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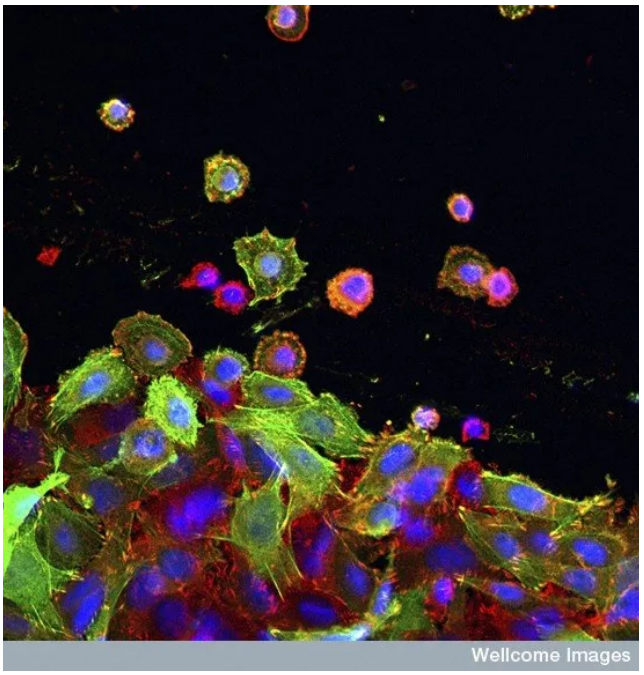
Onco-this-Week

April 28, 2019(https://sciwri.club/archives/date/2019/04/28)



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HIGHLIGHTS

1. **Approval of Pembrolizumab + Axitinib in 1L RCC patients**: We discussed Axitinib in our earlier bulletins of Onco-this-Week when it scored not just one, but two back-to-back breakthrough designations in frontline RCC. With Pembrolizumab combination securing an FDA approval this week, all the eyes will be on upcoming Avelumab data to see the differences in their OS data.
2. **Failure of yet another immunotherapy in SCCHN:** Though the results are not announced and more details are awaited, BMS today announced failure of Nivolumab + Ipilimumab vs Nivolumab in meeting primary endpoint (ORR?) in Ph II CheckMate-714 trial. Would ASCO 2019 bring more details?
3. **Performance of Pembrolizumab +/- chemotherapy in Gastric/GEJ cancers**. Merck would be hoping to duplicate Pembrolizumab's 3L setting success in frontline patients but today's updates from Ph III KEYNOTE-062 trial in PD-L1+ve patients were mixed – the good news was that Pembrolizumab monotherapy was non-inferior to chemotherapy in OS, but chemo combination was not superior for either OS or PFS vs chemo alone. The results thus seem closer to Pembrolizumab's dismal performance in second line patients. Merck's focus would now shift to KEYNOTE-585, a Ph III study of Pembrolizumab + chemo in neoadjuvant/ adjuvant settings.

DRUG APPROVALS

FDA approves Pembrolizumab + Axitinib in 1L RCC patients based on Ph III KEYNOTE-426 trial data (https://www.mrknewsroom.com/news-release/prescription-medicine-news/fda-approves-mercks-keytruda-pembrolizumab-combination-inlyt)

"This represents a new treatment option for patients with advanced renal cell carcinoma, who will now have access to KEYTRUDA as part of a first-line combination regimen," said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. "Today's approval reflects Merck's commitment to patients with cancer and further supports the use of KEYTRUDA to help improve survival outcomes for patients with advanced renal cell carcinoma."

> The FDA has approved pembrolizumab in combination with axitinib as first-line treatment for patients with advanced renal cell carcinoma. Review our updated timeline of anti-PD1/L1 antibody approvals by the FDA: https://t.co/UF6DlnBxWw (https://t.co/UF6DlnBxWw) #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/CTL5qhVtwo (https://t.co/CTL5qhVtwo)
>
> — Cancer Research Institute (@CancerResearch) April 27, 2019 (https://twitter.com/CancerResearch/status/1122142162517483521?ref_src=twsrc%5Etfw)

REGULATORY NEWS

PDGFR-α inhibitor Olaratumab to be withdrawn from the market post failure of Ph III ANNOUNCE trial in STS; access program to be developed for current patients (https://investor.lilly.com/news-releases/news-release-details/lilly-establish-access-program-patients-it-prepares-withdraw)

"Lilly wants to ensure that patients and physicians feel supported during this important time," said Anne White, president, Lilly Oncology. "Advanced soft tissue sarcoma is a rare and difficult-to-treat cancer. Establishing this program will give patients who are currently taking Lartruvo the opportunity to continue their treatment program uninterrupted."

> Eli Lilly Facilitates the Withdrawal of Lartruvo (olaratumab) from the Global Market for Advanced Soft Tissue Sarcoma @Lillypad (https://twitter.com/LillyPad?ref_src=twsrc%5Etfw) https://t.co/RWT6ANFe1d (https://t.co/RWT6ANFe1d)
>
> — PharmaShots (@Pharmashot) April 25, 2019 (https://twitter.com/Pharmashot/status/1121399884265844736?ref_src=twsrc%5Etfw)

IND accepted by NMPA for KIT/PDGFRA dual inhibitor, Avapritinib, in Ph I/II bridging registrational trial in advanced GIST patients (http://www.cstonepharma.com/en/html/news/2073.html)

> CStone Approved to Start China Bridging Trial of GIST Candidate: Suzhou's CStone Pharma HK 2616 was approved to start a bridging Phase III clinical trial in China of avapritinib in patients with unresectable or metastatic gastrointestinal stromal tumors... https://t.co/rSUiAtQ811 (https://t.co/rSUiAtQ811)
>
> — Clinical Trials News (@ClinicalPhase) April 16, 2019 (https://twitter.com/ClinicalPhase/status/1118028256307863552?ref_src=twsrc%5Etfw)

CStone Chairman and CEO Dr. Frank Jiang commented: "Avapritinib has been granted Breakthrough Therapy Designation by the U.S. FDA based on the treatment's promising data. Currently there are no approved drugs that target the PDGFRA D842V mutation. We hope to leverage the data that will be submitted to the U.S. FDA by Blueprint Medicines and the bridging study results to support an NDA submission in China."

INDA accepted for HER2-targeting engineered toxin body MT-5111; Ph I to start in R/R HER2+ve solid tumors in 3Q19 (http://ir.mtem.com/news-releases/news-release-details/molecular-templates-announces-fda-acceptance-ind-application-mt)

> Translational Research in Oncology (TRIO) Partners With Molecular Templates for First-In-Human Phase I Study for MT-5111 https://t.co/c1hAqgm4KV (https://t.co/c1hAqgm4KV)
>
> — SPI News (@NewsFromSPI) April 25, 2019 (https://twitter.com/NewsFromSPI/status/1121415290745708544?ref_src=twsrc%5Etfw)

"We are excited to be advancing MT-5111, which utilizes our proprietary de-immunized toxin scaffold, into the clinic for the treatment of patients with HER2-positive cancers. HER2 is a well validated target that is central to disease and when existing HER2-targeting therapies fail, the target persists, suggesting that a HER2-targeted therapy with a new mechanism of action has good potential to provide benefit to patients," said Eric Poma, Ph.D., CEO and CSO of Molecular Templates. "We have seen promising responses to our lead pipeline candidate MT-3724 in DLBCL and we are excited to further leverage the novel mechanism of action of our ETB platform with MT-5111. We look forward to providing an update on the Phase I study by year-end 2019."

Clinical acceleration of "Off-The-Shelf" personalized neoantigen immunotherapy program (SLATE) following FDA feedback (https://www.nasdaq.com/press-release/gritstone-oncology-announces-clinical-acceleration-of-offtheshelf-personalized-neoantigen-20190422-00235)

> Gritstone Oncology Announces Clinical Acceleration of "Off-The-Shelf" Personalized Neoantigen Immunotherapy Program (SLATE) Following FDA Feedback – GlobeNewswire: Gritstone Oncology Announces Clinical Acceleration of "Off-The-Shelf" Personalized... https://t.co/3tfqxeA5jL (https://t.co/3tfqxeA5jL)
>
> — Oncology Board (@mb_Oncology) April 28, 2019 (https://twitter.com/mb_Oncology/status/1122536588855037953?ref_src=twsrc%5Etfw)

"Both SLATE and GRANITE use the same immunogenic viral vector system to deliver tumor-specific neoantigens (TSNA) to patients with the objective of driving a powerful and sustained T-cell response against their own tumors," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "SLATE is designed for the subset of patients whose tumors carry specific oncogenic driver mutations resulting in neoantigens that are common across certain tumor types and patients. SLATE unites the expected potency of a TSNA-directed immunotherapy with the convenience of an 'off-the-shelf' product. Following our recent FDA interactions, we are expecting to open the SLATE Phase 1 study to patient enrollment as early as mid-2019, which is substantially faster than we had forecasted."

MAA submitted for erythroid maturation agent, Luspatercept,in patients with very low to intermediate risk MDS-associated anemia based on Ph III MEDALIST trial data (https://ir.celgene.com/press-releases/press-release-details/2019/Celgene-Corporation-and-Acceleron-Pharma-Announce-Submission-of-Luspatercept-Marketing-Authorization-Application-to-the-European-Medicines-Agency-EMA-for-MDS-and-Beta-Thalassemia/default.aspx)

> Celgene Corporation and Acceleron Pharma Announce Submission of Luspatercept Marketing Authorization Application to the European Medicines Agency (EMA) for MDS and Beta-Thalassemia https://t.co/nU5jmuql86 (https://t.co/nU5jmuql86)
>
> — thalassaemiaTPC (@ThalassaemiaTPC) April 26, 2019 (https://twitter.com/ThalassaemiaTPC/status/1121809817092415488?ref_src=twsrc%5Etfw)

"As a first-in-class erythroid maturation agent, luspatercept has the potential to become an important therapeutic option for patients with these serious diseases by treating the associated anemia and reducing the burden of transfusions," said Jay Backstrom, M.D., Chief Medical Officer for Celgene. "We, along with our partners at Acceleron, now look forward to the regulatory process as we strive to deliver luspatercept to patients in need."

SPECIAL STATUSES

ECT-001 Receives RMAT designation in heme malignancies (2019%20SOTI%20deliverables.xlsx)

> @ExCellThera (https://twitter.com/Excellthera?ref_src=twsrc%5Etfw) announces clearance by FDA and Health Canada for ECT-001 in new #clinical (https://twitter.com/hashtag/clinical?src=hash&ref_src=twsrc%5Etfw) trials in #UnitedStates (https://twitter.com/hashtag/UnitedStates?src=hash&ref_src=twsrc%5Etfw) and #Canada (https://twitter.com/hashtag/Canada?src=hash&ref_src=twsrc%5Etfw) for the #treatment (https://twitter.com/hashtag/treatment?src=hash&ref_src=twsrc%5Etfw) of #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw): https://t.co/TIuLLV47WC (https://t.co/TIuLLV47WC) #Research (https://twitter.com/hashtag/Research?src=hash&ref_src=twsrc%5Etfw) #GuySauvageau (https://twitter.com/hashtag/GuySauvageau?src=hash&ref_src=twsrc%5Etfw) #TheIRIC (https://twitter.com/hashtag/TheIRIC?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/XQp5wLqI6T (https://t.co/XQp5wLqI6T)
>
> — IRIC (@IRIC_umontreal) March 25, 2019 (https://twitter.com/IRIC_umontreal/status/1110275815307182081?ref_src=twsrc%5Etfw)

"The FDA's RMAT designation is a clear signal of confidence in the potential of our lead cell therapy drug product, ECT-001, to treat patients with hematologic malignancies," said Dr. Guy Sauvageau, CEO and founder of ExCellThera. "We look forward to working with the FDA within the RMAT framework to advance ECT-001 through the final phases of clinical development in an expedited manner."

Orphan drug designation granted to CD19 & CD22 (AUTO3)-targeting CAR-Ts in ALL (https://autolus.gcs-web.com/news-releases/news-release-details/autolus-therapeutics-receives-fda-orphan-drug-designation-auto3)

> Autolus Therapeutics Receives FDA Orphan Drug Designation for AUTO3 for Treatment of Acute Lymphoblastic Leukemia — https://t.co/foQemgDYfx (https://t.co/foQemgDYfx) pic.twitter.com/ph95sveQtE (https://t.co/ph95sveQtE)
>
> — ChemDiv (@ChemDiv) April 27, 2019 (https://twitter.com/ChemDiv/status/1122225368499408897?ref_src=twsrc%5Etfw)

"We are pleased to receive orphan drug designation for AUTO3 for acute lymphoblastic leukemia," said Dr. Christian Itin, chairman and chief executive officer of Autolus. "Earlier this year, we presented encouraging updated data from the AMELIA phase 1/2 trial of AUTO3 in pediatric ALL patients. We believe that AUTO3 has the potential to be a best in class therapy in pediatric ALL by addressing antigen escape, a common cause of relapse in these patients. AUTO3 may also provide an improved safety profile over currently marketed CAR T therapies with low levels of severe CRS and neurotoxicity observed in clinical studies."

TRIAL RESULTS

TRIAL FAILURE: Ph II CheckMate-714 trial of Nivolumab vs Nivolumab + Ipilimumab fails to meet primary endpoint in SCCHN patients; more details awaited (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-reports-first-quarter-financial-results-1)

> Bristol-Myers says Phase 2 CheckMate -714 trial did not meet primary endpoints https://t.co/mGFwYw4eLh (https://t.co/mGFwYw4eLh)
>
> — AwesomeCapital (@AwesomeCapital) April 25, 2019 (https://twitter.com/AwesomeCapital/status/1121407417370198016?ref_src=twsrc%5Etfw)

BMS today announced Q1 2019 results along with updates from the Ph II CheckMate-714 trial of Nivolumab vs Nivolumab + Ipilimumab in SCCHN patients. The results might get announced later, but the company confirmed that the study did not meet its primary endpoints.

Encouraging interim results observed in Ph IIa trial of CDKi Milciclib in advanced HCC patients; top-line data expected in Q3 2019 (https://www.tizianalifesciences.com/news/2019-04-24-tiziana-reports-encouraging-interim-clinical-data-from-an-ongoing-phase-2a-trial-with-milciclib-in-advanced-liver-cancer-patients)

> $TLSA (https://twitter.com/search?q=%24TLSA&src=ctag&ref_src=twsrc%5Etfw)
>
> Milciclib (TZLS-201)
> cyclin-dependent kinases (CDK) involved in cell division
>
> Foralumab (TZLS-401)
> fully human engineered anti-human CD3 antibody with advantages of short duration of treatment regimen and reduced immunogenicity.https://t.co/Rbgg8fiJaX (https://t.co/Rbgg8fiJaX) pic.twitter.com/eoul1JNqn9 (https://t.co/eoul1JNqn9)
>
> — yvsx (@yvsx) February 15, 2019 (https://twitter.com/yvsx/status/1096450138229407745?ref_src=twsrc%5Etfw)

"Demonstration of safety and clinical activity is an important milestone to move forward with strategic options for further clinical development of Milciclib either as a single agent or in combination with one of the FDA approved drugs for treatment of HCC patients," said Dr Kunwar Shailubhai, CEO & CSO of Tiziana. "We previously reported data from preclinical studies demonstrating that Milciclib produced pronounced synergistic anti-HCC activity in combination with any one of the U.S. Food and Drug Administration approved drugs such as sorafenib (Nexavar®), regorafenib (Stivarga®), and lenvatinib (Lenvima®)."

90% ORR seen with CD123-directed cytotoxin, Tagraxofusp, in BPDCN patients (https://www.mdanderson.org/newsroom/study-of-tagraxofusp-reports-90-percent-response-rate-for-deadly.h00-159302256.html)

> Study of tagraxofusp reports 90% response rate for deadly blood cancer with no prior available therapies https://t.co/EGqPPKpM70 (https://t.co/EGqPPKpM70) pic.twitter.com/FsSdXHwNYz (https://t.co/FsSdXHwNYz)
>
> — Bioengineer.org (@bioengineerorg) April 28, 2019 (https://twitter.com/bioengineerorg/status/1122454047464808448?ref_src=twsrc%5Etfw)

“In adults with BPDCN, tagraxofusp led to clinical responses regardless of whether patients had received previous therapy,” said Pemmaraju. “We observed high response rates including an overall response rate of 90 percent among frontline-treated patients. These findings offer hope for patients who have had no treatments specific to this disorder.”

TRIAL/PROGRAM STATUSES

Ph II trial of HER2-targeting bispecific antibody ZW25 in 1L HER2-expressing mGEJ cancers initiated; data to support initiation of registrational Ph III trial (https://ir.zymeworks.com/news-releases/2019/04-15-2019-114432960)

> $ZYME (https://twitter.com/search?q=%24ZYME&src=ctag&ref_src=twsrc%5Etfw) Wells Fargo Outperform rating and raises PT to $42 following initiation of phase 2 development for HER2 biparatopic antibody therapeutic ZW25 as frontline treatment for metastatic HER2+ gastroesophageal cancers (reasonable likelihood of success due to strong pb data)
>
> — Jonathan Faison (@jfais20) April 22, 2019 (https://twitter.com/jfais20/status/1120365805298782210?ref_src=twsrc%5Etfw)

“Advancing ZW25 into a Phase 2 clinical trial represents another key milestone for Zymeworks,” said Ali Tehrani, Ph.D., Zymeworks’ President & CEO. “This reaffirms our commitment to execute our ambitious drug development strategy to address unmet need in patients with HER2-expressing cancers across multiple indications and lines of therapy. We anticipate that data from this trial will support initiation of a first-line registrational trial, which could position ZW25 as the new standard of care for HER2-positive metastatic gastric cancer.”

Updates on patient recruitment in OCEAN trial and other studies provided (https://www.oncopeptides.se/en/oncopeptides-provides-new-guidance-on-the-patient-recruitment-in-the-ocean-study-and-a-clinical-program-update-in-a-webcast-at-1000-cet/)

> Randomized trials of pomalidomide combinations for MM https://t.co/6FO9edOiB4 (https://t.co/6FO9edOiB4) pic.twitter.com/Ga3qOGdcBZ (https://t.co/Ga3qOGdcBZ)
>
> — Oncology Tube (@oncologytube) April 24, 2019 (https://twitter.com/oncologytube/status/1120840023375351809?ref_src=twsrc%5Etfw)

“After the initiation of OCEAN, pomalidomide has been used more and more as a second line treatment option for patients with multiple myeloma. This is a strong positive for melflufen and its future sales potential based on the OCEAN trial design as a head-to-head comparison with pomalidomide. At the same time as being positive for the value of OCEAN it also represents a patient recruitment challenge since those patients cannot be part of the OCEAN study. It takes time to establish a new recruitment forecast since patient recruitment variability is high between different months and is further amplified by the expansion of the number of hospitals in the study. Despite all the actions taken, we have now determined that we will not meet the original enrollment goal”, commented Jakob Lindberg, CEO of Oncopeptides.

Ph Ib/II trial of HPVST therapy, TT12 + Pembrolizumab, to be initiated in recurrent or metastatic HPV16/HPV18+ve cervical cancer patients (https://www.tessatherapeutics.com/2019/04/16/tessa-therapeutics-announces-collaboration-with-msd-investigating-the-combination-of-keytruda-pembrolizumab-and-virus-specific-t-cell-therapy-targeting-human-papillomavirus-in-cervical-cancer/)

> Tessa Therapeutics Announces Collaboration with MSD Investigating the Combination of KEYTRUDAÂ pembrolizumab and VirusSpecific T Cell Therapy Targeting Human Papillomavirus in Cervical Cancer: The collaboration will evaluate the safety and efficacy of... https://t.co/M5WKO5pL8m (https://t.co/M5WKO5pL8m)
>
> — Renal Cell Carcinoma (@Renal_Bio) April 16, 2019 (https://twitter.com/Renal_Bio/status/1118050780794085376?ref_src=twsrc%5Etfw)

“We are very excited to work with MSD to evaluate the potential of KEYTRUDA® in combination with Tessa’s VST therapy for cervical cancer,” said Mr. Andrew Khoo, Tessa Therapeutics CEO and Co-Founder. “Cervical cancer is a major cause of death in women, especially in some of the most vulnerable parts of the world. Furthermore, the current prognosis and treatment options for patients with metastatic cervical cancer are poor. We look forward to developing this novel combination further, which has the potential to bring more effective treatment options for such patients.”

First patient dosed in Ph III GEMSTONE-303 trial of PD-L1 inhibitor CS1001 + chemo in 1L mGastric/GEJ adenocarcinoma patients (http://www.cstonepharma.com/en/html/news/2076.html)

> First patient dosed in Phase III GEMSTONE303 study for CS1001 in combination with chemotherapy in firstline gastric adenocarcinoma and gastroesophageal junction adenocarcinoma: SHANGHAI April 16 2019 PRNewswire CStone Pharmaceuticals the... https://t.co/NPA08LlVIx (https://t.co/NPA08LlVIx)
>
> — Renal Cell Carcinoma (@Renal_Bio) April 16, 2019 (https://twitter.com/Renal_Bio/status/1118196996500680715?ref_src=twsrc%5Etfw)

"We are pleased to get this Phase III clinical study under way with the first patient enrolled and dosed," Dr. Frank Jiang, Chairman and CEO of CStone, commented. "For the past few decades, gastric cancer incidence rate and mortality rate have decreased in most areas of the world. However, in China the number of cases of gastric cancer keeps increasing and both gastric adenocarcinoma and GEJ still represent major healthcare problems with serious unmet medical needs. We hope CS1001 can prove successful in this registration study and provide an important new treatment option for Chinese patients."

TECHNOLOGY: FasT CAR-T platform to shorten CAR-T manufacturing time from 2 weeks to 1 day; also lower manufacturing costs (https://www.prnewswire.com/news-releases/gracell-bio-announces-fast-car-t-a-breakthrough-technology-for-hematological-malignancies-300836248.html)

> CAR-T for cancer: $750k treatment. https://t.co/aY7WHwwC7G (https://t.co/aY7WHwwC7G). Need to get that price down fast.
>
> — John Gordon (@jgordonshare) April 14, 2019 (https://twitter.com/jgordonshare/status/1117230564069785602?ref_src=twsrc%5Etfw)

Dr. William Wei Cao, founder, chairman and CEO of Gracell, said, "Lengthy manufacture, high cost, relapse, and ineffectiveness in solid tumors of CAR-T products are the major challenges the CAR-T industry is facing. Gracell's mission is to develop highly effective but low cost CAR-T cancer therapies for large unmet needs. Without support from patients, their families, and clinical scientists, we wouldn't be able to advance the very promising FasT CAR-T technology."

First patient dosed in Ph I CIBI318A101 trial of Anti-PD-1 x anti-PD-L1 bispecific antibofy, IBI318, in solid tumors (http://innoventbio.com/en/#/news/140)

> Innovent Biologics doses first patient in PD-L1 x PD-1 bispecific antibody (IBI318) clinical trial (CIBI318A101) https://t.co/XRxbJbCcAq (https://t.co/XRxbJbCcAq) pic.twitter.com/BsiVuLwTy9 (https://t.co/BsiVuLwTy9)
>
> — John Blackwood (@bio_jkb) April 27, 2019 (https://twitter.com/bio_jkb/status/1122188601947840513?ref_src=twsrc%5Etfw)

"Immunotherapies such as checkpoint-blocking antibodies targeting PD-1 and PD-L1 are playing increasingly important roles in oncology therapy. However, there are still many challenges in their clinical application. Particularly, for patients without predictive biomarkers, the clinical response rate is approximately 20%. Many patients also have primary or acquired resistance to anti-PD-1/PD-L1 antibodies. We still need to actively develop the next generation of immunotherapy. We are looking forward to seeing the clinical results of IBI318," said Professor Xu Ruihua, Director of Sun Yat-Sen University Cancer Center.

Triplet combination of Pembrolizumab + Epacadostat + TAVO to be tested in TRIFECTA trial in SCCHN patients (https://ir.oncosec.com/press-releases/detail/1990/oncosec-announces-triple-combination-immunotherapy-clinical)

> OncoSec amongst others will be participating in an investigator-initiated clinical trial using TAVO™, epacadostat and KEYTRUDA® at @UCSFCancer (https://twitter.com/UCSFCancer?ref_src=twsrc%5Etfw) called, TRIFECTA. Learn more about this study: https://t.co/2bhAoTTogT (https://t.co/2bhAoTTogT)
>
> — OncoSec Medical (@OncoSec) April 23, 2019 (https://twitter.com/OncoSec/status/1120725451599745024?ref_src=twsrc%5Etfw)

"Effective anticancer immune responses require three steps, including immune priming and tumor infiltration with T cells; activation of partially exhausted TILs; and selective modulation of T cell populations to maximize the ratio of effector to regulatory immune cells," said Dr. Alain Algazi, Associate Professor of Clinical Medicine at UCSF and Clinical Strategic Advisor to OncoSec. "Based on this framework, we hypothesize that the combination of TAVO's tumor infiltration mechanism, with pembrolizumab's TIL technology and epacadostat's T cell modulating capabilities will substantially increase the ORR to pembrolizumab in patients with SCCHN and that the combination will be well tolerated in this population."

First patient enrolled in Ph III trial of E-selectin inhibitor Uproleselan + cytarabine/daunorubicin in 1L fit AML patients (https://ir.glycomimetics.com/news-releases/news-release-details/glycomimetics-announces-enrollment-first-patient-nci-sponsored)

> GlycoMimetics Announces Enrollment of First Patient in NCI-Sponsored Phase 3 Trial of Uproleselan in AML | Business Wire https://t.co/1xz0EH4kSk (https://t.co/1xz0EH4kSk)
>
> — Pategou Joseph (@JosephPategou) April 28, 2019 (https://twitter.com/JosephPategou/status/1122506695983476737?ref_src=twsrc%5Etfw)

"The initiation of the NCI-sponsored trial is an important milestone for our uproleselan program, a drug candidate with the potential to address significant unmet treatment needs across the spectrum of AML," noted Helen Thackray, M.D., FAAP, GlycoMimetics Senior Vice President, Clinical Development, and Chief Medical Officer. "Along with our global pivotal Phase 3 clinical trial testing the investigational drug in patients with relapsed/refractory acute myeloid leukemia, this trial will facilitate our growing understanding of how uproleselan may fit into the continuum of care for individuals living with AML."

First patient dosed in Ph Ib/II combination trial of T cell amplifier Hyleukin-7 + Pembrolizumab in R/R TNBC patients (https://www.businesswire.com/news/home/20190426005270/en/Genexine-NeoImmuneTech-Announce-Dosing-Patient-Combination-Trial)

> US FDA grants orphan drug designation for Hyleukin-7, an #immuno (https://twitter.com/hashtag/immuno?src=hash&ref_src=twsrc%5Etfw)–#oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) agent that boosts T cell production and functionality, for the treatment of Idiopathic CD4 lymphocytopenia (ICL) https://t.co/neFzOTmE5b (https://t.co/neFzOTmE5b)
>
> — Hugo Cabrera (@huguitomc) April 23, 2019 (https://twitter.com/huguitomc/status/1120788910366515201?ref_src=twsrc%5Etfw)

"This combination regimen trial of Hyleukin-7 and KEYTRUDA is very meaningful, in that it attempts to treat advanced or metastatic TNBC patients who respond poorly to standard-of-care treatments," said Jung Won Woo, Ph.D., Senior Vice President, Head of Clinical Division of Genexine. "We believe Hyleukin-7 could deliver improvements for patients non-responsive to immunotherapy regimens by treating lymphopenia, which is commonly observed in TNBC patients, as well as amplifying tumor-infiltrating lymphocytes (TILs) that may enhance anti-tumor response."

COLLABORATIONS & MERGERS

Mateon Therapeutics and Oncotelic Inc. merge; new pipeline focuses on TGF-β RNA Therapeutics for late stage cancers, including gliomas, pancreatic cancer and melanoma (http://investor.mateon.com/news-releases/news-release-details/mateon-and-oncotelic-complete-their-merger-and-create-new-immuno)

> $MATN (https://twitter.com/search?q=%24MATN&src=ctag&ref_src=twsrc%5Etfw) #OTCQB (https://twitter.com/hashtag/OTCQB?src=hash&ref_src=twsrc%5Etfw) Mateon Therapeutics, Inc. (MATN: OTCQB) | Mateon and Oncotelic Complete Their Merger and Create a New Immuno-Oncology Company with a Late-Stage Clinical Asset Against Cancer and a Promising Product Pipeline https://t.co/fQQnnmNxjw (https://t.co/fQQnnmNxjw)
>
> — OTC WATCH News 📰 (@otc_watch_news) April 25, 2019 (https://twitter.com/otc_watch_news/status/1121411675461017604?ref_src=twsrc%5Etfw)

"I would like to welcome Mateon's Dr. William D. Schwieterman and Matthew M. Loar to our team. They have been steadfast in their goal to maximize shareholder value. We structured the merger with the CVR to preserve the intrinsic value of the current Mateon's pipeline for its prior shareholders, while allowing their participation in our pipeline and the growth potential of the new combined company," stated Vuong Trieu, Ph.D., Chairman and Chief Executive Officer. "Now that this merger is complete, we look forward to further value creation for our shareholder base as we advance the combined pipeline together, with the goal of having an approvable anti-cancer drug within a few years. I look forward to meeting our shareholders at various investor conferences including the upcoming BIO2019 in Philadelphia where we will present the combined pipeline."

COMPANION Dx

VENTANA HER2 Dual ISH companion diagnostic test launched for detection of HER2 biomarker in breast and gastric cancer patients eligible for targeted therapy (http://hugin.info/174806/R/2241733/884337.pdf)

> #VENTANA (https://twitter.com/hashtag/VENTANA?src=hash&ref_src=twsrc%5Etfw) assay is designed to be completed within a day, giving clinicians results back quicker than other common methods for confirming #HER2 (https://twitter.com/hashtag/HER2?src=hash&ref_src=twsrc%5Etfw). Results can be read using light microscopy, eliminating the need for specialised fluorescence microscope. https://t.co/pMUaTFr8yQ (https://t.co/pMUaTFr8yQ)
>
> — Amine Korchi MD (@AmineKorchiMD) April 25, 2019 (https://twitter.com/AmineKorchiMD/status/1121290211646947328?ref_src=twsrc%5Etfw)

"The new VENTANA HER2 Dual ISH assay advances Roche's commitment to personalized healthcare by delivering critical information on treatment options for breast and gastric cancer patients faster," said Michael Heuer, CEO

Roche Diagnostics. “Quick results are crucial in the fight against cancer, and every additional day that a clinician and a patient must wait for test results is a day too long.”

Q1 2019 FINANCIAL RESULTS

1. AstraZeneca announces Q1 2019 results (https://www.astrazeneca.com/media-centre/press-releases/2019/Q1-2019-results.html)
2. BMS announces Q1 2019 results; Ph II CheckMate-714 trial fails to meet its primary endpoints (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-reports-first-quarter-financial-results-1)
3. Daiichi Sankyo announced consolidated financial results for year ended March 31, 2019 (Fiscal 2018) (https://www.daiichisankyo.com/media_investors/investor_relations/ir_calendar/files/005441/FY2018%20Q4_Financial%20Results.pdf)
4. Seattle Genetics reports Q12019 financial results (http://investor.seattlegenetics.com/news-releases/news-release-details/seattle-genetics-reports-first-quarter-2019-financial-results)

CONFERENCE COVERAGE

> Due to popular demand @OncoAlert (https://twitter.com/OncoAlert?ref_src=twsrc%5Etfw) is releasing its Top 5 abstracts to be presented at #ASCO19 (https://twitter.com/hashtag/ASCO19?src=hash&ref_src=twsrc%5Etfw) in every tumor type. Release date, May 5th #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) #LungCancer (https://twitter.com/hashtag/LungCancer?src=hash&ref_src=twsrc%5Etfw) #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw) #prostatecancer (https://twitter.com/hashtag/prostatecancer?src=hash&ref_src=twsrc%5Etfw) #bladdercancer (https://twitter.com/hashtag/bladdercancer?src=hash&ref_src=twsrc%5Etfw) #OvarianCancer (https://twitter.com/hashtag/OvarianCancer?src=hash&ref_src=twsrc%5Etfw) #cervicalcancer (https://twitter.com/hashtag/cervicalcancer?src=hash&ref_src=twsrc%5Etfw) #GeriOnc (https://twitter.com/hashtag/GeriOnc?src=hash&ref_src=twsrc%5Etfw) #lymphoma (https://twitter.com/hashtag/lymphoma?src=hash&ref_src=twsrc%5Etfw) #PalliativeCare (https://twitter.com/hashtag/PalliativeCare?src=hash&ref_src=twsrc%5Etfw) #CRCSM (https://twitter.com/hashtag/CRCSM?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/RhShzRNU4O (https://t.co/RhShzRNU4O)
>
> — OncoAlert (@OncoAlert) April 24, 2019 (https://twitter.com/OncoAlert/status/1121118606471979008?ref_src=twsrc%5Etfw)

1. ASCO 2019: Abstracts from pivotal stage Oraxol (Oral paclitaxel and HM30181A) program and preliminary results from Oratecan (Oral irinotecan and HM30181A) Ph I trial to be presented (http://ir.athenex.com/phoenix.zhtml?c=254495&p=irol-newsArticle&ID=2395278)
2. ASCO 2019: TLR9 agonist SD-101 data to be presented (http://investors.dynavax.com/news-releases/news-release-details/dynavax-present-data-toll-receptor-9-agonist-sd-101-asco-annual)
3. ASCO 2019: Bria-IMT data from Ph I/IIa trial in advanced breast cancer patients to be presented (https://briacell.com/briacell-announces-publication-at-american-society-of-clinical-oncology-asco-meeting-and-presentation-at-precision-breast-cancer-summit-in-boston/)
4. ASCO 2019: NSCLC and AML clinical updates from AXL inhibitor Bemcentinib program to be presented (https://www.bergenbio.com/bergenbio-to-present-nsclc-and-aml-clinical-data-from-phase-ii-development-programme-with-selective-axl-inhibitor-bemcentinib-at-asco-2019/)
5. ASCO 2019: Pembrolizumab monotherapy meets primary endpoint of non-inferior OS vs chemo in PD-L1+ve pts; Pembrolizumab + chemotherapy found not superior in OS vs chemo in Ph III KEYNOTE-062 trial in 1L GEJ/Gastric cancer pts (https://www.mrknewsroom.com/news-release/oncology/merck-provides-update-phase-3-keynote-062-trial-evaluating-keytruda-pembrolizu)
6. ASCO 2019: TLR9 agonist SD-101 + Pembrolizumab data from Ph Ib/II trial in PD-(L)1 naive or ref melanoma, SCCHN patients to be presented (http://investors.dynavax.com/news-releases/news-release-details/dynavax-present-data-toll-receptor-9-agonist-sd-101-asco-annual)
7. ASCO 2019: Top studies to be presented at ASCO (including 5-yr survival data of Pembro in mNSCLC patients in KEYNOTE-001 trial) (https://www.asco.org/about-asco/press-center/news-releases/asco-announces-top-studies-be-presented-2019-annual-meeting)
8. ASCO 2019: Updates from STING agonist ADU-S100 and anti-APRIL antibody BION-1301 to be presented (http://investors.aduro.com/news-releases/news-release-details/aduro-biotech-abstracts-accepted-presentation-2019-american)
9. ASCO 2019: Updates from CASSIOPEIA, MAIA, COLUMBA, CASTOR, POLLUX, CEPHEUS, SGNTV-001, innovaTV 208, COMPLEMENT 1 and PERSEUS trials to be presented (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-data-be-presented-2019-asco-annual-meeting)
10. ASCO 2019: PV10 updates from Ph I and Ib trials in mNET and cutaneous melanoma patients to be presented (https://www.provectusbio.com/news/press-releases/provectus-pr-20190417-1)
11. ELCC 2019: mOS NR at 20-month follow-up with Atezolizumab with Bev and Chemo in 1L non-sq and 2L EGFR/ALK+ mNSCLC in Ph III IMpower150 trial (https://www.onclive.com/conference-coverage/elcc-2019/atezolizumab-regimen-improves-os-after-tki-failure-in-egfr-positive-nsclc)
12. ELCC 2019: Updated Entrectinib data in overall and CNS positive cohorts from Ph I ALKA-372-001, STARTRK-1 and Ph II STARTRK-2 trials presented (https://www.onclive.com/conference-coverage/elcc-2019/entrectinib-data-highlighted-as-fda-weighs-approval-for-ros1-nsclc?eKey=cnRld2FyaUBzbWFydGFuYWx5c3QuY29t&utm_medium=email&utm_campaign=ONCSS%20Conference%20Coverage%20360%20ELCC%20
13. ELCC 2019: 77% ORR with Osimertinib in 1L EGFR+ NSCLC patients in Ph I AURA trial; supports Ph III FLAURA trial results and approval (https://www.onclive.com/conference-coverage/elcc-2019/update-further-supports-osimertinib-in-frontline-egfr-positive-nsclc?eKey=cnRld2FyaUBzbWFydGFuYWx5c3QuY29t&utm_medium=email&utm_campaign=ONCSS%20Conference%20Coverage%20360%20ELCC%20
14. ESMO GI 2019: Update on allogeneic and autologous NKG2D-based CAR-T candidates in refractory mCRC patients to be presented (https://www.celyad.com/en/news/celyad-to-present-update-on-allogeneic-and-

autologous-nkg2d-based-car-t-candidates-in-refractory-mcrc-at-esmo-21st-world-gi-congress)

OTW Trivia

Q: What is an antibody drug conjugate (ADC)?

A: An ADC is a 'targeted cytotoxic' drug. It is made up of cytotoxic payload conjugated to an antibody through linkers. The antibody provides specificity to the molecule, and cytotoxic drug kills the targeted tumor cell.

Q: What should be kept in the mind when designing an ADC molecule?

A: To design an effective ADC drug, it is important to identify an appropriate target, properly design the monoclonal antibody, the linker and the cytotoxic moiety. It is also crucial to conjugate them in a scalable and reproducible manner.

Q: Name some common ADCs in clinical trials.

A: Some common ADCs in clinical trials are:

Asset Name	Company	Target	Cytotoxic moiety
Anetumab ravtansine	Bayer	Mesothelin	Maytansinoid DM4
Brentuximab vedotin	Seattle Genetics	CD30	MMAE
Depatuxizumab mafodotin	AbbVie	EGFR	MMAF
Enfortumab Vedotin	Astellas Pharma	Nectin 4	MMAE
Gemtuzumab ozogamicin	Pfizer	CD33	Calicheamicin
Glembatumumab vedotin	Celldex Therapeutics	GPNMB	MMAE
Inotuzumab ozogamicin	Pfizer	CD22	Calicheamicin
Rovalpituzumab tesirine (Rova-T)	Stemcentrx (AbbVie)	DLL3	Pyrrolobenzodiazepine (PDB) dimer
Sacituzumab govitecan	Immunomedics	TROP2	SN38
Trastuzumab emtansine	Genentech, Roche	HER2	Maytansine DM1

About the Author:


(https://io.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: "Confocal micrograph of cultured colon cancer cells showing the nuclei stained with DAPI in blue, the actin cytoskeleton in red and plectin (isoform 1k) in green. Plectin interacts with cytoskeletal actin, affecting its behaviour. This subtype of plectin promotes the migration of cells and may affect metastasis." Source (http://cellimagelibrary.org/images/38917)

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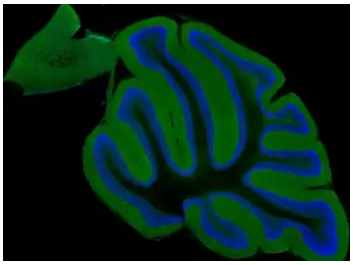

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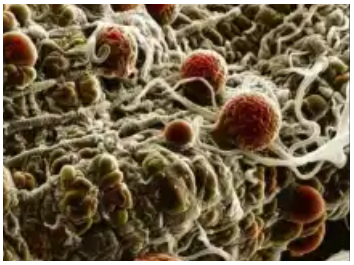

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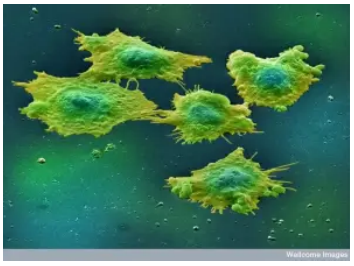

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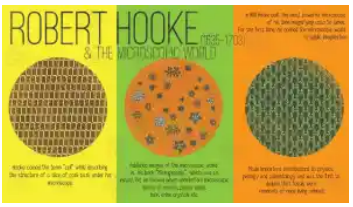
The road ahead for Life Science PhDs – the industry options (https://sciwri.club/archives/133)



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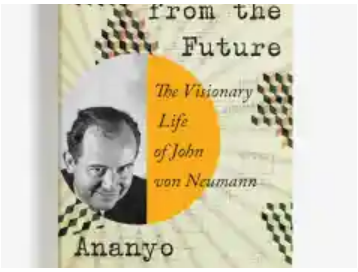

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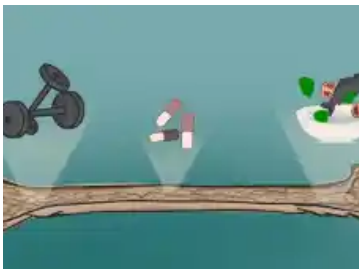

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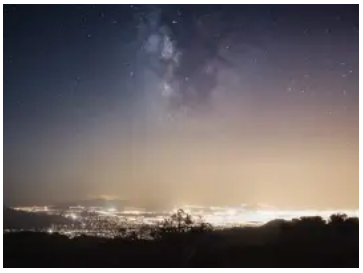

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