checkpoint immune-oncology molecules in our pipeline."

> CORRECTING and REPLACING – Yuhan Corp and Sorrento Therapeutics Announce Completion of Phase 1 Clinical Study of Anti-PD-L1 Antibody IMC-001 https://t.co/pJqx04vOBD (https://t.co/pJqx04vOBD) pic.twitter.com/njSzL2jlrQ (https://t.co/njSzL2jlrQ)
>
> — Stocks News Feed (@feed_stocks) March 11, 2019 (https://twitter.com/feed_stocks/status/1105154181491417090?ref_src=twsrc%5Etfw)

First patient dosed in Ph II trial of liposomal cisplatin formulation, LiPlaCis, in prostate cancer; DRP to identify patients most likely to benefit (https://oncologyventure.com/press-release/first-patient-dosed-in-a-phase-2-study-with-liplacis-in-prostate-cancer/)

"It is known that platin products are active in prostate cancer, but previous clinical studies have not been able to show sufficient effect to obtain marketing approval. We believe this is mainly due to treating a too broad patient population and will examine if the DRP can identify the individuals who benefit from the LiPlaCis treatment as we can do in breast cancer," comments Peter Buhl Jensen, M.D., CEO of Oncology Venture.

We are pleased to announce that the first patient has been dosed in a Phase 2 study with LiPlaCis® in #prostatecancer (https://twitter.com/hashtag/prostatecancer?src=hash&ref_src=twsrc%5Etfw) Read more: https://t.co/Rn6JXcJorx (https://t.co/Rn6JXcJorx) #precisionmedicine (https://twitter.com/hashtag/precisionmedicine?src=hash&ref_src=twsrc%5Etfw) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/KH1kliMZUB (https://t.co/KH1kliMZUB)

— OncologyVenture (@OncologyVenture) March 11, 2019 (https://twitter.com/OncologyVenture/status/1105085209152770049?ref_src=twsrc%5Etfw)

First patient dosed in Ph IIa AVID100-01 trial of EGFR-targeting ADC, AVID100, in EGFR+ SCCHN patients (https://forbius.com/press-releases/fobius-announces-first-patient-dosed-in-phase-2a-squamous-cell-carcinoma-of-the-head-and-neck-scchn-trial-of-avid100-a-novel-anti-egfr-adc)

First patient was dosed in a Ph IIa SCCHN (AVID100-01; NCT03094169), which is designed to evaluate the efficacy, safety, and tolerability of AVID100 in EGFR+ patients. AVID100-01 follows the previously announced Ph IIa trial of AVID100 in advanced squamous NSCLC patients.

#Forbius (https://twitter.com/hashtag/Forbius?src=hash&ref_src=twsrc%5Etfw) (Formation Biologics) has initiated the dosing of #AVID100 (https://twitter.com/hashtag/AVID100?src=hash&ref_src=twsrc%5Etfw) last week, in a phase 2a study of squamous cell carcinoma of the head and neck (SCCHN). The multicentre study evaluates the efficacy, safety, and tolerability of AVID100 in patients with EGFR IHC 3+ tumours. #ADC (https://twitter.com/hashtag/ADC?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/26dIYrOekS (https://t.co/26dIYrOekS)

— Beacon Intelligence (@BeaconIntel) March 13, 2019 (https://twitter.com/BeaconIntel/status/1105830873927163904?ref_src=twsrc%5Etfw)

First patient dosed in Ph IIa TELE-ABC trial of Telotristat Ethyl in Biliary Tract Cancer (http://www.lexpharma.com/media-center/news/704-lexicon-pharmaceuticals-announces-dosing-of-first-patient-in-tele-abc-study-a-phase-2a-clinical-study-of-telotristat-ethyl-in-biliary-tract-cancer)

“With our ongoing commitment to bring innovative therapies to patients with debilitating diseases, we are pleased to advance telotristat ethyl into a proof-of-concept study in patients with biliary tract cancer,” said Praveen Tyle, Ph.D., executive vice president of research and development. “We believe this is an important opportunity to explore telotristat ethyl’s potential outside of carcinoid syndrome diarrhea based on the drug’s mechanism of action and on the critical role serotonin plays in regulating several major physiological processes, including cell proliferation. Initiation of the TELE-ABC study is an important next step in our plan to expand the number and types of patients who may benefit from telotristat ethyl.”

Lexicon Pharmaceuticals Announces Dosing of First Patient in TELEABC Study: Lexicon Pharmaceuticals NASDAQLXRX has announced the dosing of the first patient in the Telotristat Ethyl for Advanced Biliary Tract Cancer TELEABC in a Phase2a clinical study of... https://t.co/04QvkvmQ7O (https://t.co/04QvkvmQ7O)

— Cancer News (@Cancer_bio) March 15, 2019 (https://twitter.com/Cancer_bio/status/1106606368570499072?ref_src=twsrc%5Etfw)

First patient dosed in Ph I trial of FoIRα-targeting SC209 ADC, STRO-002, in Ovarian and Endometrial Cancers

(https://www.sutrobio.com/sutro-biopharma-initiates-phase-i-clinical-trial-of-stro-002-for-the-treatment-of-ovarian-and-endometrial-cancers/)

"Moving our second product candidate into human clinical trials is another momentous milestone in Sutro's evolution from a technology platform company to a clinical stage company," said Sutro CEO Bill Newell. "Our goal is to ultimately help fill the unmet need for more targeted therapies for patients with ovarian and endometrial cancer and advancing STRO-002 into the clinic brings us one step closer to achieving this."

> Sutro Biopharma Initiates Phase I Clinical Trial of STRO-002 for the Treatment of Ovarian and Endometrial Cancers https://t.co/gRzV3fDLon (https://t.co/gRzV3fDLon)
>
> — RazzleTazzle (@RazzleTazzleMag) March 15, 2019 (https://twitter.com/RazzleTazzleMag/status/1106513697915072513?ref_src=twsrc%5Etfw)

COLLABORATIONS

Seres Therapeutics and AstraZeneca to advance development of potential microbiome-based therapies for cancer (http://ir.serestherapeutics.com/phoenix.zhtml?c=254006&p=irol-newsArticle&ID=2390857)

"We are very pleased to be collaborating with AstraZeneca, a global leader in oncology, to advance the development of potential microbiome-based therapies for cancer. Through the activities under this collaboration and in our SER-401 Phase 1b clinical study in metastatic melanoma, we hope to meaningfully advance our understanding of the potential for microbiome therapeutics to magnify the impact of cancer immunotherapy," said Eric Shaff, President and Chief Executive Officer of Seres Therapeutics.

> Under a three-year agreement, British pharma giant @AstraZeneca (https://twitter.com/AstraZeneca?ref_src=twsrc%5Etfw) pays €20m and R&D costs to Seres Therapeutics, which will identify patterns in the #microbiome (https://twitter.com/hashtag/microbiome?src=hash&ref_src=twsrc%5Etfw) predicting therapy response to cancer immune therapies. https://t.co/ERozfgaUVU (https://t.co/ERozfgaUVU)
>
> — European Biotech (@EuroBiotechNews) March 13, 2019 (https://twitter.com/EuroBiotechNews/status/1105821751299264514?ref_src=twsrc%5Etfw)

Dx ASSAY

VENTANA PD-L1 (SP142) assay approved as first companion diagnostic to identify TNBC patients eligible for treatment with Atezolizumab + Nab-paclitaxel (http://hugin.info/174806/R/2237525/881825.pdf)

"Triple-negative breast cancer is an aggressive disease that, until now, has had limited treatment options," said Michael Heuer, CEO of Roche Diagnostics. "This assay plays a pivotal role in helping physicians identify patients that can benefit from Tecentriq therapy, providing better patient care. At Roche, we build on our capacity to research both targeted medicines and companion diagnostics under one roof, so we can provide the right treatment to the right patient at the right time."

> We continue to expand our approach to cancer testing as we launch Ventana's PD-L1 SP142 Assay for the first cleared immunotherapy in metastatic triple-negative breast cancer. #TNBC (https://twitter.com/hashtag/TNBC?src=hash&ref_src=twsrc%5Etfw) #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/Miohq0I1p3 (https://t.co/Miohq0I1p3) pic.twitter.com/gajwtZgn42 (https://t.co/gajwtZgn42)
>
> — NeoGenomics (@NeoGenomics) March 14, 2019 (https://twitter.com/NeoGenomics/status/1106179178704060416?ref_src=twsrc%5Etfw)

VeriStrat data demonstrates independent prediction of IO outcomes in advanced NSCLC patients (https://www.marketwatch.com/press-release/biodesixveristrat-data-demonstrate-independent-predictionof-immunotherapy-outcomes-for-nsclc-patients-2019-03-14)

"Additional studies are needed to establish the clinical utility of biomarker testing when choosing appropriate treatment regimens," said Patricia Rich, M.D., medical oncologist and Medical Director of Thoracic Oncology at Cancer Treatment Centers of America. "Real-world data from this large registry observational study suggests that the overall survival for patients receiving a frontline ICI added to chemotherapy, or alone, may not be significantly different from platinum-based chemotherapy.This is potentially good news for patients that are not eligible for ICI therapy, cannot tolerate it, or simply cannot afford it."

> Biodesix VeriStrat Data Demonstrate Independent Prediction of Immunotherapy Outcomes for NSCLC Patients https://t.co/YSCNsTVJBm (https://t.co/YSCNsTVJBm)
>
> — PharmaMKT (@PharmaMKTnet) March 15, 2019 (https://twitter.com/PharmaMKTnet/status/1106565588485328896?ref_src=twsrc%5Etfw)

OTW Trivia

Q: What is expanded access?

A: Expanded access, also known as compassionate use, ensures patients with an immediately life-threatening condition gaining access to an investigational drug for treatment outside of clinical trials.

Q: When is expanded access provided?

A: Expanded access is provided only when no comparable or satisfactory alternative therapy options are available to patients in dire needs.

Q: What are the risks associated with expanded access?

A: Investigational drugs provided to patients as part of expanded access have not yet been approved or cleared by a regulatory agency (e.g., FDA) and there is no evidence of safety and efficacy for these drugs. Moreover, the use of the drugs may cause unexpected serious side effects.

(Source: https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.htm (https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/default.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:

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

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

Image Sources: Wikipedia and Twitter

Cover image: "A confocal micrograph of an intestinal biopsy from a child infected with shiga toxin-producing E. coli. Shiga toxin is an extremely potent toxin that is produced when the bacterium contains a bacteriophage carrying the toxin gene. It is closely linked with Haemolytic Uraemic Syndrome and acute renal failure in children. After ingestion via contaminated food or water the E. coli bacteria colonize the gut and produce the toxin, which then crosses the gastrointestinal barrier to enter the systemic circulation and reach the kidney and

other target organs. In this image, the toxin (green) has crossed into the intestine and is binding to the endothelial cells of the lamina propria (red)." Source (http://cellimagelibrary.org/images/38952)

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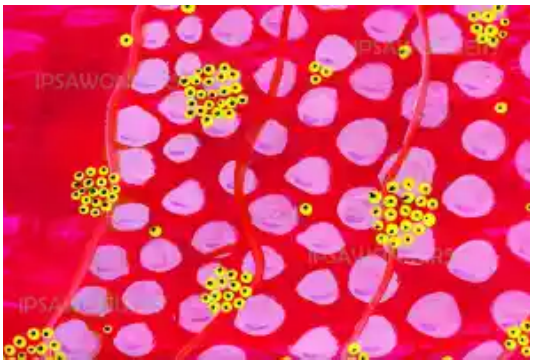

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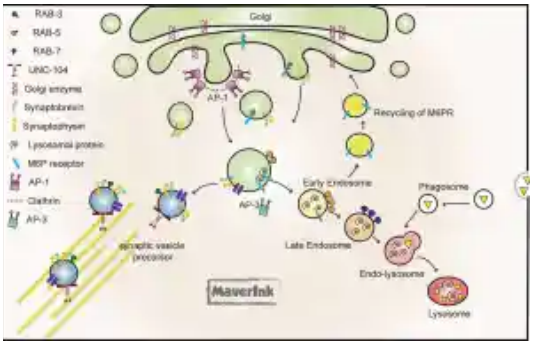

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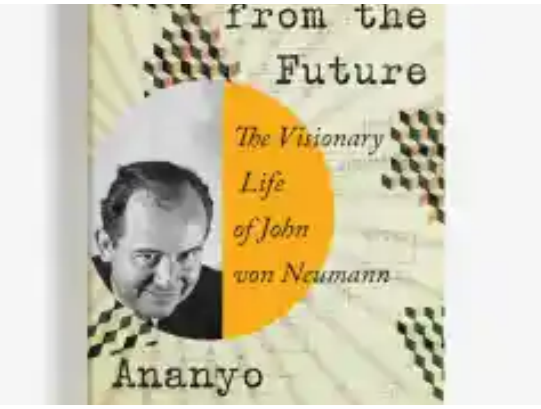

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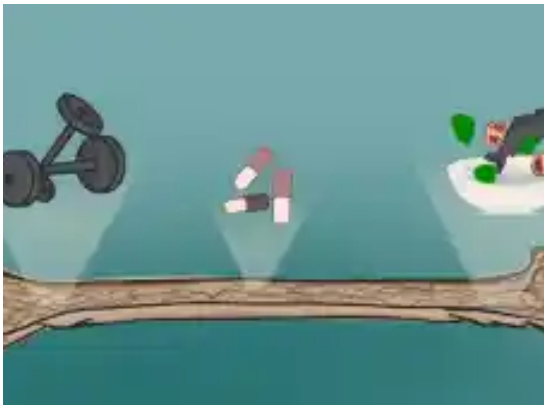

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