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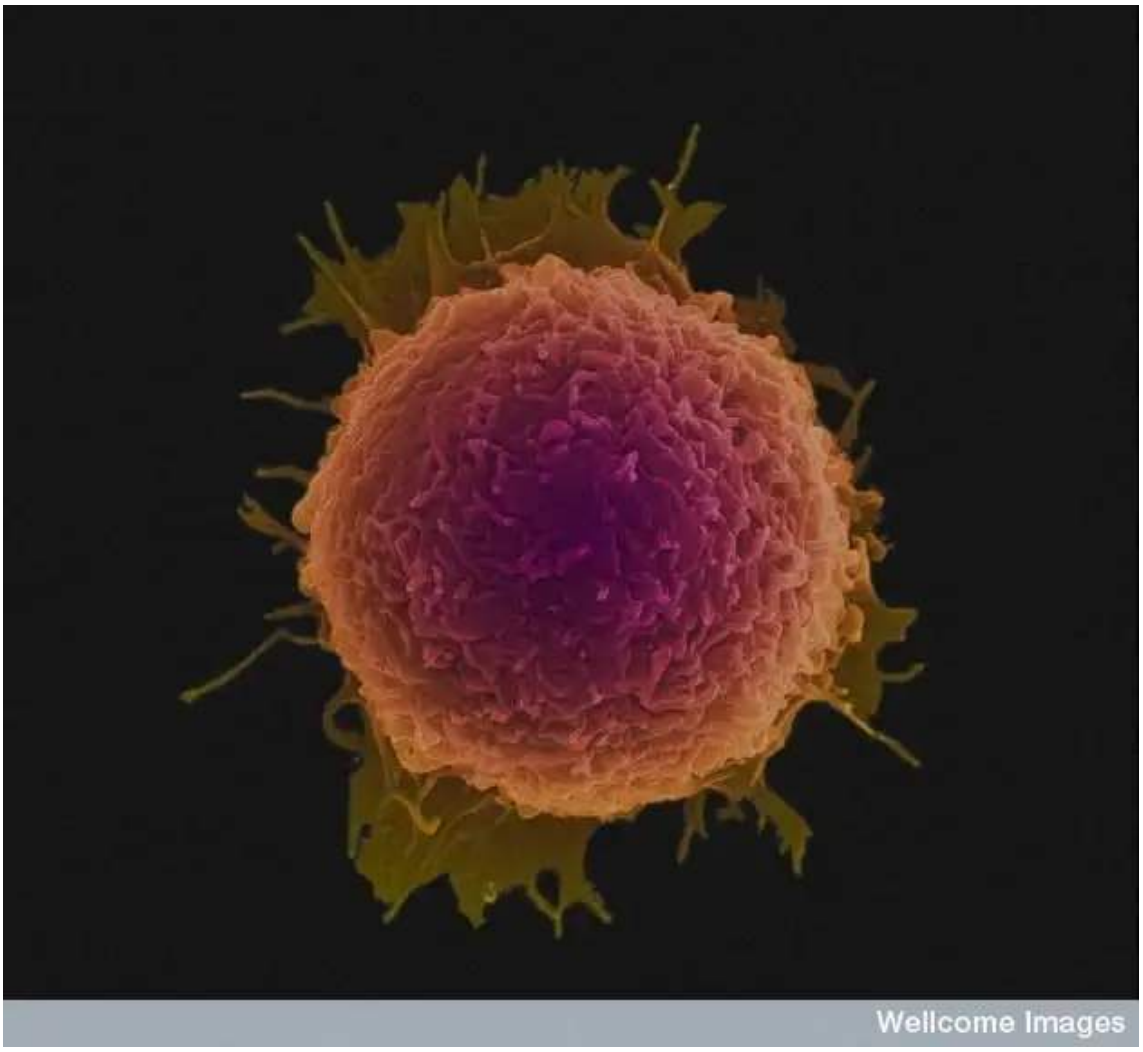
Onco-this-Week

November 18, 2018(https://sciwri.club/archives/date/2018/11/18)



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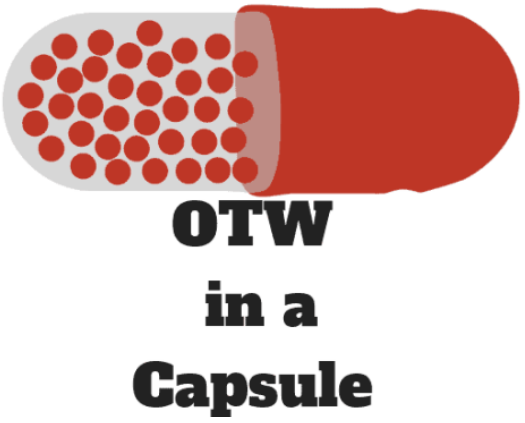
In Onco-this-Week, check Ipsen's Cabometyx's EU approval for the treatment of advanced HCC and find out which drug went from Breakthrough Designation to FDA approval within a day. In major regulatory news, check out acceptance of sBLA from FDA for Roche's Tecentriq + Abraxane for Metastatic Triple-Negative Breast Cancer and Astra Zeneca's Lynparza getting sNDA by FDA in patients with BRCA-mutated advanced Ovarian cancer. We have multiple updates from clinical trials of lung cancer, esophageal cancer, angiosarcoma, HER2-driven cancers

and AML. Also in this edition are updates from the recently concluded **EORTC-NCI-AACR 2018** conference and our trivia on non-small cell lung cancers.



1. **Trial failures in NSCLC**: The two high-profile trials that just announced negative results are Ph III MYSTIC trial of Durvalumab + Tremelimumab (didn't meet primary endpoint of OS improvement in previously untreated NSCLC patients) and Ph III FALUCA trial of pan-VEGFR inhibitor fruquintinib (did not meet primary endpoint of OS improvement in 3L+ NSCLC patients). Both the trials got added to the list of studies which showed promising improvement in surrogate endpoints but failed to translate the clinical benefit to OS improvement. However, with non-squamous NSCLC already being saturated with several treatment options, these failures would be soon forgotten.
2. **FDA approval of Brentuximab vedotin in 1L PTCL patients:** All it took FDA was a day to change the status of Brentuximab vedotin's application from breakthrough designation to complete approval. In fact, the time after submission of the complete application to approval was less than two weeks, all thanks to Real-Time Oncology Review Pilot Program. This news not only brought a hope to PTCL patients who didn't have any FDA-approved therapy in front line settings, but also to all oncology physicians and patients due to the speedy processing time.
3. **Priority review to Atezolizumab + Abraxane combination PD-L1+ mTNBC patients:** Though Ph III IMpassion130 data didn't show a statistical improvement in OS in all comers, there was a clinically meaningful OS improvement observed in the PD-L1+ patients. Regardless of dismal OS news in all comers, the combination managed to secure priority review from the FDA since the space has a huge unmet need – TNBC patients lack both HR and HER2 receptors thus limiting their treatment options severely. The PDUFA is Mar 2019 and it will be interesting to see if this combination is deemed worthy of an approval.

Biotechnologies

(https://goo.gl/XM63s6)

(https://goo.gl/VLv3K1)

DRUG APPROVALS

Cabozantinib approved in EU for Sorafenib-treated HCC patients based on Ph III CELESTIAL trial data (https://www.ipsen.com/media/press-relases/post_custom_datacustom_datapost_custom_datacustom_dataeuropean-commission-approves-ipsens-cabometyx-cabozantinib-for-the-treatment-of-hepatocellular-carcinoma-in/)

> Ipsen's Cabometyx (cabozantinib, as monothx) Receives EU Approval for the Treatment of 2L Advance HCC @IpsenGroup (https://twitter.com/IpsenGroup?ref_src=twsrc%5Etfw) https://t.co/2MXwZMYzzs (https://t.co/2MXwZMYzzs) pic.twitter.com/45ZhfAdvo6 (https://t.co/45ZhfAdvo6)
>
> — PharmaShots (@Pharmashot) November 16, 2018 (https://twitter.com/Pharmashot/status/1063403367588864000?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Today's EC approval for the use of Cabometyx® provides a much needed new option for HCC patients. Until now, physicians in Europe had only one approved therapy for the 2nd line treatment of this aggressive and difficult-to-treat cancer.[i],[ii] We are proud to offer Cabometyx® as an innovative treatment that has been shown to extend survival in previously treated patients with HCC", said Harout Semerjian, Chief Commercial Officer, Ipsen, "This new indication reinforces Ipsen's commitment to improve patients' lives through the expansion of the clinical benefit of Cabometyx® in the treatment of solid tumors."

Philippe Merle, M.D., Ph.D., Hepatology and Gastroenterology specialist at La Croix-Rousse Hospital, Lyon, stated: "Patients with HCC in Europe can now benefit from a treatment that has, through the CELESTIAL trial, proven effective in prolonging life and delaying disease progression. This is a very encouraging development for liver cancer patients, and provides physicians with a new therapeutic option for this complex disease."

FDA approves CD30-targeting MMAE ADC, Brentuximab vedotin, in 1L PTCL patients based on Ph III ECHELON-2 data (http://investor.seattlegenetics.com/news-releases/news-release-details/seattle-genetics-announces-fda-approval-adcetrisr-brentuximab-1)

> .@US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) gives speedy approval to brentuximab for peripheral T-cell #lymphoma (https://twitter.com/hashtag/lymphoma?src=hash&ref_src=twsrc%5Etfw)https://t.co/OTWs6jewKC (https://t.co/OTWs6jewKC) pic.twitter.com/QCXquaXXH3 (https://t.co/QCXquaXXH3)
>
> — AJMC (@AJMC_Journal) November 16, 2018 (https://twitter.com/AJMC_Journal/status/1063534673538633728?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The current standard of care for initial treatment of peripheral T-cell lymphoma is multi-agent chemotherapy. That treatment has not significantly changed in decades and is too often unsuccessful in leading to long-term remissions, underscoring the need for new treatments," said Steven Horwitz, M.D., Department of Medicine, Lymphoma Service, Memorial Sloan Kettering Cancer Center, New York. "The ECHELON-2 clinical trial demonstrated ADCETRIS plus CHP was superior to the current standard of care, CHOP, for both progression-free survival and all other key secondary endpoints, including, most importantly, overall survival. With this approval, clinicians have the opportunity to transform the way newly diagnosed CD30-expressing PTCL patients are treated."

"By participating in the FDA's Real-Time Oncology Review process and working closely with the FDA, we are now able to make the ADCETRIS regimen available to previously untreated patients with CD30-expressing PTCL in an unprecedented less than two weeks after submission of our supplemental BLA," said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. "The ECHELON-2 clinical trial demonstrated ADCETRIS plus CHP results in a superior outcome for patients when compared to current standard of care, CHOP. We want to thank the patients, physicians and their staff who participated in the ECHELON-2 trial, which supported this FDA approval."

REGULATORY NEWS

Breakthrough designation granted to CD30-targeting MMAE ADC, Brentuximab vedotin, in 1L PTCL patients based on Ph III ECHELON-2 data (http://investor.seattlegenetics.com/news-releases/news-release-details/fda-grants-breakthrough-therapy-designation-adcetrisr)

> $SGEN (https://twitter.com/search?q=%24SGEN&src=ctag&ref_src=twsrc%5Etfw) FDA Grants BTD to ADCETRIS® for Frontline Peripheral T-Cell Lymphomas https://t.co/waSDDNdv4y (https://t.co/waSDDNdv4y)
>
> — Odi Bruckman (@odibro) November 15, 2018 (https://twitter.com/odibro/status/1063055770110083072?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Data from the ECHELON-2 phase 3 trial of ADCETRIS in combination with chemotherapy showed superior progression-free survival and overall survival versus the standard of care chemotherapy regimen, CHOP, in the treatment of frontline CD30-expressing peripheral T-cell lymphomas," said Clay Siegall, Ph.D., President and Chief Executive Officer of Seattle Genetics. "This is the third Breakthrough Therapy Designation for ADCETRIS and supports our goal to make this therapy available to patients with newly diagnosed peripheral T-cell lymphomas as soon as possible. We look forward to presenting the data from our phase 3 ECHELON-2 trial at the upcoming ASH Annual Meeting."

212Pb-labeled somatostatin analog AlphaMedix(TM) grated Orphan drug designation for the treatment of neuroendocrine tumors (http://radiomedix.com/news/radiomedix-and-orano-med-receive-fda-orphan-drug-

designation-for-alphamedixtm-for-the-treatment-of-neuroendocrine-tumors/)

> READ: @RadioMedix (https://twitter.com/RadioMedix?ref_src=twsrc%5Etfw) & @OranoMed (https://twitter.com/OranoMed?ref_src=twsrc%5Etfw) receive FDA Orphan Drug Designation for AlphaMedix to fight #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/aSdvWtb2v6 (https://t.co/aSdvWtb2v6)
>
> — Orano Med (@OranoMed) November 14, 2018 (https://twitter.com/OranoMed/status/1062801656524562432?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"TAT has brought new hope to our patients with cancer, and the range of available therapies in this area will only increase in the near future. We are pleased to conduct the first TAT clinical trial in the U.S. for neuroendocrine cancers, with the aim of registration of the drug," said Dr. Ebrahim S. Delpassand, CEO of RadioMedix and Medical Director of the clinical studies. "We are hoping that AlphaMedixTM will provide a breakthrough therapy that will benefit our patients soon," added Dr. Delpassand. "We are excited about the progress of our dose escalation studies of AlphaMedixTM", echoed Dr. Izabela Tworowska, Ph.D., CSO of RadioMedix.

"FDA's decision to grant Orphan drug Designation is an important regulatory milestone for AlphaMedixTM, a key program in our pipeline of 212Pb-labeled compounds," said Julien Dodet, CEO of Orano Med. "We believe TAT with 212Pb represents a promising new approach and that AlphaMedixTM has the potential to have a meaningful impact on patients".

Atezolizumab + Abraxane combination gets priority review in PD-L1+ mTNBC patients based on Ph III IMpassion130 data; PDUFA: Mar 2019 (http://hugin.info/174806/R/2225295/872846.pdf)

> Roche Reports Acceptance of sBLA from FDA for its Tecentriq (atezolizumab) + Abraxane (nab-paclitaxel) for 1L Metastatic Triple- Negative Breast Cancer (TNBC) @Roche (https://twitter.com/Roche?ref_src=twsrc%5Etfw) https://t.co/RG2jxWhcMd (https://t.co/RG2jxWhcMd) pic.twitter.com/nUk9AnRfms (https://t.co/nUk9AnRfms)
>
> — PharmaShots (@Pharmashot) November 13, 2018 (https://twitter.com/Pharmashot/status/1062266382488809472?ref_src=twsrc%5Etfw)

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

Priority review granted to Olaparib in 1L maintenance BRCA+ ovarian cancer patients based on results from Ph III SOLO-1 trial; PDUFA: Q1, 2019 (https://www.astrazeneca.com/media-centre/press-releases/2018/us-fda-accepts-regulatory-submission-for-lynparza-maintenance-therapy-in-newly-diagnosed-brca-mutated-advanced-ovarian-cancer-and-grants-priority-review-12112018.html)

> AstraZeneca Announces Acceptance of Priority Review of Lynparza's (olaparib) sNDA by FDA in Patients with BRAC-Mutated Advance Ovarian Cancer @AstraZenecaUS (https://twitter.com/AstraZenecaUS?ref_src=twsrc%5Etfw) https://t.co/bAFGMsYI9U (https://t.co/bAFGMsYI9U) pic.twitter.com/IaEYJ5rsLe (https://t.co/IaEYJ5rsLe)
>
> — PharmaShots (@Pharmashot) November 12, 2018 (https://twitter.com/Pharmashot/status/1061932671582920704?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Merck and AstraZeneca announced that the FDA accepted sNDA for Priority Review for olaparib in 1L maintenance settings in BRCA-mutated advanced ovarian cancer patients who achieved CR/PR with frontline platinum-based chemotherapy. The PDUFA date is given as first quarter of 2019.

TRIAL RESULTS

FAILED TRIAL: Ph III MYSTIC trial of Durvalumab + Tremelimumab didn't meet primary endpoint of OS improvement (https://www.astrazeneca.com/media-centre/press-releases/2018/astrazeneca-provides-update-on-the-phase-iii-mystic-trial-of-imfinzi-and-tremelimumab-in-stage-iv-non-small-cell-lung-cancer16112018.html)

> Disappointing results of MYSTIC Trial: Durvalumab and Durvalumab + tremelimumab did not improve Overall Survival compared with chemotherapy in stage IV NSCLC #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) #LCSM (https://twitter.com/hashtag/LCSM?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/707zXtCLZH (https://t.co/707zXtCLZH)
>
> — Manuel Dómine (@ManuelDomine) November 16, 2018 (https://twitter.com/ManuelDomine/status/1063537418463264768?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "We are encouraged to see that Imfinzi monotherapy activity is in-line with that of the anti-PD-1 class in previously-untreated patients with Stage IV non-small cell lung cancer; however, we are disappointed that these results missed statistical significance. We remain confident in Imfinzi as the cornerstone of our IO programme and continue to evaluate its potential in ongoing non-small cell lung cancer trials, including Imfinzi and Imfinzi plus tremelimumab in combination with chemotherapy."

FAILED TRIAL: Ph III FALUCA trial of pan-VEGFR inhibitor fruquintinib did not meet primary endpoint of OS improvement in 3L+ NSCLC patients (https://www.chi-med.com/phase-iii-faluca-results/)

> Fruquintinib fails to meet primary endpoint in latest Chi-Med trial https://t.co/AOFAdlePWK (https://t.co/AOFAdlePWK)
>
> — Digital Look/Web FG (@DigitalLookNews) November 16, 2018 (https://twitter.com/DigitalLookNews/status/1063459395240148993?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"While the study demonstrates a significant reduction in disease progression in this challenging lung cancer patient population, we are disappointed that this benefit did not translate into an increase in overall survival," commented Simon To, Chairman of Chi-Med. He added, "We remain confident that the high selectivity and lower off-target toxicities of fruquintinib are major points of differentiation. The recent first approval of fruquintinib monotherapy for advanced colorectal cancer, the imminent launch in China, and the

commencement of several combination collaborations with immunotherapies both in China and in the U.S., reinforces our belief in fruquintinib."

Pembrolizumab significantly improved OS in PD-L1+ advanced esophageal or EGJ carcinoma patients in Ph III KEYNOTE-181 trial (https://www.mrknewsroom.com/news-release/oncology/mercks-keytruda-pembrolizumab-significantly-improved-overall-survival-os-compa)

"In this pivotal trial, KEYTRUDA resulted in a statistically significant and clinically meaningful improvement over standard chemotherapy in overall survival for patients with advanced esophageal or esophagogastric junction carcinoma whose tumors express PD-L1 with a CPS of 10 or greater. This marks the sixth tumor type where KEYTRUDA has demonstrated a survival benefit, and represents the first time an anti-PD-1 therapy has achieved overall survival for this patient population," said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. "We are encouraged by these results of KEYTRUDA as monotherapy in previously-treated patients, and look forward to continuing our research efforts in this significant area of unmet need with our ongoing Phase 3 trial, KEYNOTE-590, evaluating KEYTRUDA in combination with chemotherapy as a first-line treatment for patients with esophageal carcinoma."

New CTC data from Ph III TAPPAS Trial of Anti-Endoglin antibody TRC105 and Pazopanib in Angiosarcoma patients announced (https://traconpharma.gcs-web.com/news-releases/news-release-details/tracon-pharmaceuticals-presents-new-circulating-tumor-cell-data)

> A multi-country clinical trial of the antibody to endoglin, TRC105, for angiosarcoma is recruiting patients. This links to all the sites where the study is open or will open. https://t.co/qdmLoRbzjE (https://t.co/qdmLoRbzjE) https://t.co/qdmLoRbzjE (https://t.co/qdmLoRbzjE)
>
> — Sarcoma Alliance (@SarcomaAlliance) November 15, 2018 (https://twitter.com/SarcomaAlliance/status/1063038921414795269?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The CTC analysis done as part of the TAPPAS Phase 3 trial has been robust and we have seen differences in CTC count following treatment which will be unblinded and correlated with treatment arm in the final analysis. Change in CTC count on study may be useful as a prognostic biomarker, and baseline CTC count may be useful as a predictive biomarker," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "In the meantime, we look forward to the Phase 3 TAPPAS trial interim analysis expected in the first quarter of 2019."

KIT/PDGFRa dual inhibitor Avapritinib shows encouraging results across all lines of therapies in GIST patients in Ph I NAVIGATOR trial (http://ir.blueprintmedicines.com/news-releases/news-release-details/blueprint-medicines-announces-updated-navigator-trial-results)

"With an increased understanding of molecular drivers of GIST over the last decade, it is encouraging to see an investigational drug, like avapritinib, bring a precision therapy approach to GIST," said Michael Heinrich, M.D., Professor of Medicine at Oregon Health & Science University and an investigator on the NAVIGATOR trial. "Avapritinib has the potential to be a significant therapeutic advance in GIST, a rare cancer with high medical needs across lines of treatment. In particular, the updated data demonstrate the broad clinical impact of avapritinib for patients with PDGFRα D842V-driven GIST and fourth-line GIST, where there are currently no effective therapies. In addition, the data strongly support clinical development of avapritinib in early lines, including second- and third-line treatment."

> A multi-country clinical trial of the antibody to endoglin, TRC105, for angiosarcoma is recruiting patients. This links to all the sites where the study is open or will open. https://t.co/qdmLoRbzjE (https://t.co/qdmLoRbzjE) https://t.co/qdmLoRbzjE (https://t.co/qdmLoRbzjE)
>
> — Sarcoma Alliance (@SarcomaAlliance) November 15, 2018 (https://twitter.com/SarcomaAlliance/status/1063038921414795269?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"These data highlight the potential of avapritinib, a potent and highly selective inhibitor of KIT and PDGFRA mutant kinases, to be a cornerstone precision therapy in GIST," said Andy Boral, M.D., Ph.D., Chief Medical Officer of Blueprint Medicines. "The results validate Blueprint Medicines' approach to designing precision therapies that specifically target genetic drivers of disease, with the goals of delivering transformative benefit to patients and enabling rapid progress toward registration. Avapritinib's highly potent anti-tumor activity in PDGFRα D842V-driven GIST, combined with differentiated activity across treatment lines in KIT-driven GIST, reflect its promise as a potentially foundational treatment option across multiple GIST populations. We are committed to advancing a comprehensive and scientifically driven clinical development program with the goal of improving the lives of GIST patients."

HER2-targeting antibody ZW25 shows promising efficacy in Esophagus, gastric and bowel cancer patients in Ph I trial (https://www.ecco-org.eu/Global/News/ENA/ENA2018-PR/Patients-with-cancers-respond-well-to-new-anti-HER2-drug)

> NEWS: A Phase I trial of antibody ZW25, which binds to HER2 receptors, has had a good response in patients with HER2-driven cancers. Read more below:
>
> — Oncology Central (@OncologyCentral) November 14, 2018 (https://twitter.com/OncologyCentral/status/1062663432942600192?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Dr Murali Beeram, a medical oncologist and clinical investigator at the START Center for Cancer Care, San Antonio, USA, told "As a clinician, I am excited by the single agent anti-tumour activity and tolerability we are seeing with ZW25, particularly in these patents with advanced HER2 expressing cancers that have progressed after multiple prior therapies, including HER2 targeted agents. In fact, trastuzumab is the only HER2 targeted therapy approved for gastric cancer and there are no approved HER2-targeted therapies for other types of cancer that are driven by the HER2 receptor. ZW25 has been well tolerated to date, which should allow it to be used in combination with other agents for potentially even better responses."

Encouraging dose-escalation data observed with FATE-NK100 (http://ir.fatetherapeutics.com/news-releases/news-release-details/fate-therapeutics-announces-encouraging-dose-escalation-clinical)

> FATE-NK100, 1st-in-class allogeneic NK cell immunoncology therapy using specialized adaptive memory NK cells, shows clinical benefit in R/R AML & ovarian trials. @FateThx (https://twitter.com/FateThx?ref_src=twsrc%5Etfw) #CellTherapy (https://twitter.com/hashtag/CellTherapy?src=hash&ref_src=twsrc%5Etfw) #pre (https://twitter.com/hashtag/pre?src=hash&ref_src=twsrc%5Etfw) https://t.co/YNrwKiuoqW (https://t.co/YNrwKiuoqW) pic.twitter.com/pbIz4xjoCa (https://t.co/pbIz4xjoCa)
>
> — Key Biologics, LLC (@keybio) November 12, 2018 (https://twitter.com/keybio/status/1062045783028088833?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“The safety and clinical benefit observed with a single infusion of FATE-NK100 as a monotherapy in heavily pre-treated cancer patients, including in refractory AML patients that have high leukemic blast burden in the marrow and in advanced solid tumor patients with progressive disease, are encouraging,” said Sarah Cooley, M.D., Associate Professor of Medicine, Division of Hematology, Oncology and Transplantation at the University of Minnesota and the lead investigator of the VOYAGE study. “We are particularly excited that a repeat dose of FATE-NK100 was well-tolerated and showed persistence. Importantly, all three subjects re-treated with a second dose have demonstrated disease control. These data provide compelling proof-of-concept for FATE-NK100 and support earlier intervention with NK cell therapy using a multi-dose treatment cycle.”

NICE ASSESSMENTS

NICE recommends tisagenlecleucel for patients for young patients with R/R B-ALL (https://www.nice.org.uk/news/article/nice-recommends-cutting-edge-therapy-for-young-people-with-blood-cancer)

> More #CARTcell (https://twitter.com/hashtag/CARTcell?src=hash&ref_src=twsrc%5Etfw) therapy news – @NICEcomms (https://twitter.com/NICEcomms?ref_src=twsrc%5Etfw) has announced it is recommending tisagenlecleucel for people under 25 with B-cell acute lymphoblastic leukaemia that has not responded to treatment or has come back after a stem cell transplant https://t.co/s2qcW0BjKK (https://t.co/s2qcW0BjKK) #BloodCancer (https://twitter.com/hashtag/BloodCancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/LvLQrUXgPB (https://t.co/LvLQrUXgPB)
>
> — LymphomaAction (@LymphomaAction) November 16, 2018 (https://twitter.com/LymphomaAction/status/1063487871858995201?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Meindert Boysen, director of the Centre for Health Technology Evaluation at NICE said: “NICE’s recommendation of tisagenlecleucel marks a new generation of personalised medicine that has the potential to transform the care of patients with cancer worldwide.

“CART-cell therapy is expensive and complex. We have worked in partnership with our stakeholders, NHS England and the company to make the therapy available to patients quickly. Novartis have agreed to offer tisagenlecleucel at a lower price so that people using the NHS can be among the first in the world to access this exciting new treatment.”

Dr Alasdair Rankin, Director of Research at the blood cancer charity Bloodwise, said: “CART-cell therapy can give children with leukaemia the real possibility of long-term survival if they do not respond to standard treatments. Today’s announcement will come as a huge relief for a number of worried families. We hope that people will be able to access the therapy as soon as possible.”

TRIAL STATUSES

Ph I trial of SEA-BCMA antibody initiated in R/R MM patients (http://investor.seattlegenetics.com/news-releases/news-release-details/seattle-genetics-initiates-phase-1-clinical-trial-sea-bcma)

> Seattle Genetics Initiates Phase 1 Clinical Trial of SEABCMA for Patients with Relapsed or Refractory Multiple Myeloma: SEABCMA is a Novel Empowered Antibody Targeting BCMA for Multiple Myeloma Adds to Seattle Genetics Robust ClinicalStage Development... https://t.co/tUfRfifz1S (https://t.co/tUfRfifz1S)
>
> — Antibody News (@AntibodyNews) November 14, 2018 (https://twitter.com/AntibodyNews/status/1062692577378394112?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Despite recent advances in the treatment of multiple myeloma, it remains an incurable disease with a need for active and well-tolerated agents," said Roger D. Dansey, M.D., Chief Medical Officer of Seattle Genetics. "BCMA is a validated therapeutic target for multiple myeloma. SEA-BCMA represents a novel empowered antibody treatment approach that has demonstrated antitumor activity and an acceptable safety profile in preclinical evaluation to date. We look forward to evaluating SEA-BCMA through our clinical development program and hope to meaningfully improve outcomes for multiple myeloma patients."

Ph I trial of BTKi TG-1701 open for enrollment in patients with R/R B-cell malignancies (http://ir.tgtherapeutics.com/news-releases/news-release-details/tg-therapeutics-announces-phase-i-study-novel-btk-inhibitor-tg)

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased to announce the commencement of our first TG sponsored trial of TG-1701, our proprietary BTK inhibitor which was licensed from Jiangsu Hengrui earlier this year. The pre-clinical data presented at the European Hematology Association (EHA) annual congress this past summer on TG-1701 showed a highly selective kinase profile giving us confidence in its clinical potential." Mr. Weiss continued, "We are excited to see the study is off to a strong start with the first cohort rapidly enrolled and the first patient achieving a PR at our lowest evaluated dose. Seeing early activity should accelerate our ability to identify a dose appropriate for use in combination with U2 and for expansion cohorts. We look forward to seeing more data from TG-1701 in 2019 and starting combination therapy with U2."

CONFERENCE COVERAGE // EORTC-NCI-AACR 2018

> Thank you to everyone who attended #NCRI2018 (https://twitter.com/hashtag/NCRI2018?src=hash&ref_src=twsrc%5Etfw) – see you in Glasgow next year for #NCRI2019 (https://twitter.com/hashtag/NCRI2019?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/fNnWRDgpJr (https://t.co/fNnWRDgpJr)
>
> — NCRI Partnership (@NCRI_partners) November 6, 2018 (https://twitter.com/NCRI_partners/status/1059877056748625921?ref_src=twsrc%5Etfw)

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1. Results announced from Ph II trial of dabrafenib + trametinib in BRAF V600E m+ patients with BTC and adenocarcinoma of the small intestine (ASI) (https://www.ecco-org.eu/Global/News/ENA/ENA2018-PR/Patients-with-rare-incurable-digestive-tract-cancers-respond-to-new-drug-combination-News)
2. NSCLC data from combination of NIR178 (PBF-509) and spartalizumab (PDR001) presented (https://

www.ecco-org.eu/Global/News/ENA/ENA2018-PR/Combination-of-two-immunotherapies-shows-activity-in-nonsmall-cell-lung-cancer-patients)

3. mCRC data from combination of nivolumab and pixatimod presented (%20Difficult-to-treat%20bowel%20cancers%20respond%20in%20first%20study%20of%20new%20drug%20combination)
4. Dose escalation data from Ph I trial of CDK7i SY-1365 in solid tumor patients announced (https://ir.syros.com/press-releases/detail/146/syros-announces-dose-escalation-data-from-phase-1-trial-of)

OTW Trivia

Q: What are the different subtypes of non small cell lung cancer (NSCLC)?

A: NSCLC is of mainly two different subtypes differentiated based on the histology: non-squamous and squamous NSCLC.

Q: What is the percentage of these two different subtypes?

A: Non-squamous histology is more prevalent and is present in approximately two-third of all NSCLC patients; whereas squamous histology is present in just one-third NSCLC patients.

Q: How does the treatment strategy in two subtypes differ?

A: Non-squamous NSCLC has several driver mutations (EGFR mutations; ALK fusions; ROS1 chromosomal rearrangements etc.), presence of which enables physicians with more treatment options in terms of targeted therapies. These driver mutations are rare in squamous NSCLC, which hence becomes more difficult to treat with fewer treatment options.

Q: What is the most commonly used therapeutic regimen in patients with squamous NSCLC?

A: Platinum-based doublet chemotherapy is the standard of care in front line advanced and/or metastatic squamous NSCLC.

Q: What is the latest breakthrough in the treatment algorithm of patients with squamous NSCLC?

A: Recently, Pembrolizumab in combination with chemotherapy became the first immunotherapy to win FDA's approval in front line advanced, metastatic squamous NSCLC patients. The combination improved overall survival along with other outcomes in all comers, regardless of PD-L1 expression.

Source: http://www.lillyoncology.com/education/squamous-nsclc.html (http://www.lillyoncology.com/education/squamous-nsclc.html)

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)

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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)Colorized scanning electron micrograph of a cell cultured lung cancer cell. This image is part of an image group, CIL 42801-42803, showing several colorized scanning electron micrographs of cell cultured lung cancer cells. Technical Details-B0008533 Lung cancer cell. 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/42802)

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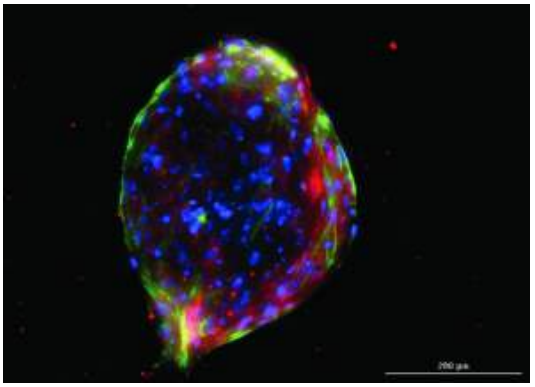

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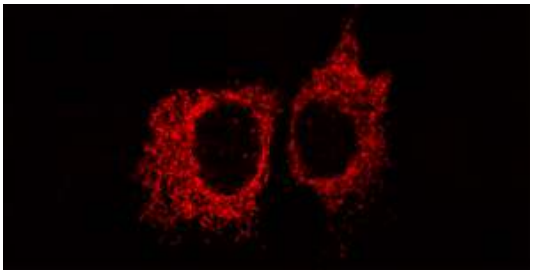

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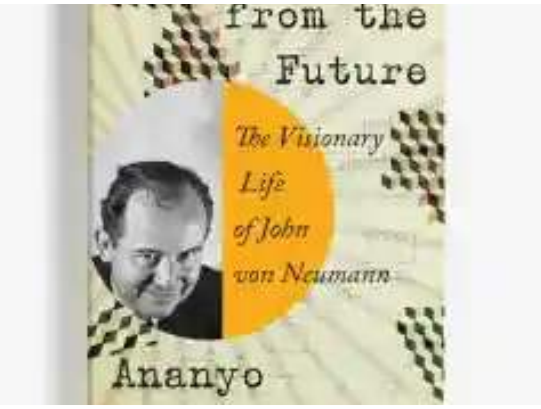

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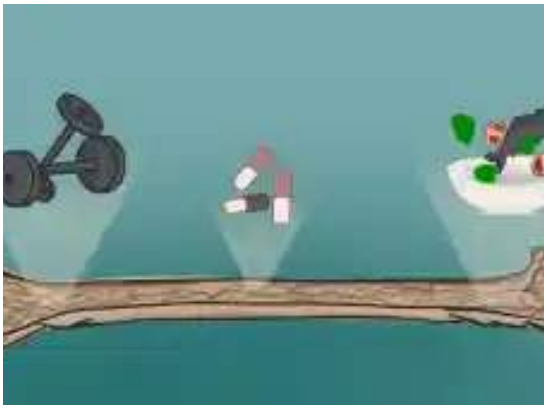

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