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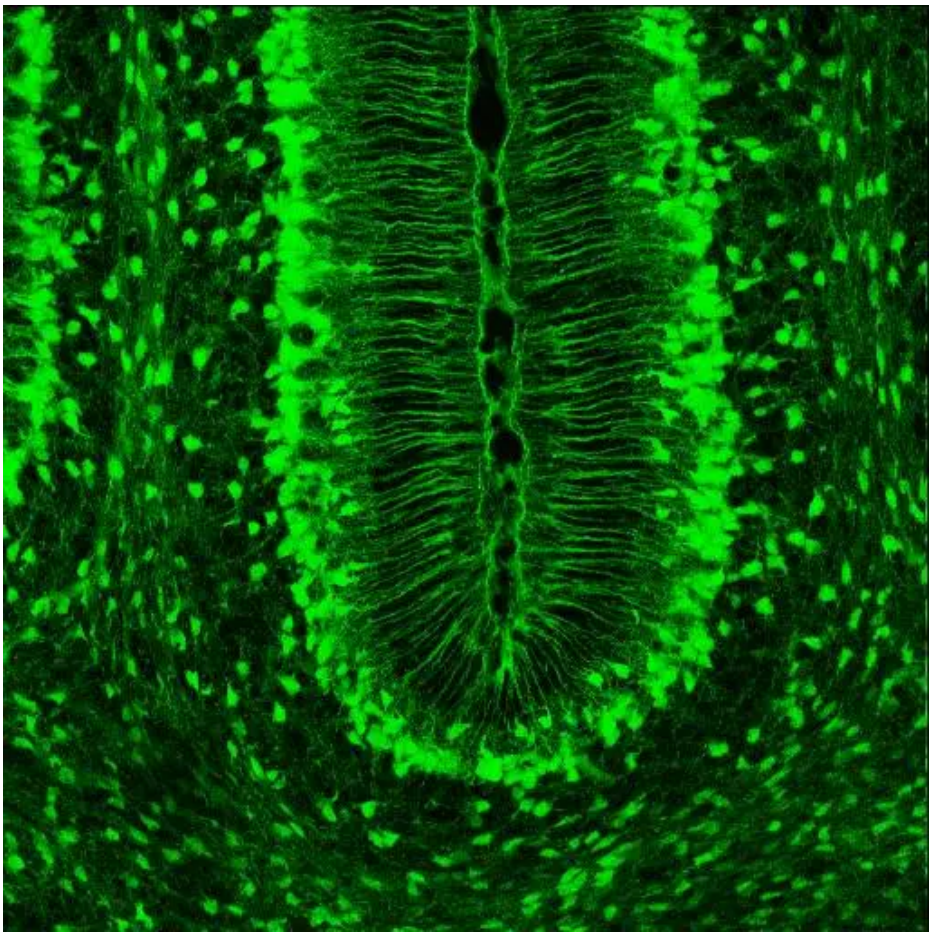
Onco-this-Week

December 1, 2018(https://sciwri.club/archives/date/2018/12/01)



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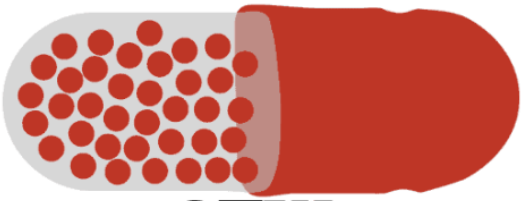
The highlighted news in Richa Tewari's Onco-this-Week include FDA approval of Larotrectinib in TRK-fusion positive cancer patients, failure of Ph III CheckMate-451 of Nivolumab + Ipilimumab in extensive-disease Small Cell Lung Cancer patients and approval of Gilteritinib in FLT3+ relapsed/refractory Acute Myeloid Leukemia patients. There are multiple clinical trial updates from G1 Therapeutics, Mustang Bio, OncoSec, Genomic Health, Celgene, Bluebird Bio and Rafael Pharmaceuticals. Check out our Trivia on evaluating performance status of cancer patients based on Zubrod and ECOG scales. There is even more oncology news from across the world, especially with several collaborations pushing the boundaries of cancer care, so don't miss out on them.- Abhi Dey



OTW in a Capsule

1. **FDA approval of Larotrectinib in TRK+ patients.** The era of tumor-agnostic treatments, which started with approval of Pembrolizumab in MSI-H or dMMR tumors last year, got another push with FDA approval of TRK inhibitor, Larotrectinib, in TRK fusion positive tumors. Both these approvals follow the non-traditional approach of not treating the tumors by type of cancers or age of patients, but by targeting a genetic mutation in patients. Larotrectinib was previously granted breakthrough therapy designation, rare pediatric disease designation, and orphan drug designation and its approval is an accelerated approval based on ORR and DoR. Hopefully this approval will guide drug development towards targeted medicine.
2. **Failure of Ph III CheckMate-451 of Nivolumab + Ipilimumab in ED SCLC patients.** Following the footprints of CheckMate-331 trial, combination of Nivolumab and Ipilimumab didn't meet primary endpoint of OS improvement in CheckMate-451 trial in patients receiving 1L maintenance therapy. Not only these back-to-back failures consolidate the positioning of SCLC to be a tough-to-treat cancer with severely limited treatment options, they also translate into a significant setback for BMS as the company loses any near-term opportunities to advance Nivolumab into 2L therapy or 1L maintenance.
3. **Approval of Gilteritinib approved in FLT3+ R/R AML patients**. AML patients have another encouraging news (after last week's dual approvals in 1L elderly and frail patients) – Astellas' FLT3 inihibitor which had earned fast-track status, got FDA approval in FLT3 mutation positive relapsed/refractory AML patients based on interim data from ADMIRAL trial. Such patients, who are at a higher risk of relapse, so far were limited to chemotherapy as their treatment options, and approval of Gilteritinib brings a promise of fewer and milder side effects compared to traditional chemotherapy.

(https://goo.gl/VLv3K1)

DRUG APPROVALS

TRK inhibitor Larotrectinib gets FDA approval in advanced solid tumor cancer patients with an NTRK Gene Fusion (https://ir.loxooncology.com/press-releases/2378241-Fda-approves-vitrakvi-larotrectinib-the-first-ever-trk-inhibitor-for-patients-with-advanced-solid-tumors-harboring-an-ntrk-gene-fusion12)

"The FDA approval of larotrectinib marks an important milestone in how we treat cancers that have an NTRK gene fusion – a rare driver of cancer. I have seen firsthand how treatment with larotrectinib, which is designed specifically for this oncogenic driver, can deliver clinically meaningful responses in patients with TRK fusion cancer, regardless of patient age or tumor type," said David Hyman, M.D., chief of the Early Drug Development Service at Memorial Sloan Kettering Cancer Center and a global principal investigator for a larotrectinib clinical trial. "We now have the first therapy approved for this genomic alteration, regardless of cancer type."

> Breaking News @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) approves #Larotrectinib (https://twitter.com/hashtag/Larotrectinib?src=hash&ref_src=twsrc%5Etfw), 1st targeted cancer drug approved based on mutation rather than tumor type & approved simultaneously for adults and children. Hear more from MSK experts who led the research on this newly approved treatment https://t.co/SaZ7yS2nVu (https://t.co/SaZ7yS2nVu)
>
> — Memorial Sloan Kettering Cancer Center (@sloan_kettering) November 26, 2018 (https://twitter.com/sloan_kettering/status/1067174583739056128?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Today's approval of Vitrakvi is the culmination of years of hard work and research by many people to bring the first ever treatment to patients with TRK fusion cancer. TRK fusions are rare, but occur across many different tumor types. In this era of precision medicine, we are delivering on Bayer's commitment to advance the future of cancer care while providing value for patients and physicians," said Robert LaCaze, member of the executive committee of Bayer's Pharmaceuticals Division and head of the Oncology Strategic Business Unit at Bayer. "It is very rewarding to provide a therapy specifically for patients with advanced solid tumors harboring an NTRK gene fusion."

Truxima (rituximab-abbs) approved by FDA as the first biosimilar to Rituxan for CD20+ B-NHL patients as monotherapy or in combination with chemotherapy (https://www.celltrion.com/en/pr/reportDetail.do?seq=530)

"The approval of TRUXIMA is a significant milestone for Celltrion and, more notably, for the patients who need access to this important medication," said Woosung Kee, Chief Executive Officer of Celltrion. "TRUXIMA is the very first rituximab biosimilar to be approved in the United States for three non-Hodgkin's lymphoma indications and may help provide greater accessibility for patients."

> The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) has approved #Truxima (https://twitter.com/hashtag/Truxima?src=hash&ref_src=twsrc%5Etfw) to treat patients with CD20-positive, B-cell non-Hodgkin's lymphoma. https://t.co/9lmNjw90mA (https://t.co/9lmNjw90mA) pic.twitter.com/uULT7Kg8Co (https://t.co/uULT7Kg8Co)
>
> — Global Onc Academy (@GOA_CME) November 30, 2018 (https://twitter.com/GOA_CME/status/1068520296506748928?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"This is an exciting time to be involved in the biosimilars space and we look forward to bringing the product to market," said Brendan O'Grady, Executive Vice President and Head of North America Commercial at Teva. "There is a stronger focus than ever, particularly within oncology, on bringing greater value to the healthcare system through biosimilars increasing the number of treatment options."

FLT3 inhibitor Gilteritinib approved in FLT3+ R/R AML patients based on interim data from ADMIRAL trial (https://www.astellas.com/us/news/14406)

"Our ability to use precision medicine to help patients with FLT3-mutated AML takes an important step forward with the approval of XOSPATA," said Alexander Perl, M.D., Abramson Cancer Center, University of Pennsylvania. "There is an urgent need in the clinic for more targeted agents to help patients whose disease is either refractory to the initial therapy, or who have relapsed."

> Astellas' Xospata (gilteritinib) Receives FDA 's Approval for 1L R/R Acute Myeloid Leukemia (AML) in Adults @AstellasUS (https://twitter.com/AstellasUS?ref_src=twsrc%5Etfw) https://t.co/MjKjusabUM (https://t.co/MjKjusabUM) pic.twitter.com/84ThHNvT6j (https://t.co/84ThHNvT6j)
>
> — PharmaShots (@Pharmashot) November 30, 2018 (https://twitter.com/Pharmashot/status/1068397746195968000?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"XOSPATA offers new hope to patients for whom the treatment path forward is unclear," said Steven Benner, M.D., senior vice president and global therapeutic area head, Oncology Development, Astellas. "For the first time, people with relapsed or refractory FLT3 mutation-positive AML have an FDA approved FLT3-targeting treatment available to them. The approval of XOSPATA is also a proud, landmark moment for our oncology program and marks the first approval of a medicine that will be the cornerstone of our new presence in blood cancers."

REGULATORY NEWS

Expedited development path planned for Galinpepimut-S in AML (https://www.sellaslifesciences.com/investors/news/News-Details/2018/SELLAS-Life-Sciences-Announces-Expedited-Development-Path-for-Galinpepimut-S-GPS-in-Acute-Myeloid-Leukemia-AML-Following-Feedback-from-FDA/default.aspx)

> New Post: FDA Grants Fast Track Designation to Galinpepimut-S for Treating Multiple Myeloma https://t.co/MESGp9rQZ8 (https://t.co/MESGp9rQZ8) pic.twitter.com/TLgANat9Zs (https://t.co/TLgANat9Zs)
>
> — Immuno-Oncology News (@immunooncnews) August 8, 2018 (https://twitter.com/immunooncnews/status/1027178912500129792?ref_src=twsrc%5Etfw)

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"Following discussion with the FDA, we are embarking upon a revised Phase 3 study for GPS in the monotherapy maintenance setting for AML patients who have achieved CR2. The new design is expected to streamline sample size, time to accrual completion, primary endpoint readout and potential time to market, as well as costs. We believe this new study design provides SELLAS with a quicker path to approval, provided the study is positive," said Dr. Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. "In addition to a statistical analysis plan which we believe accords a viable pathway for meeting the primary endpoint, we have built in an adaptive design, thus further enhancing the probability of a positive study."

Positive recommendation to Regorafenib in Sorafenib-treated advanced HCC patients from NICE for use on the NHS (https://www.nice.org.uk/news/article/life-extending-treatment-for-patients-with-advanced-liver-cancer-recommended-by-nice)

"We are pleased that the company has responded by seeking a rapid review of our original guidance and offered a price that allows us to conclude that the drug is cost-effective for routine use on the NHS in England and Wales."

> NICE has given Bayer's advanced #liver (https://twitter.com/hashtag/liver?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) therapy Stivarga (regorafenib) the go-ahead after it undertook a rapid review following earlier guidance that rejected the #drug (https://twitter.com/hashtag/drug?src=hash&ref_src=twsrc%5Etfw). #PharmaceuticalReport (https://twitter.com/hashtag/PharmaceuticalReport?src=hash&ref_src=twsrc%5Etfw) #PharmaceuticalNews (https://twitter.com/hashtag/PharmaceuticalNews?src=hash&ref_src=twsrc%5Etfw) https://t.co/ECZyJyc06s (https://t.co/ECZyJyc06s)
>
> — Pharma_report (@parma_report) December 1, 2018 (https://twitter.com/parma_report/status/1068890022185758720?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Judi Rhys, chief executive of the British Liver Trust, said: "Hepatocellular carcinoma (HCC) is the most common form of liver cancer. It is particularly aggressive with the 5-year survival rate being on average only 12% and a diagnosis is therefore devastating for the patient and their families.

"There are also very few effective treatments so the decision to approve regorafenib for routine use in England and Wales is a welcome step forward. Access to the drug will potentially provide patients with valuable extra time with their loved ones."

TRIAL RESULTS

Positive myelopreservation data observed with Trilaciclib + chemotherapy/Atezolizumab in 1L SCLC patients in Ph II trial (http://investor.g1therapeutics.com/news-releases/news-release-details/g1-therapeutics-announces-positive-myelopreservation-data?field_nir_news_date_value%5bmin%5d=2018)

> G1 Therapeutics Announces Positive Myelopreservation Data: G1 Therapeutics (NasdaqGTHX) a clinical stage oncology company today announced positive topline data from its randomized doubleblind placebocontrolled Phase 2 trial evaluating trilaciclib in... https://t.co/PPCZiDBms4 (https://t.co/PPCZiDBms4)
>
> — Drug Discovery News (@DiscoveryDrug) November 27, 2018 (https://twitter.com/DiscoveryDrug/status/1067484389422977025?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“The robust multi-lineage myelopreservation benefits of trilaciclib shown in this trial confirm the results we observed in our earlier trial in first-line small cell lung cancer,” said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. “Trilaciclib may also extend overall survival in patients receiving chemotherapy and Tecentriq, and we expect to report those data when available.”

Ph I data of MB-102 (CD123 CAR) presented in R/R AML and BPDCN patients (http://ir.mustangbio.com/file/Index?KeyFile=395917488)

Martina Sersch, M.D., Ph.D., Chief Medical Officer of Mustang, said, “We are excited about the additional data demonstrating MB-102’s (CD123 CAR T) potential to treat patients with AML and BPDCN. Initial safety and tolerability data as well as preliminary data on efficacy are very promising in a population with high unmet medical need. Based on the Phase 1 data, we expect to submit an IND filing for MB-102 and look forward to initiating a multicenter Phase 1/2 clinical trial in 2019 in patients with AML, BPDCN and high-risk myelodysplastic syndrome.”

> Mustang Bio $MBIO (https://twitter.com/search?q=%24MBIO&src=ctag&ref_src=twsrc%5Etfw) Announces Presentation of MB-102 (CD123 CAR) Safety and Efficacy Data at AACR Special Conference on Tumor Immunology and Immunotherapyhttps://t.co/wIsIAJECSW (https://t.co/wIsIAJECSW)
>
> — LifeSci Advisors (@LifeSciAdvisors) November 28, 2018 (https://twitter.com/LifeSciAdvisors/status/1067863412225523712?ref_src=twsrc%5Etfw)

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Lihua Elizabeth Budde, M.D., Ph.D., assistant professor in the Department of Hematology & Hematopoietic Cell Transplantation at City of Hope and principal investigator for the Phase 1 trial, said, “There is increased expression of CD123 on AML blasts, leukemic stem cells and BPDCN cells compared to normal hematopoietic stem cells, and it is therefore a promising target for cellular immunotherapy. We remain encouraged by interim data showing MB-102’s potential to treat BPDCN and AML and continue to evaluate MB-102’s clinical benefits in our ongoing Phase 1 clinical trial.”

Intratumoral Monotherapy TAVO™ induces abscopal responses in metastatic melanoma patients (https://ir.oncosec.com/press-releases/detail/1971/oncosec-presents-new-data-during-oral-presentation-at)

> OncoSec presents new data during oral presentation at Melanoma Bridge demonstrating intratumoral monotherapy TAVO™ induces abscopal responses in metastatic melanoma patients with 47% experiencing regression in at least one untreated lesion, details via: https://t.co/oFsRKWnqpS (https://t.co/oFsRKWnqpS)
>
> — OncoSec Medical (@OncoSec) November 29, 2018 (https://twitter.com/OncoSec/status/1068177872660123649?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“These findings are significant because they clearly demonstrate that intratumoral treatment with TAVO is having a systemic effect that goes beyond the treated tumor, and to see that effect in nearly half of treated patients is remarkable, particularly with such a well-tolerated therapy,” said Alain Algazi, M.D., Lead Trial Investigator, Associate Professor, Department of Medicine (Hematology/Oncology), at the University of California San Francisco (UCSF) Helen Diller Family Comprehensive Cancer Center and Strategic Clinical Advisor to OncoSec. “These findings build upon our previous report from this study showing an approximate 30 percent overall

response rate with monotherapy TAVO and further support the potential value of TAVO therapy for this patient population."

New analysis of NSABP randomized B-20 study confirms TAILORx study conclusions and validates predictive power of Oncotype DX test (http://newsroom.genomichealth.com/releasedetail.cfm?ReleaseID=1082937)

"We previously had an unprecedented amount of data on patients with Oncotype DX Breast Recurrence Score results of 25 or lower, and now with the results from TAILORx and the new B-20 analysis, we have critical confirmation for patients with scores over 25 that they should be treated with chemotherapy," said Norman Wolmark, M.D., chairman of the NSABP Foundation in Pittsburgh, Pennsylvania. "Our publication underscores the important clinical value of the Oncotype DX test in guiding treatment decision in every early-stage, HER2-negative breast cancer patient."

> Learn how the #TAILORx (https://twitter.com/hashtag/TAILORx?src=hash&ref_src=twsrc%5Etfw) study, which used the #OncotypeDX (https://twitter.com/hashtag/OncotypeDX?src=hash&ref_src=twsrc%5Etfw) test, fundamentally changed the way doctors treat women with early #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw). https://t.co/gqkSjTdPyW (https://t.co/gqkSjTdPyW) pic.twitter.com/wtL6FyJODs (https://t.co/wtL6FyJODs)
>
> — Oncotype IQ® (@OncotypeIQ) November 27, 2018 (https://twitter.com/OncotypeIQ/status/1067438911637606400?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The new B-20 study analysis, combined with the published results from TAILORx, provide unparalleled evidence from randomized patients that Oncotype DX can predict which patients will benefit from chemotherapy," said Steven Shak, M.D., chief scientific officer and chief medical officer, Genomic Health. "Also recognized by the National Comprehensive Cancer Network (NCCN) as the only multi-gene test to predict chemotherapy benefit, physicians can now tell every patient more confidently, based on Oncotype DX, whether they should receive chemotherapy or not."

TRIAL STATUSES

Celgene and Bluebird Bio complete enrollment of pivotal KarMM trial of anti-BCMA Car T Cell Therapy bb2121 in RRMM patients (https://ir.celgene.com/press-releases/press-release-details/2018/Celgene-Corporation-and-bluebird-bio-Complete-Enrollment-of-Pivotal-KarMMa-Study-of-anti-BCMA-Car-T-Cell-Therapy-bb2121-in-Patients-with-Relapsed-and-Refractory-Multiple-Myeloma/default.aspx)

> Celgene Corporation and bluebird bio Complete Enrollment of Pivotal KarMMa Study of antiBCMA Car T Cell Therapy bb2121 in Patients with Relapsed and Refractory Multiple Myeloma: Celgene Corporation Nasdaq CELG and bluebird bio Inc. Nasdaq BLUE today... https://t.co/hDqd1ssYtx (https://t.co/hDqd1ssYtx)
>
> — Gene Therapy (@TherapyGene) November 27, 2018 (https://twitter.com/TherapyGene/status/1067399903192657920?ref_src=twsrc%5Etfw)

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"We continue to be excited about bb2121 as a potential first-in-class BCMA-targeted therapy for patients with multiple myeloma," said Alise Reicin, M.D., President, Global Clinical Development for Celgene. "We would like to thank everyone who enabled this achievement, especially the patients and caregivers, and we congratulate the physicians and others involved in the KarMMa study, including our dedicated partners at bluebird bio. We look

forward to seeing the data from this study and are progressing our broader bb2121 development program as we advance closer toward delivering this important new option to appropriate patients in need."

"We are committed to developing new treatment options to improve the care of patients with multiple myeloma, and completing enrollment of the KarMMa study moves us closer to this goal," said David Davidson, M.D., chief medical officer, bluebird bio. "As we advance our clinical studies of bb2121 in earlier lines of therapy in collaboration with our partners at Celgene, we remain very grateful to the patients, families and healthcare providers who have made this program possible."

Ph III ARMADA 2000 trial of metabolism regulator CPI-613 (devimistat) inititated in R/R AML patients (http://www.globenewswire.com/news-release/2018/11/29/1659032/0/en/Rafael-Pharmaceuticals-Announces-Initiation-of-Pivotal-Phase-3-Trial-ARMADA-2000-of-CPI-613-devimistat-in-Patients-with-Relapsed-or-Refractory-Acute-Myeloid-Leukemia-AML.html)

Howard Jonas, Chairman of Rafael Pharmaceuticals, said, "It is not only our goal to prolong life but to keep working towards a cure for AML and other difficult to treat cancers. We have great hope both for the success of this trial and even better results in years to come with our follow-on compounds. We are optimistic that our cancer metabolism drugs may create a new paradigm in oncology treatment."

> Rafael Pharmaceuticals Announces Initiation of Pivotal Phase 3 Trial ARMADA 2000 of CPI613 devimistat in Patients with Relapsed or Refractory Acute Myeloid Leukemia AML: Newark NJ Nov. 29 2018 GLOBE NEWSWIRE Rafael Pharmaceuticals Inc. Rafael a leader in... https://t.co/QQLeQTqKld (https://t.co/QQLeQTqKld)
>
> — Leukemia News (@Leukemia_bio) November 29, 2018 (https://twitter.com/Leukemia_bio/status/1068163883804745730?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Sanjeev Luther, President and Chief Executive Officer of Rafael Pharmaceuticals, commented, "Our motto, 'To Save A Life Is To Save A Universe,' reflects our commitment to develop potential treatments for patients with significant unmet clinical needs. Initiation of our ARMADA 2000 trial is a significant milestone in that direction. We believe that CPI-613 has the potential to change the course of treatment in elderly patients with AML. Given that the clinical development of CPI-613 started at Wake Forest Baptist Health, we wanted this to be the site to enroll the first patient in this Phase 3 trial. We are grateful to all the individuals that have been involved with clinical development of CPI-613. Given the importance of this trial we have partnered with a reputable contract research organization, IQVIA, for study execution."

COLLABORATIONS

Aileron and Pfizer to evaluate p53 mimetic ALRN-6924 + Palbociclib in MDM2-amplified cancers (https://investors.aileronrx.com/news-releases/news-release-details/aileron-enters-clinical-trial-collaboration-pfizer-evaluate-alrn)

"We are excited about this combination trial with Pfizer's palbociclib," stated Manuel Aivado, MD, PhD, President and Chief Executive Officer of Aileron. "The combination of ALRN-6924 and palbociclib demonstrated enhanced antitumor activity and meaningfully delayed tumor growth in animal models over single agents alone. We believe the combination of these two drugs represents a complementary attack on the proliferation of cancer cells that may benefit patients with a variety of different cancers."

> Aileron & @pfizer (https://twitter.com/pfizer?ref_src=twsrc%5Etfw) to collab on Ph1b #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) of ALRN-6924 + palbociclib vs MDM2-amplified #cancers (https://twitter.com/hashtag/cancers?src=hash&ref_src=twsrc%5Etfw) in Q1 2019
>
> ALRN-6924 is a cell-permeating #peptide (https://twitter.com/hashtag/peptide?src=hash&ref_src=twsrc%5Etfw) that mimics p53 #tumor (https://twitter.com/hashtag/tumor?src=hash&ref_src=twsrc%5Etfw) suppressor proteinhttps://t.co/2jMJVJKM9Z (https://t.co/2jMJVJKM9Z)#oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #proteomics (https://twitter.com/hashtag/proteomics?src=hash&ref_src=twsrc%5Etfw) #biologics (https://twitter.com/hashtag/biologics?src=hash&ref_src=twsrc%5Etfw) @LifeSciAdvisors (https://twitter.com/LifeSciAdvisors?ref_src=twsrc%5Etfw) pic.twitter.com/UsbyYdrAvq (https://t.co/UsbyYdrAvq)
>
> — DDNews Online (@DDNewsOnline) November 27, 2018 (https://twitter.com/DDNewsOnline/status/1067463310684102656?ref_src=twsrc%5Etfw)

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

Combination of oncolytic immunotherapy CG0070 and Pembrolizumab to be tested in BCG-ref NMIBC patients (https://www.businesswire.com/news/home/20181128005171/en/Cold-Genesys-Announces-Clinical-Trial-Collaboration-Evaluate)

"We are delighted to be collaborating with Merck on this innovative combination approach," said Arthur Kuan, CEO of Cold Genesys. "CG0070, which has demonstrated clinical safety and efficacy in over 100 patients for the treatment of NMIBC, may potentially exhibit additional effect when combined with KEYTRUDA, which also has demonstrated single agent activity in the indication."

> Cold Genesys Announces Clinical Trial Collaboration to Evaluate the Combination of CG0070 and KEYTRUDA® (pembrolizumab) in Bladder Cancer https://t.co/do6AfCxhcE (https://t.co/do6AfCxhcE) pic.twitter.com/wbZvJdlEis (https://t.co/wbZvJdlEis)
>
> — PharmaMKT (@PharmaMKTnet) November 29, 2018 (https://twitter.com/PharmaMKTnet/status/1068143000172339203?ref_src=twsrc%5Etfw)

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BeiGene acquires exclusive development and commercial rights to Zymeworks' bispecific candidates, ZW25 and ZW49, in Asia (excluding Japan), Australia, and New Zealand (media.corporate-ir.net/media_files/IROL/25/254246/Zymeworks-BeiGene%20Press%20Release%2011.26.18_EN.pdf)

> BeiGene acquires rights to Zymeworks' ZW25 and ZW49 bispecific candidates in Asia-Pacific https://t.co/k66ZA9RMGD (https://t.co/k66ZA9RMGD)
>
> — pharmabr (@PharmaBR) November 28, 2018 (https://twitter.com/PharmaBR/status/1067720191071715328?ref_src=twsrc%5Etfw)

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"Zymeworks' promising candidates ZW25 and ZW49 complement our oncology pipeline and further advance our mission to develop treatments for patients who often have limited options," commented Dr. Xiaobin Wu, General Manager of China and President of BeiGene, Ltd. "Our deep clinical experience in China is an integral part of our business development efforts, as these trial data can be used to support global regulatory filings. We are excited by the clinical prospects of ZW25 and ZW49 in HER2-expressing cancers." "At Zymeworks we are committed to developing new therapies to help address unmet medical need on a global basis," said Diana Hausman, MD,

Zymeworks' Chief Medical Officer. "We are looking forward to collaborating with BeiGene and benefiting from their extensive experience in oncology drug development in China and elsewhere. We expect that this collaboration will accelerate the development of ZW25 and ZW49 as potential new therapies for patients with HER2-expressing solid tumors, including gastric, breast and other cancers."

Tocagen and NRG Oncology to collaborate on a Ph II/III trial of Toca 511 & Toca FC in newly diagnosed Glioblastoma (http://ir.tocagen.com/phoenix.zhtml?c=254300&p=irol-newsArticle&ID=2378701)

"The Brain Tumor Committee at NRG Oncology elected to conduct and sponsor the Toca 511 & Toca FC clinical trial in patients with newly diagnosed GBM based on the merits of published clinical data, which show extended overall survival compared to historical controls, durable complete responses and a favorable safety profile in patients with recurrent high grade glioma along with preclinical data that support a novel immune-activating mechanism of action, synergy with radiation therapy and additive efficacy in combination with temozolomide," said Minesh P. Mehta, chair of the Brain Tumor Committee at NRG Oncology.

> NRG Oncology collaborates with Tocagen on a Phase 2/3 Trial of Toca 511 & Toca FC in newly diagnosed #glioblastoma (https://twitter.com/hashtag/glioblastoma?src=hash&ref_src=twsrc%5Etfw). The proposed NRG-BN006 trial is expected to begin enrollment in 2019. Read the press release here: https://t.co/yfBgknLnRg (https://t.co/yfBgknLnRg) #BTSM (https://twitter.com/hashtag/BTSM?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/W3ax7sqJY7 (https://t.co/W3ax7sqJY7)
>
> — NRG Oncology (@NRGonc) November 29, 2018 (https://twitter.com/NRGonc/status/1068238392767512577?ref_src=twsrc%5Etfw)

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Added Manmeet Ahluwalia, Principal Investigator of the proposed study, "Glioblastoma remains a very high unmet need and there is excitement among the NRG Oncology membership to explore the potential of Toca 511 & Toca FC to enhance standard treatment to achieve greater tumor response and extend survival of patients with this aggressive type of cancer."

Tracon Pharma and I-Mab Biopharma to collaborate on clinical development of CD73 inhibitor TJD5 (http://ir.traconpharma.com/news-releases/news-release-details/tracon-pharmaceuticals-and-i-mab-biopharma-announce-strategic)

"There is a great strategic fit between the two companies. We have complementary development capabilities and share a passion for science. We are pleased to work with TRACON to facilitate clinical development of TJD5 and any selected BsAbs in North America through a capital efficient partnership," said Jingwu Zang, M.D., Ph.D., CEO of I-Mab. "This partnership recognizes and values the potential of our innovative assets and strong drug discovery and development capabilities." "Partnering with TRACON is an important part of our global development strategy to bring innovative biologics to patients worldwide. It further strengthens our presence in North America following the establishment of our US office and is the latest addition to our growing global partnerships spanning from drug candidates to clinical assets," Zang added.

> TRACON & I-Mab to share regulatory & clinical costs of #immuno_oncology (https://twitter.com/hashtag/immuno_oncology?src=hash&ref_src=twsrc%5Etfw) programs in North America
>
> Projects include anti-CD73 lead TJD5 & up to 5 #bispecific (https://twitter.com/hashtag/bispecific?src=hash&ref_src=twsrc%5Etfw) #antibody (https://twitter.com/hashtag/antibody?src=hash&ref_src=twsrc%5Etfw) leadshttps://t.co/IlQFLKG2bT (https://t.co/IlQFLKG2bT)#oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) @LifeSciAdvisors (https://twitter.com/LifeSciAdvisors?ref_src=twsrc%5Etfw) pic.twitter.com/h3pwtegEdu (https://t.co/h3pwtegEdu)
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> — DDNews Online (@DDNewsOnline) November 29, 2018 (https://twitter.com/DDNewsOnline/status/1068218034077102080?ref_src=twsrc%5Etfw)

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“We are excited to enter into this broad strategic transaction with I-Mab, an innovative biologics company with a broad pipeline of immuno-oncology assets with great potential to impact the treatment of cancer patients. We are particularly impressed with the similarities in corporate cultures between I-Mab and TRACON,” said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. “This agreement expands TRACON’s portfolio of potential first-in-class and best-in-class immuno-oncology therapies and further validates TRACON’s product development solution for companies looking to develop innovative products in the U.S. In particular, we believe our existing in-house drug development expertise can reduce both the cost and time of clinical development for our partners and, when combined with our willingness to cost share, this can be an attractive development option. Given TRACON’s ability to expand our development capacity for additional products, we expect to continue leveraging our platform.”

Efficacy of combinations of VEGFR inhibitors Surufatinib and Fruquintinib with PD-1 checkpoint inhibitors to be evaluated (https://www.chi-med.com/a181129/)

> Chi-Med Enters into Multiple Collaborations to Evaluate Combinations of Surufatinib and Fruquintinib with PD-1 Checkpoint Inhibitors https://t.co/3gEzKWUZEa (https://t.co/3gEzKWUZEa) pic.twitter.com/ZoroJFYoUr (https://t.co/ZoroJFYoUr)
>
> — Hutchison China MediTech (@HChiMed) November 29, 2018 (https://twitter.com/HChiMed/status/1068063951563309056?ref_src=twsrc%5Etfw)

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“Recent innovations in solid tumor drugs have focused on targeted therapies and immunotherapies which, as monotherapies, have both provided improved patients outcomes,” said Christian Hogg, Chief Executive Officer of Chi-Med. “We believe that the future of oncology treatments increasingly lies in combining therapies, utilizing multiple mechanisms of action (“MOA”) to confront tumors. Our unique next-generation anti-angiogenesis VEGFR inhibitors, with high selectivity and tolerability, make them ideal candidates for such combinations with immunotherapy agents such as PD-1/L1 monoclonal antibodies to prolong and expand the benefits of these therapies to more patients.”

OTW Trivia

Q: What is performance status in cancer patients?

A: Performance status is a very important parameter in cancer care and treatment of patients. It is a scoring criterion to assess the patient's ability to carry out certain ***activities of daily living (ADLs)*** without others' assistance or help.

Q: What are the different performance status scores available?

A: Different performance status criteria available and used in oncology are ECOG (Eastern Cooperative Oncology Group), Zubrod, or Karnofsky scales. Zubrod and ECOG scales range between 0 to 4, with 0 being fully functional and asymptomatic, and 4 being completely dependent on others and bedridden. On the other hand, Karnofsky scale ranges from 10 (moribund) to 100 (normal).

Q: How to compare ECOG and Karfnosky scales?

A: ECOG-ACRIN cancer research support group compares the two scales as below:

ECOG PERFORMANCE STATUS	KARNOFSKY PERFORMANCE STATUS
0—Fully active, without restriction – able to carry on all pre-disease performance	100—Normal, no complaints; asymptomatic 90—Able to carry on normal activity; minor signs or symptoms of disease
1—Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work	80—Normal activity with effort 70—Cares for self but unable to carry on normal activity or to do active work
2—Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours	60—Requires occasional assistance but independent for most of personal needs 50—Requires considerable assistance and frequent medical care
3—Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours	40—Disabled; requires special care 30—Severely disabled

4—Completely disabled; cannot carry on any selfcare; totally confined to bed or chair	20—Very ill; hospitalization and active supportive care necessary 10—Moribund
5—Dead	0—Dead

Source: https://ecog-acrin.org/resources/ecog-performance-status

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: (Wikimedia) Slc1a3 gene expressed in the Bergmann glia of the cerebellum of a mice aged 7 days; saggital section. The Gene Expression Nervous System Atlas (GENSAT) Project, NINDS Contract # N01NS02331 to The Rockefeller University (New York, NY). Source (https://commons.wikimedia.org/wiki/File:Slc1a3_in_Bergmann_Glia.jpg)

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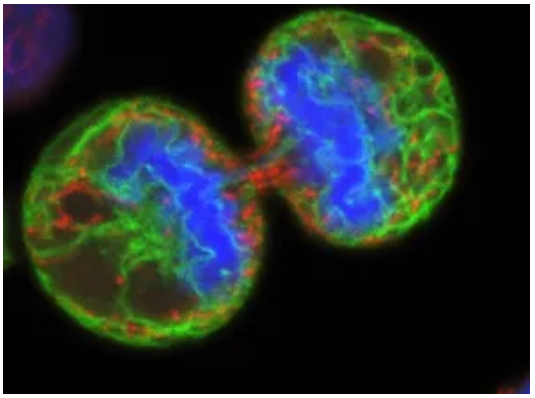

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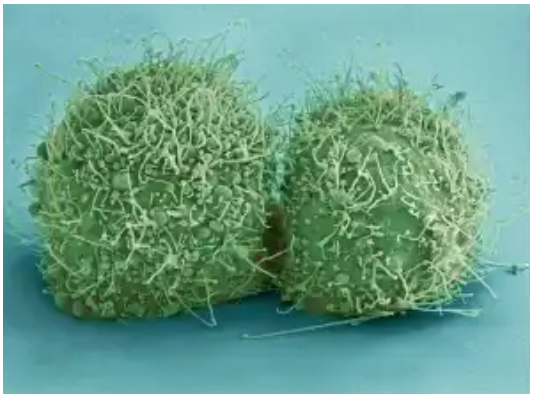

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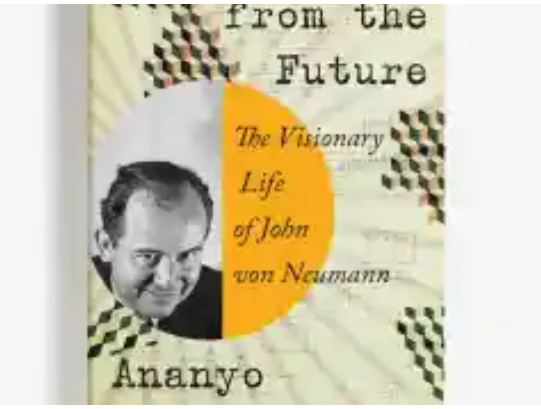

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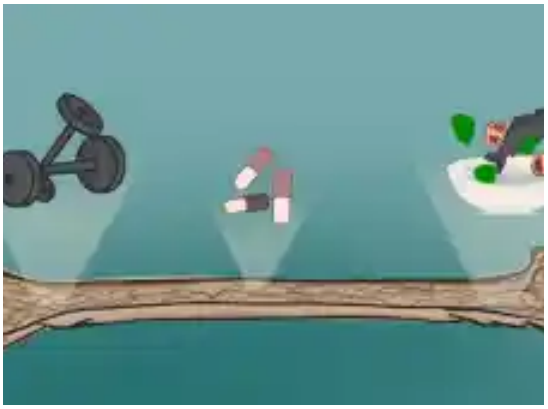

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