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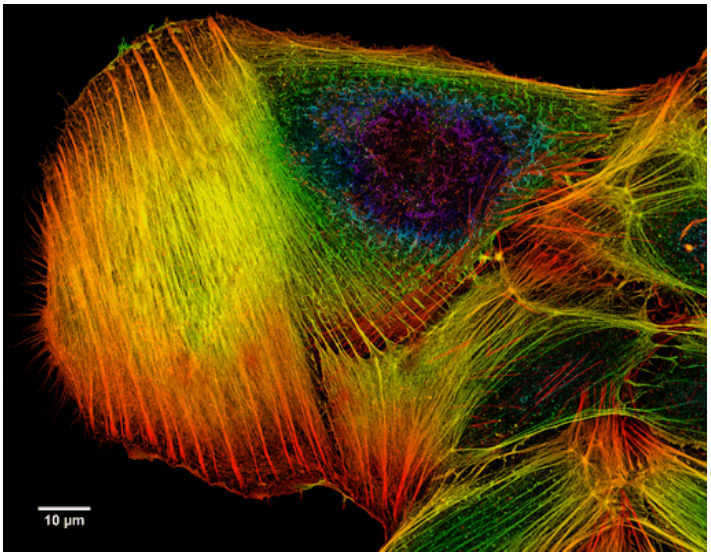
Onco-this-Week

September 30, 2018(https://sciwri.club/archives/date/2018/09/30)



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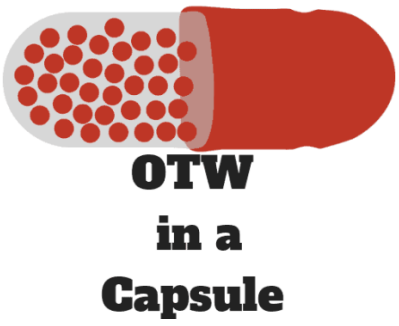
The current edition of Onco-this-Week by Richa Tewari showcases FDA approval of Libtayo® for advanced cutaneous squamous cell carcinoma (CSCC) along with the news about Dacomitinib (Vizimpro, Pfizer) approved by FDA as 1st-line treatment for metastatic #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash) with EGFR exon 19 deletion or exon 21 L585R substitution. In a major step forward, the @US_FDA (https://twitter.com/US_FDA) lifts its hold on @EpizymeRx (https://twitter.com/EpizymeRx)'s trials for tazemetostat, an inhibitor that might cure cancers that affect the blood and lymph system. An orphan drug designation by @US_FDA (https://twitter.com/US_FDA) for cerdulatinib has been granted for the treatment of peripheral T-cell #lymphoma (https://twitter.com/hashtag/lymphoma?src=hash) (#PTCL (https://twitter.com/hashtag/PTCL?src=hash)). In the clinical trials, check out the news about a combination of a HPV vaccine from Dutch Biotech ISA Pharmaceuticals with anti-PD1 checkpoint inhibitor nivolumab which proved to be successful in Phase 2 clinical trial. We have a special coverage from IASLC World Conference on Lung Cancer (WCLC) 2018 and our Trivia describes BITE Technology in Immuno-Oncology. We hope you enjoy this information packed edition of OTW and stay tuned for more oncology updates.- Abhi Dey (https://www.linkedin.com/in/abhinavdey/)



1. **OS and PFS improvement with Atezolizumab + chemotherapy in the initial treatment of ED-SCLC patients.** SCLC has a 5-year survival of only about 1% to 3%. Extensive stage SCLC patients have had very limited treatment options in last two decades, which is why a significant OS and PFS improvement in frontline therapy with Atezolizumab in combination with chemotherapy is perceived as a great news. Though

welcomed by oncologists, numerically it still translates into just two months of improvement over current standard of therapy.

2. **Approval of PD-1 inhibitor Cemiplimab for advanced CSCC patients.** Cutaneous squamous cell carcinoma or CSCC is the second most common cancer in the United States. A majority of early stage CSCC patients undergo surgical resection; however, it is the advanced disease state (also called as locally advanced, unresectable or metastatic CSCC), which had no standard of treatment so far. Cemiplimab is the first FDA approved treatment in this patient segment and offers a hope in terms of significant clinical benefits and long-term survival.
3. **Approval of Dacomitinib in 1L EGFR+ NSCLC patients.** Dacomitinib, a second-gen EGFR inhibitor, showed better efficacy than well-established first-gen TKIs (Erlotinib and Gefitinib) in frontline patients, thus earning the recent approval. However, a bigger challenge awaits Dacomitinib – would it be able to consolidate its position in a segment saturated with several TKIs, specially when ARCHER trial didn't show any improvement in overall response rate or overall survival, and toxicity was much higher than Gefitinib. In fact, a more interesting challenge for Dacomitinib would be to address the unmet need in patients who acquire resistance to frontline Osimertinib.

DRUG APPROVALS

FDA approves PD-1 inhibitor Cemiplimab for advanced CSCC patients based on data from Ph II EMPOWER-CSCC-1 and the two advanced CSCC expansion cohorts from a Ph I trial (http://hugin.info/152918/R/2217053/867105.pdf)

"Today's FDA decision is great news for patients with advanced CSCC, who previously had no approved treatment options. This is especially true because these patients are no longer candidates for curative surgery or radiation," said Michael R. Migden, M.D., a lead investigator in the pivotal CSCC clinical program and Professor in the Departments of Dermatology and Head and Neck Surgery at The University of Texas MD Anderson Cancer Center. "Libtayo is an important new immunotherapy option for U.S. physicians to help address a significant unmet need in this patient group."

> Our Clinical Accelerator team has updated their timeline of anti-PD-1/L1 antibody approvals by the FDA, following the @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) approval of Libtayo® (cemiplimab-rwlc) for advanced cutaneous squamous cell carcinoma (CSCC). #SkinCancer (https://twitter.com/hashtag/SkinCancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/1EnghnTRoF (https://t.co/1EnghnTRoF)
>
> — Cancer Research Institute (@CancerResearch) September 29, 2018 (https://twitter.com/CancerResearch/status/1045826765023834112?ref_src=twsrc%5Etfw)

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

"By following the science, we identified early on that advanced CSCC was a promising target for investigation with Libtayo," said Israel Lowy, M.D., Ph.D., Vice President of Global Clinical Development and Head of Translational

Science and Clinical Oncology, Regeneron. “We are proud to offer patients in the U.S. this first and only treatment for advanced CSCC and remain focused on advancing our clinical research investigating Libtayo as a potential monotherapy and combination therapy in other cancer types.”

FDA approves Dacomitinib for frontline EGFR+ NSCLC based on data from Ph III ARCHER trial (https://www.pfizer.com/news/press-release/press-release-detail/u_s_fda_approves_vizimpro_dacomitinib_for_the_first_line_treatment_of_patients_with_egfr_mutated_metastatic_non_small_ce

“Improving outcomes for patients is the central focus of why we develop and deliver new medicines. VIZIMPRO is yet another example of Pfizer’s commitment to providing more options in lung cancer where there is great unmet need,” said Andy Schmeltz, Global President, Pfizer Oncology. “With today’s approval, Pfizer has medicines that target three unique lung cancer biomarkers, marking real progress for patients which has been achieved through a diverse and persistent drug development approach.”

> Dacomitinib (Vizimpro, Pfizer) approved by FDA as 1st-line treatment for metastatic #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) with EGFR exon 19 deletion or exon 21 L585R substitution https://t.co/KS41kjve4l (https://t.co/KS41kjve4l) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/QnvbyCPKbd (https://t.co/QnvbyCPKbd)
>
> — Encore BioMed (@EncoreBioMed) September 28, 2018 (https://twitter.com/EncoreBioMed/status/1045737173855752192?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“Today’s approval of VIZIMPRO is a direct result of our commitment to precision drug development and improving outcomes for patients with mutation-driven lung cancers. Pfizer now has two medicines that can tackle three different forms of mutation-driven lung cancer: XALKORI for patients with ALK-positive or ROS1-positive non-small cell lung cancer and VIZIMPRO for patients with EGFR-mutated non-small cell lung cancer,” said Mace Rothenberg, MD, chief development officer, Oncology, Pfizer Global Product Development.

CD19-targeting CD3 Bispecific T Cell Engager Blinatumomab approved In Japan for the treatment of R/R B-cell ALL based on data from Ph III TOWER study and Japan Ph Ib/II Horai study (https://www.amgen.com/media/news-releases/2018/09/blincyto-blinatumomab-approved-in-japan-for-the-treatment-of-relapsed-or-refractory-bcell-acute-lymphoblastic-leukemia/)

“As proof-of-concept for our bispecific T cell engager technology, BLINCYTO has laid the groundwork for Amgen to deliver on our passion of addressing cancer by exploring numerous biologic pathways and therapeutic modalities,” said David M. Reese, M.D., executive vice president of Research and Development at Amgen. “This innovation is a good example of how we provide new options to patients with serious illnesses like cancer. In bringing BLINCYTO to Japanese patients, we reinforce our commitment to deliver novel cancer therapies on behalf of patients worldwide.”

> BLINCYTO® (blinatumomab) Approved In Japan For The Treatment Of Relapse.. https://t.co/AEH45Wp4Hg (https://t.co/AEH45Wp4Hg) https://t.co/T5jPBde6cy (https://t.co/T5jPBde6cy) #Biotech (https://twitter.com/hashtag/Biotech?src=hash&ref_src=twsrc%5Etfw) #stocks (https://twitter.com/hashtag/stocks?src=hash&ref_src=twsrc%5Etfw)
>
> — Biotech Stocks 🇺🇸 (@Stocks_Biotech) September 25, 2018 (https://twitter.com/Stocks_Biotech/status/1044564756139466752?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“Today’s approval of BLINCYTO marks a significant milestone that reinforces our commitment to addressing unmet medical needs of patients in Japan,” said Steve Sugino, president and representative director, AABP. “As our first oncology treatment approved in the region, we are proud to provide a much-needed innovative treatment option for adults and children with relapsed or refractory B-cell ALL, one of the most aggressive B-cell malignancies.”

Hitoshi Kiyoi, M.D., Ph.D., professor of internal medicine, Hematology and Oncology, Nagoya University Graduate School of Medicine said, “The standard therapy for relapsed or refractory B-cell ALL has not been established in Japan and therefore different chemotherapy regimens have been selected, depending on the condition and background of each patient. BLINCYTO is a much-needed and important new treatment option for patients with relapsed or refractory B-cell ALL, as demonstrated by the efficacy and survival benefit seen in the TOWER study.”

EU approves Durvalumab as adjuvant maintenance therapy for unresectable Stage III PD-L1+ NSCLC patients based on Ph III PACIFIC trial data (https://www.astrazeneca.com/media-centre/press-releases/2018/european-commission-approves-imfinzi-for-locally-advanced-unresectable-nsclc-24092018.html)

Dave Fredrickson, Executive Vice President, Head of the Oncology Business, said: “Patients in Europe diagnosed with locally-advanced, unresectable non-small cell lung cancer now have a new treatment option. Imfinzi is the only immunotherapy to be approved in this curative-intent setting, and we are proud to bring a new standard of care for this difficult disease.”

> Original Article: Overall Survival with Durvalumab after Chemoradiotherapy in Stage III NSCLC (PACIFIC OS) https://t.co/RRGqfYw34k (https://t.co/RRGqfYw34k) #WCLC2018 (https://twitter.com/hashtag/WCLC2018?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/QeDQlpHFTO (https://t.co/QeDQlpHFTO)
>
> — NEJM (@NEJM) September 25, 2018 (https://twitter.com/NEJM/status/1044562217260240899?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Dr. Luis Paz-Ares, co-principal investigator of the PACIFIC trial, from the Hospital Universitario Doce de Octubre, Madrid, Spain, said: “Lung cancer is the leading cause of cancer-related death in Europe and approximately a third of European patients with NSCLC present with locally-advanced disease. For decades, the standard of care for these patients has been chemotherapy and radiation therapy followed by active surveillance, after which the majority of patients progress to advanced disease. Imfinzi has demonstrated a compelling survival benefit for these patients in this area of significant unmet need.”

REGULATORY NEWS

Positive CHMP opinion to Enzalutamide for adult men with high-risk nmCRPC based on Ph III PROSPER trial data (https://newsroom.astellas.us/2018-09-24--Receives-Positive-CHMP-Opinion-for-XTANDI-R-enzalutamide-for-Adult-Men-with-High-Risk-Non-Metastatic-Castration-Resistant-Prostate-Cancer)

> Important @EUplatinum (https://twitter.com/EUplatinum?ref_src=twsrc%5Etfw) paper re #prostatecancer (https://twitter.com/hashtag/prostatecancer?src=hash&ref_src=twsrc%5Etfw) drug-drug interactions: “In all patients treated with enzalutamide and fentanyl the concentrations of fentanyl were virtually undetectable.” Use non-CYP3A4-metabolised opiates instead eg morphine. Abi is OK. https://t.co/Rb5z6djPF5 (https://t.co/Rb5z6djPF5) pic.twitter.com/AYUiWzjl8o (https://t.co/AYUiWzjl8o)
>
> — Ian Davis (@Prof_IanD) September 26, 2018 (https://twitter.com/Prof_IanD/status/1044852405857325057?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“In nmCRPC, the high risk patient is at a stage where his cancer is growing even though it’s not visible yet despite hormone therapy and will manifest itself given time. The objective of early access to enzalutamide in these patients is to delay the emergence of metastasis with the hope of improving quantity and quality of life,” said Maha Hussain, MD, FACP, FASCO, Genevieve Teuton Professor of Medicine, Robert H. Lurie Comprehensive Cancer Center of Northwestern University, United States, and lead study investigator. “The potential of an effective treatment option for this stage of disease signifies an important therapeutic advancement.”

FDA lifts partial clinical hold on Tazemetostat clinical program (https://epizyme.gcs-web.com/news-releases/news-release-details/epizyme-announces-us-food-and-drug-administration-lifts-partial)

> The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) has lifted its hold on @EpizymeRx (https://twitter.com/EpizymeRx?ref_src=twsrc%5Etfw)‘s trials for tazemetostat, an inhibitor that might treat cancers that affect the blood and lymph system. https://t.co/H92GnozjLJ (https://t.co/H92GnozjLJ)
>
> — Healthcare Weekly (@HealthcareWkly) September 28, 2018 (https://twitter.com/HealthcareWkly/status/1045696382517084161?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“The Epizyme team has worked diligently to provide a comprehensive response back to the FDA, and through constructive dialogue, we successfully resolved the partial clinical hold. This allows us to turn our full attention to our key priorities: preparing for our first NDA submission for tazemetostat in epithelioid sarcoma and defining our registration path in FL,” said Robert Bazemore, president and chief executive officer of Epizyme. “We, along with our investigators and the global experts we consulted to support our complete response, continue to believe in the positive benefit/risk of tazemetostat as we move forward in our clinical development program. We remain steadfast in our commitment to bringing this potential therapeutic option to cancer patients in need of safe and effective new treatments.”

SPECIAL STATUSES

Oral Syk/JAK inhibitor cerdulatinib designated orphan drug designation in PTCL (http://investors.portola.com/phoenix.zhtml?c=198136&p=irol-newsArticle&ID=2368929)

> .@portola_pharma (https://twitter.com/portola_pharma?ref_src=twsrc%5Etfw)'s cerdulatinib has been granted an orphan drug designation by @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) for the treatment of peripheral T-cell #lymphoma (https://twitter.com/hashtag/lymphoma?src=hash&ref_src=twsrc%5Etfw) (#PTCL (https://twitter.com/hashtag/PTCL?src=hash&ref_src=twsrc%5Etfw)). Here's what you should know: https://t.co/tggfEFB14F (https://t.co/tggfEFB14F) pic.twitter.com/ZZU7mrPQId (https://t.co/ZZU7mrPQId)
>
> — Rare Disease Report (@RareDR) September 26, 2018 (https://twitter.com/RareDR/status/1045062873901346817?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are pleased that the FDA has granted cerdulatinib Orphan Drug Designation, as it recognizes its potential to provide a significant clinical benefit to a group of patients with limited treatment options," said John Curnutte, M.D., Ph.D., Portola's interim co-president and head of research and development. "We look forward to presenting additional data from the Phase 2a trial at a scientific congress early next year and to continuing discussions with the FDA regarding next steps for the development of cerdulatinib, including the potential for an accelerated approval pathway."

TRIAL RESULTS

Positive Ph IIa proof of concept data of Bria-IMT™ in advanced breast cancer patients announced; combination study with Pembrolizumab or Ipilimumab to be initiated (http://briacell.com/2018/09/26/briacell-announces-positive-phase-iia-proof-of-concept-data-in-advanced-breast-cancer-initiates-combination-study/)

"Bria-IMT™ appears to be most effective in patients who match with Bria-IMT™ at 2 HLA loci (types) further supporting BriaCell's HLA Matching Hypothesis, and the development of Bria-OTS™ to cover 90% of the patient population. We are delighted with these positive clinical findings that confirm our HLA Matching Hypothesis in the Phase I/IIa trial in advanced breast cancer showing significant tumor shrinkage without serious side effects," stated BriaCell's President and CEO Dr. Bill Williams. "We believe that combination studies with immune checkpoint inhibitors should create even more potent anti-cancer immune responses, leading to our strategy of combination studies of Bria-IMT™ with Keytruda® or Yervoy®."

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

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"This top-line data compares very well with data from existing breast cancer therapies which have a sizable market share when they were at a similar stage of clinical development, as well as with other promising breast cancer treatments currently under study. In our view, the combination of Bria-IMT™ with Keytruda® or Yervoy® has the potential to provide a new therapeutic option and substantial clinical benefit in heavily pre-treated advanced breast cancer patients where there remains a significant unmet need.", Dr. Williams added.

Combination of nivolumab + HPV16 vaccine ISA101 shows encouraging efficacy; Ph IIa trial meets primary endpoint of improved responses with combination vs. checkpoint inhibitor alone (https://www.mdanderson.org/newsroom/2018/09/vaccine-anti-pd1-drug-show-promise-against-incurable-hpv-related-cancers.html)

"That encouraging response rate is about twice the rate produced by PD1 checkpoint inhibitors in previous clinical trials, so these results will lead to larger, randomized clinical trials of this combination," said principal investigator Bonnie Glisson, M.D., professor of Thoracic/Head and Neck Medical Oncology and Abell-Hanger Foundation Distinguished Professor at MD Anderson.

> A combination of a HPV vaccine from Dutch Biotech ISA Pharmaceuticals with anti-PD1 checkpoint inhibitor nivolumab proved to be successful in Phase 2 clinical trial.#cancerresearch (https://twitter.com/hashtag/cancerresearch?src=hash&ref_src=twsrc%5Etfw) #endcancer (https://twitter.com/hashtag/endcancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/dZO1SywXJB (https://t.co/dZO1SywXJB)
>
> — Ruud Waterval (@RuudWaterval) September 27, 2018 (https://twitter.com/RuudWaterval/status/1045424554812805121?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Vaccines specific to HPV antigens found on tumors had previously sparked a strong immune response, but had not,

by themselves, been active against established cancers, Glisson said.

“Vaccines are revving up the immune system, but the immunosuppressive tumor microenvironment probably prevents them from working,” Glisson said. “Our thinking was that inhibition of PD-1 would address one mechanism of immunosuppression, empowering the vaccine-activated T lymphocytes to attack the cancer.”

Two Ph III trials of [Fam-] Trastuzumab Deruxtecan (DS-8201) in HER2+ metastatic Breast Cancer including Head-to-Head Versus T-DM1 and Post-T-DM1 to be started (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006908.html)

> Shine of light for HER2+ (hyperexpressed or mutated) lung cancer patients with trastuzumab deruxtecan. pic.twitter.com/JKm1qXoSyx (https://t.co/JKm1qXoSyx)
>
> — Marcelo Corassa (@MarceloCorassa) September 24, 2018 (https://twitter.com/MarceloCorassa/status/1044252592086413314?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“The DESTINY-Breast03 trial is a key element of our comprehensive development strategy to determine the potential of [fam-] trastuzumab deruxtecan as a second-line therapy in patients with HER2 positive metastatic breast cancer,” said Gilles Gallant, BPharm, PhD, Vice President, DS-8201 Global Team Leader, Oncology Research and Development, Daiichi Sankyo. “DESTINY-Breast03 will also help assess whether our investigational and proprietary ADC linker and payload technology used in [fam-] trastuzumab deruxtecan demonstrates clinical relevance when compared to another HER2 targeting ADC currently approved in this setting.”

Nintedanib failed to improve PFS in Ph III LUME-Meso trial in malignant pleural mesothelioma patients (https://www.boehringer-ingelheim.com/press-release/lume-meso-phase-iii-results?)

Lead investigator Professor Giorgio V. Scagliotti, Chair of the Department of Oncology, University of Torino, Italy commented, “Malignant pleural mesothelioma (MPM) is a rare and difficult-to-treat cancer; it has a poor prognosis with a median survival of nine to 12 months from diagnosis. Developing therapies to treat MPM has proven to be very challenging for the scientific community. Data from the LUME-Meso study will provide valuable insights and information for researchers continuing to explore new advancements for treating the unmet needs of mesothelioma patients.”

> Lung-MESO phase III trial of nintedanib plus chemo in 1st line #mesothelioma (https://twitter.com/hashtag/mesothelioma?src=hash&ref_src=twsrc%5Etfw). Unfortunately, previous positive Ph2, failed to demonstrate PFS or OS benefit. This highlights the importance of large randomised clinical trials. @IASLC (https://twitter.com/IASLC?ref_src=twsrc%5Etfw) #WCLC18 (https://twitter.com/hashtag/WCLC18?src=hash&ref_src=twsrc%5Etfw) #LCSM (https://twitter.com/hashtag/LCSM?src=hash&ref_src=twsrc%5Etfw) @giorgioscaglio3 (https://twitter.com/giorgioscaglio3?ref_src=twsrc%5Etfw) pic.twitter.com/G1q2wWPjFJ (https://t.co/G1q2wWPjFJ)
>
> — Dr. Antonio Calles (@Tony_Calles) September 25, 2018 (https://twitter.com/Tony_Calles/status/1044583471786717184?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Dr. Victoria Zazulina, Global Head of Solid Tumour Oncology, Medicine at Boehringer Ingelheim commented, “We are disappointed that the encouraging efficacy signal observed for nintedanib in Phase II was not confirmed in a larger Phase III trial, as there still remains a big gap in treatment options for patients with malignant pleural mesothelioma. We will ensure that the data and learnings generated from the LUME-Meso programme are shared with the scientific community to guide future research and we remain dedicated to advancing our innovative cancer research programmes.”

TRIAL AND PROGRAM STATUSES

Second dosing cohort of PLK1 inhibitor Onvansertib + Decitabine completed in ongoing Ph Ib/II AML trial (http://trovagene.investorroom.com/2018-09-27-Trovagene-Announces-Completion-of-Dosing-Cohort-of-Patients-Treated-with-Onvansertib-in-Combination-with-Decitabine-in-Ongoing-Phase-1b-2-AML-Trial)

“While we are still early in the trial, we continue to be excited by what we are seeing so far from both a safety and efficacy standpoint,” said Amer Zeidan, MBBS, MHS, assistant professor of Medicine at Yale School of Medicine, Hematology expert at Yale Cancer Center, and lead investigator on the trial. “We did not see any dose limiting toxicities and treatment has been well tolerated in the cohort of three patients who received Onvansertib at 18 mg/m^2 in combination with decitabine. One of our patients is about to start his 6th cycle of combination therapy, with significant reductions in his blast counts, transfusion independence, and no significant side effects. This is a very gratifying response to see, especially in the incurable setting of relapsed AML post allogeneic stem cell

transplantation, where the focus is on quality of life improvement in addition to prolonging survival."

> Trovagene Announces Completion of Dosing Cohort of Patients Treated with Onvansertib in Combination with Decitabine https://t.co/YnzwbKx7Vo (https://t.co/YnzwbKx7Vo)
>
> — Crwe World (@CrweWorld) September 27, 2018 (https://twitter.com/CrweWorld/status/1045316447742742528?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are pleased with the progress we are making to identify our maximum tolerated dose and recommended Phase 2 dose for the continuation segment of our AML trial, as well as for use in other trials that we may do in the future in hematologic (leukemias/lymphomas) cancers," said Dr. Mark Erlander, Chief Scientific Officer of Trovagene.

PFS results to support full approval of the ublituximab plus umbralisib (U2) combination in Ph III UNITY-CLL trial (http://ir.tgtherapeutics.com/news-releases/news-release-details/tg-therapeutics-announces-update-regarding-unity-cll-phase-3)

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "While we are disappointed that we were not able to report positive ORR today, we feel that making the decision to focus on PFS, the primary endpoint for the study, is an important step to getting everyone aligned on the endpoint of this study that matters most to the Company and its long-term shareholders. From a timing standpoint, we could have a PFS read out in 2019, and we remain extremely optimistic about the prospects for a successful PFS result. Other B-Cell Receptor antagonists have shown dramatic improvements in PFS in similarly designed studies and we believe the umbralisib early clinical data supports our confidence in a positive PFS outcome from UNITY-CLL."

> TG stock sinks after setback to blood cancer trial: TG Therapeutics has abandoned plans to seek accelerated FDA approval of its ublituximab-umbralisib combination in chronic lymphocytic leukemia. The biotech made the decision because its phase 3 overall... https://t.co/3ITHD69mEo (https://t.co/3ITHD69mEo)
>
> — cafepharma (@cafepharma) September 25, 2018 (https://twitter.com/cafepharma/status/1044608477937582081?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Mr. Weiss continued, "We now have 5 fully enrolled registration-directed programs, including UNITY-CLL, UNITY-NHL (including Follicular Lymphoma, Marginal Zone Lymphoma and Diffuse Large B-cell Lymphoma cohorts) and the ULTIMATE Phase 3 MS program and are awaiting pivotal data from all of them. With all of these exciting data read-outs to come, we believe we remain well positioned to deliver significant value for our shareholders."

COLLABORATIONS AND LICENSING

Geron regains the global rights of first-in-class telomerase inhibitor Imetelstat; collaboration with Janssen discontinued (http://ir.geron.com/news-releases/news-release-details/geron-announces-discontinuation-imetelstat-collaboration-janssen)

> . @JanssenGlobal (https://twitter.com/JanssenGlobal?ref_src=twsrc%5Etfw) Ends Collaboration with Geron ($GERN) to Develop #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) Candidate Imetelstat: https://t.co/9euvCW12Eo (https://t.co/9euvCW12Eo) pic.twitter.com/Ny8yoHKLdN (https://t.co/Ny8yoHKLdN)
>
> — GEN (@GENbio) September 30, 2018 (https://twitter.com/GENbio/status/1046435785396965378?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are grateful for the collaboration with Janssen, who successfully managed two Phase 2 trials of imetelstat," said John A. Scarlett, M.D., Geron's President and Chief Executive Officer. "We believe the clinical results from IMbark provide valuable insights into the potential future development of imetelstat for an underserved relapsed and refractory myelofibrosis patient population. We also believe the combined data of 38 patients from the initial and expansion cohorts for the target patient population from the Phase 2 portion of IMerge support further development of imetelstat, and we are therefore prioritizing the initiation of the Phase 3 portion of IMerge."

Efficacy of triple combination of BioXcel Therapeutics' BXCL701, Nektar's NKTR-214 and a checkpoint inhibitor to be tested in pancreatic cancer (http://www.bioxceltherapeutics.com/news-details.php?id=NTU=)

"We are excited to expand our collaboration with Nektar to initiate a clinical program for this novel triplet combination regimen," said Vimal Mehta, Chief Executive Officer of BTI. "Mechanistically, we believe the action of

BXCL701 on macrophages and neutrophils within the tumor tissue can activate the innate immune system and then in combination with NKTR-214 and an anti-PD1, we can then prime adaptive immune cells in order to trigger T-cell driven anti-cancer activity and the generation of T-cell memory. The exciting preclinical data presented at this year's ASCO Meeting highlighted the complementary mechanisms by which these three agents can synergize to generate durable responses in various animal models."

> BioXcel Therapeutics Expands Immuno-Oncology Partnership with Nektar into Clinical Development in Pancreatic Cancerhttps://t.co/yMQGUoc6Sv (https://t.co/yMQGUoc6Sv)
>
> — BioXcel Therapeutics (@BioXcel_Tx) September 25, 2018 (https://twitter.com/BioXcel_Tx/status/1044551484698849280?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We believe it is essential to target multiple dimensions of the immune system in parallel in order to address the multi-faceted etiologies underlying cancer cell growth in difficult-to-treat tumors such as pancreatic cancer," said Jonathan Zalevsky, Senior Vice President, Biology & Preclinical Development of Nektar Therapeutics. "This experimental triplet combination regimen of BXCL701, NKTR-214 and a checkpoint inhibitor is designed to leverage multiple mechanisms of action at once to better fight pancreatic cancer while potentially generating long-term cancer immunity. We're pleased to be working with BTI on this program."

IASLC World Conference on Lung Cancer (WCLC) 2018 COVERAGE

Proof of concept data showing BLU-667 + Osimertinib's combination overcoming treatment resistance in two WFGR mutantm RET fusion +ve NSCLC patients published (http://ir.blueprintmedicines.com/news-releases/news-release-details/blueprint-medicines-announces-proof-concept-data-showing)

"The combination of two highly selective agents — BLU-667 and osimertinib — has the potential to become an important new tool to overcome treatment resistance in a subset of patients with EGFR-mutant, non-small cell lung cancer," said Lecia V. Sequist, M.D., Ph.D., medical oncologist, Massachusetts General Hospital Cancer Center and Associate Professor of Medicine, Harvard Medical School, and senior author of the oral presentation and paper. "We found that two pre-treated patients with advanced disease, who acquired RET fusions resulting in resistance to standard therapy, each showed a meaningful response only eight weeks after initiating the combination regimen. These results are highly encouraging and support further study of BLU-667 in combination with osimertinib in additional patients."

mOS data from STELLAR registration trial of TTFs in Mesothelioma presented (https://www.novocure.com/data-from-stellar-registration-trial-of-tumor-treating-fields-in-mesothelioma-to-be-presented-at-the-iaslc-19th-world-conference-on-lung-cancer/)

"Mesothelioma is an aggressive cancer with limited treatment options," said Mary Hesdorffer, Nurse Practitioner and Executive Director of the Mesothelioma Applied Research Foundation (MARF). "We in the mesothelioma community are extremely pleased to see these promising data presented at the IASLC 19th World Conference on Lung Cancer, the world's largest meeting dedicated to lung cancer and other thoracic malignancies. At MARF, we work every day to eradicate the life-ending and vicious effects of mesothelioma."

> Data from STELLAR Registration Trial of Tumor Treating Fields in Mesothelioma to be Presented at the IASLC 19th World Conference on Lung Cancer https://t.co/T5Z5OsKjrR (https://t.co/T5Z5OsKjrR) pic.twitter.com/tuC19btfl8 (https://t.co/tuC19btfl8)
>
> — Latest News from Business Wire (@NewsFromBW) September 25, 2018 (https://twitter.com/NewsFromBW/status/1044551619151458306?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Mesothelioma patients face a very poor prognosis with a median overall survival of only 12 months," said Charles B. Simone, Medical Director of the Maryland Proton Treatment Center and Associate Professor of Radiation Oncology at the University of Maryland School of Medicine in Baltimore. "This extreme unmet need calls for progress. Based on these data, I believe Tumor Treating Fields has the potential to improve survival for people affected by malignant pleural mesothelioma."

Positive preliminary safety and efficacy data from an ongoing Ph I/II trial of Third gen EGFR inhibitor CK-101 presented (http://ir.checkpointtx.com/Cache/1001243468.PDF?O=PDF&T=&Y=&D=&FID=1001243468&iid=4660467)

> Highlights from Checkpoint Therapeutics' oral presentation of data from its ongoing Phase 1/2 clinical trial of CK-101, a 3rd-generation #EGFR (https://twitter.com/hashtag/EGFR?src=hash&ref_src=twsrc%5Etfw) inhibitor being evaluated in #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw), at the @IASLC (https://twitter.com/IASLC?ref_src=twsrc%5Etfw) 19th World Conference on Lung Cancer: https://t.co/LYUSc9x6e6 (https://t.co/LYUSc9x6e6) $CKPT (https://twitter.com/search?q=%24CKPT&src=ctag&ref_src=twsrc%5Etfw) $FBIO (https://twitter.com/search?q=%24FBIO&src=ctag&ref_src=twsrc%5Etfw) pic.twitter.com/TQjyeoBzqV (https://t.co/TQjyeoBzqV)
>
> — Fortress Biotech (@fortressbio) September 25, 2018 (https://twitter.com/fortressbio/status/1044640512202993665?ref_src=twsrc%5Etfw)

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"The oral presentation included exciting updates to the data released in the abstract, including intracranial disease responses to treatment with CK-101 in patients with brain metastases present at baseline indicating that CK-101 may cross the blood-brain barrier to reach metastases in the central nervous system, as well as an additional partial response post-data cutoff in a T790M mutation-positive NSCLC patient that failed previous TKI therapy," said James F. Oliviero, President and Chief Executive Officer of Checkpoint Therapeutics. "Based on these data, we believe CK-101 has the potential to be an effective and differentiated treatment option in a potential $6 billion market currently dominated by one approved therapy."

LOXO-292 demonstrated encouraging, early evidence of durable activity (https://ir.loxooncology.com/press-releases/2368923-Loxo-oncology-announces-loxo-292-durability-update-in-patients-with-ret-fusion-positive-non-small-cell-lung-cancer-from-libretto-001-at-the-iaslc-19th-world-conference-on-lung-cancer)

> $LOXO (https://twitter.com/search?q=%24LOXO&src=ctag&ref_src=twsrc%5Etfw) announced that abstracts from its LOXO-292 and larotrectinib programs have been accepted for presentation at the International Association for the Study of Lung Cancer #IASLC (https://twitter.com/hashtag/IASLC?src=hash&ref_src=twsrc%5Etfw) – can LOXO-292 and Larotrectinib impress again? #Bayer (https://twitter.com/hashtag/Bayer?src=hash&ref_src=twsrc%5Etfw) $BAYN (https://twitter.com/search?q=%24BAYN&src=ctag&ref_src=twsrc%5Etfw) $BGNE (https://twitter.com/search?q=%24BGNE&src=ctag&ref_src=twsrc%5Etfw) $BPMC (https://twitter.com/search?q=%24BPMC&src=ctag&ref_src=twsrc%5Etfw) https://t.co/PPoHte8hwf (https://t.co/PPoHte8hwf) pic.twitter.com/fbyXVwUOmX (https://t.co/fbyXVwUOmX)
>
> — Michel Doepke (@MichelDoepke) September 22, 2018 (https://twitter.com/MichelDoepke/status/1043399870088982528?ref_src=twsrc%5Etfw)

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

"I am pleased that the attendees of World Lung were able to see the activity of LOXO-292 in RET fusion-positive lung cancer," said Geoffrey R. Oxnard, M.D., associate professor of medicine at Harvard Medical School and thoracic oncologist at Dana-Farber Cancer Institute. "It has been just a few months since ASCO, but the additional follow-up afforded by today's data provide encouraging evidence that LOXO-292 can deliver durable responses in heavily pre-treated patients. It was additionally reassuring to see that that LOXO-292 appears to be well tolerated at the Phase 2 dose of 160 mg BID. With Breakthrough Therapy Designation in hand, LOXO-292 is moving rapidly through clinical development, so it is important for investigators and patients to pay attention to this emerging target and class of medicines."

OS data from the Ph I/II study of lurbinectedin + doxorubicin in relapsed SCLC patients in Ph I/II trial presented (https://www.pharmamar.com/wp-content/uploads/2018/09/PR_IASLC-2018-PharmaMar_20180921.pdf)

Dr. Martin Forster, MD, PhD, of the University College London Hospitals and UCL Cancer Institute, UK, has commented, "I have been involved in a wide number of trials with lurbinectedin for more than five years, both in studies as a single agent and in combination, and I think that it is a molecule with a novel mechanism of action and promising anti-cancer activity, which has exhibited acceptable safety profile both as a single agent and in combination. I consider lurbinectedin as an innovative molecule, which I think may have an important role to play in the treatment of patients with this particularly aggressive type of lung cancer, if approved."

> #PharmaMar (https://twitter.com/hashtag/PharmaMar?src=hash&ref_src=twsrc%5Etfw) will release results of a #ClinicalTrial (https://twitter.com/hashtag/ClinicalTrial?src=hash&ref_src=twsrc%5Etfw) cohort for #lurbinectedin (https://twitter.com/hashtag/lurbinectedin?src=hash&ref_src=twsrc%5Etfw) in combination with #doxorubicin (https://twitter.com/hashtag/doxorubicin?src=hash&ref_src=twsrc%5Etfw) in relapsed small cell #lung (https://twitter.com/hashtag/lung?src=hash&ref_src=twsrc%5Etfw) cancer during the IASLC conference taking place from 23 to 26 in Toronto. @IASLC (https://twitter.com/IASLC?ref_src=twsrc%5Etfw)
> 🔗 https://t.co/egEseJXaB5 (https://t.co/egEseJXaB5) pic.twitter.com/PFcyEvHcx6 (https://t.co/PFcyEvHcx6)
>
> — PharmaMar (@PhrmMar) September 20, 2018 (https://twitter.com/PhrmMar/status/1042775709339537408?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Dr. Emiliano Calvo, MD, from the START Madrid-CIOCC Early Phase Clinical Drug Development program, at Hospital Universitario HM Sanchinarro, Madrid, Spain, has affirmed that “it is very necessary to have new alternatives for the treatment of this type of aggressive cancer. As we have been able to observe in the Overall Survival data, the combination of lurbinectedin plus doxorubicin appears to show a greater benefit than the current standard treatments, therefore, possibly providing a new therapeutic alternative for the patients that suffer this terrible illness.” He adds, “patients with small cell lung cancer need new therapeutic alternatives, and the results of this lurbinectedin study could help change the landscape of treatment in an environment where, unfortunately, important progress has not been made within the last 15-20 years.”

Poziotinib maintains high response rate against EGFR and HER2 mutations in Ph II trial (https://www.mdanderson.org/newsroom/2018/09/poziotinib-maintains-high-response-rate-against-harmful-lung-cancer-mutation.html)

“These findings confirm earlier observations that poziotinib is highly active against this previously untargetable mutation and durable responses are observed, with some patients on treatment now for more than a year,” said principal investigator John Heymach, M.D., Ph.D., professor and chair of Thoracic/Head and Neck Medical Oncology.

> Poziotinib potentially fulfills an unmet need. Preliminary data compelling. Ongoing trial recruitment advertised at #WCLC18 (https://twitter.com/hashtag/WCLC18?src=hash&ref_src=twsrc%5Etfw) @iaslc (https://twitter.com/IASLC?ref_src=twsrc%5Etfw) #lcsm (https://twitter.com/hashtag/lcsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/11CHSNDpWa (https://t.co/11CHSNDpWa)
>
> — Dr. Linda Coate (@lindacoate) September 24, 2018 (https://twitter.com/lindacoate/status/1044266780330471424?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Encouraging durable responses observed in ENCORE 601 and ENCORE 602 trials (http://www.syndax.com/wp-content/uploads/2018/09/SNDX_IASLC-Data_vFINAL.pdf)

> #Entinostat (https://twitter.com/hashtag/Entinostat?src=hash&ref_src=twsrc%5Etfw)/#Pembrolizumab (https://twitter.com/hashtag/Pembrolizumab?src=hash&ref_src=twsrc%5Etfw) Combo Shows Promise in #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) Subgroup https://t.co/3YPGNDf2Qq (https://t.co/3YPGNDf2Qq) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw)
>
> — CancerWallonia (@CancerWallonia) September 29, 2018 (https://twitter.com/CancerWallonia/status/1046111084590043137?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“The observation of durable responses seen with the entinostat-pembrolizumab combination in NSCLC patients previously treated with both chemotherapy and PD-(L)1 therapy is an important result, and we look forward to more fully characterizing patient selection tools to identify those who are most likely to respond,” said Peter Ordentlich, Ph.D., Syndax co-founder and Chief Scientific Officer. “The exploratory finding that baseline peripheral classical monocytes may predict clinical benefit to the combination provides an opportunity to potentially correlate a readily measurable circulating biomarker with the state of the tumor microenvironment and supports the use of this approach for patient selection in future studies.”

Brigatinib in ALTA-1L trial shows a reduction in risk of disease progression or death of more than 50% vs Crizotinib in 1L advanced ALK+ NSCLC (https://www.takeda.com/newsroom/newsreleases/2018/takeda-to-present-positive-data-from-alunbrig-brigatinib-alta-1l-trial/)

“The ALK+ NSCLC treatment landscape has experienced tremendous change over the last decade, and the ALTA-1L

trial demonstrates that brigatinib has the potential to be a key player in the first-line setting," said D. Ross Camidge, MD, PhD, Joyce Zeff Chair in Lung Cancer Research at the University of Colorado Cancer Center and the lead investigator of ALTA-1L. "The ALTA-1L trial offers unique aspects, including the real-world applicability of the data. The study's design offered enrollment to a broader population by allowing patients to participate even if they had received prior chemotherapy and enrolled patients based on local standard of care ALK testing as opposed to mandating confirmation at a central lab. We look forward to further follow-up, which will provide even better understanding of the role of brigatinib in the evolving landscape."

> Presentation from #WCLC2018 (https://twitter.com/hashtag/WCLC2018?src=hash&ref_src=twsrc%5Etfw): Brigatinib Becomes Potential New First-Line Option for ALK-Positive Non-Small #LungCancer (https://twitter.com/hashtag/LungCancer?src=hash&ref_src=twsrc%5Etfw) @CUCancerCenter (https://twitter.com/CUCancerCenter?ref_src=twsrc%5Etfw) https://t.co/qkAXPDh7j5 (https://t.co/qkAXPDh7j5) pic.twitter.com/wH6e8mKuZw (https://t.co/wH6e8mKuZw)
>
> — Pulmonary Cell News (@pulmonary_news) September 29, 2018 (https://twitter.com/pulmonary_news/status/1046041934467420162?ref_src=twsrc%5Etfw)

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"We are thrilled to share these highly anticipated results with the lung cancer community," said David Kerstein MD, Global Clinical Lead for Brigatinib and Lung Cancer Clinical Portfolio Strategy Lead, Takeda. "The ALTA-1L data demonstrate that ALUNBRIG is superior to crizotinib in the first-line setting, reducing disease progression or death by more than half, with particularly pronounced activity in the brain. We would like to thank all the investigators, and especially the patients and their caregivers who participated in this important clinical research."

Atezolizumab + chemotherapy significantly improved OS and PFS in the initial treatment of ED-SCLC pts in Ph III IMpower133 study (https://www.gene.com/media/press-releases/14746/2018-09-25/genentechs-tecentriq-in-combination-with)

> NEWS: Atezolizumab, an immunotherapy aimed at extensive-stage small-cell lung cancer patients, has been announced to significantly improve OS and PFS when combined with standard-of-care chemotherapy as a first-line therapy – in the Phase III trial IMpower133
>
> — Oncology Central (@OncologyCentral) September 30, 2018 (https://twitter.com/OncologyCentral/status/1046512510004674560?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The results with this TECENTRIQ combination in the initial treatment of extensive-stage small cell lung cancer represent the first clinically meaningful advance in the disease in over 20 years," said Sandra Horning, M.D., chief medical officer and head of Global Product Development. "Our goal is to find treatment options for all types of lung cancer, and we are eager to work with global health authorities to bring this TECENTRIQ regimen to people living with this particularly difficult-to-treat form of lung cancer as soon as possible."

[Fam-] Trastuzumab Deruxtecan (DS-8201) shows encouraging results in heavily pretreated HER2 Mutated or HER2 Expressing NSCLC pts in Ph I trial (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006906.html)

"These preliminary results seen with [fam-] trastuzumab deruxtecan are encouraging, particularly given the existing unmet medical need for patients with metastatic NSCLC with HER2 alterations that have progressed on several prior therapies," said Junji Tsurutani, MD, PhD, Advanced Cancer Translational Research Institute, Showa University, Tokyo, Japan, a study investigator. "These results also demonstrate that continued evaluation of treatments that target the HER2 receptor is warranted in patients with NSCLC."

> From @IASLC (https://twitter.com/IASLC?ref_src=twsrc%5Etfw) #WCLC2018 (https://twitter.com/hashtag/WCLC2018?src=hash&ref_src=twsrc%5Etfw) :Updated Results for Trastuzumab Deruxtecan in Patients with HER2 Mutated or HER2 Expressing Non-Small Cell #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/AMsBOMX9Y5 (https://t.co/AMsBOMX9Y5) pic.twitter.com/irXOkju3aE (https://t.co/irXOkju3aE)
>
> — Gil Morgan (@weoncologists) September 24, 2018 (https://twitter.com/weoncologists/status/1044238090250997760?ref_src=twsrc%5Etfw)

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"Patient enrollment is currently underway into our phase 2 study of [fam-] trastuzumab deruxtecan in patients with advanced HER2 mutated or HER2 overexpressing NSCLC," said Gilles Gallant, BPharm, PhD, Vice President, DS-8201 Global Team Leader, Oncology Research and Development, Daiichi Sankyo. "Since there are no therapies specifically approved to treat patients with HER2 altered NSCLC, continued study of [fam-] trastuzumab

deruxtecan is needed to better understand the potential role of a HER2 targeting antibody drug conjugate in treating these patients."

Atezolizumab + Pemetrexed + Platinum-Based Chemotherapy reduce the risk of disease worsening or death in 1L non-squamous NSCLC patients in Ph III IMpower132 study (https://www.gene.com/media/press-releases/14744/2018-09-24/genentechs-tecentriq-in-combination-with)

"This is our third Phase III trial in non-squamous non-small cell lung cancer demonstrating that a TECENTRIQ-based regimen can help reduce the risk of disease progression for people living with this disease," said Sandra Horning, M.D., chief medical officer and head of Global Product Development. "We will discuss these results with health authorities globally."

> Frontline atezolizumab plus chemotherapy improves PFS in NSCLC – https://t.co/wn7UiTl8wl (https://t.co/wn7UiTl8wl)#atezolizumab (https://twitter.com/hashtag/atezolizumab?src=hash&ref_src=twsrc%5Etfw) #carboplatin (https://twitter.com/hashtag/carboplatin?src=hash&ref_src=twsrc%5Etfw) #cisplatin (https://twitter.com/hashtag/cisplatin?src=hash&ref_src=twsrc%5Etfw) #Genentech (https://twitter.com/hashtag/Genentech?src=hash&ref_src=twsrc%5Etfw) #non (https://twitter.com/hashtag/non?src=hash&ref_src=twsrc%5Etfw)-squamousecelllungcancer #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) #PD (https://twitter.com/hashtag/PD?src=hash&ref_src=twsrc%5Etfw)-L1 #pemetrexed (https://twitter.com/hashtag/pemetrexed?src=hash&ref_src=twsrc%5Etfw) #platinum (https://twitter.com/hashtag/platinum?src=hash&ref_src=twsrc%5Etfw)-doublet #Roche (https://twitter.com/hashtag/Roche?src=hash&ref_src=twsrc%5Etfw) #Tecentriq (https://twitter.com/hashtag/Tecentriq?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/KXh6GrrG2Q (https://t.co/KXh6GrrG2Q)
>
> — ScienTerrific (@MediNews_Asia) September 25, 2018 (https://twitter.com/MediNews_Asia/status/1044421347244310528?ref_src=twsrc%5Etfw)

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Entrectinib demonstrated ORR of 77% in ROS-1+ NSCLC patients and 55% in patients with CNS mets in pooled analysis of pivotal Ph II STARTRK-2, Ph I STARTRK-1 and Ph I ALKA trials (https://www.roche.com/media/releases/med-cor-2018-09-24c.htm)

> Update from #WCLC2018 (https://twitter.com/hashtag/WCLC2018?src=hash&ref_src=twsrc%5Etfw): Promising Phase I/II Results for Entrectinib against ROS1+ Non-Small Cell #LungCancer (https://twitter.com/hashtag/LungCancer?src=hash&ref_src=twsrc%5Etfw) @CUCancerCenter (https://twitter.com/CUCancerCenter?ref_src=twsrc%5Etfw) https://t.co/V8hsl3z4io (https://t.co/V8hsl3z4io) pic.twitter.com/v8SUP7ujm6 (https://t.co/v8SUP7ujm6)
>
> — Pulmonary Cell News (@pulmonary_news) September 30, 2018 (https://twitter.com/pulmonary_news/status/1046477319366463489?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"These results show the potential of precision medicines to deliver tailored and effective treatment options for people with non-small cell lung cancer, including those whose tumours have spread to the central nervous system," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "We are also investigating entrectinib in NTRK fusion-positive tumours across several different cancer types, and look forward to presenting those results in the near future."

Q: What is Bispecific T cell Engager (BiTE®) technology?

A: Bispecific T cell Engager (BiTE®) technology is a platform designed to help engage the body's endogenous T cells to target malignant cells.

Q: How do endogenous T cells help in immune defense?

A: Cytotoxic T cells constantly circulate through blood, lymph and tissues in search of malignant target cells and activate when T-cell receptors bind to antigens on the surface of target cells. The T cells then eliminate target cells through variety of mechanism:

- Release of perforins, which cause cell lysis by forming pores in membrane of target cells
- Release of granzymes, or cytoxic serine proteases, which degrade vital cell structures,
- Initiation of apoptosis through engagement of Fas-L pathway

Q: Why then T cells are not able to destruct all malignant cells?

A: Because malignant cells can evade this destruction through one or more of the following mechanisms:

- Impairing antigen presentation by introducing genetic mutations
- Blocking TCR signaling processes
- Down-regulating T cell immune responses by removing regulatory control of negative co-stimulatoy signals
- Secreting immune-suppressive factors

Q: How is BiTE® technology supposed to overcome this evasion?

A: BiTE® antibody construct contains two flexibly-linked, single-chain antibodies: one specific to a selected surface antigen on targeted malignant cells; and other to CD3, which is tied to TCR complex

Q: What is the latest example of efficacy of BiTE® technology?

A: Blinatumomab, a bispecific CD19-directed CD3 T cell engager, recently got approved in USA, EU and Japan for the treatment of R/R B-cell acute lymphoblastic leukemia (ALL) patients and in USA in MRD+ ALL patients.

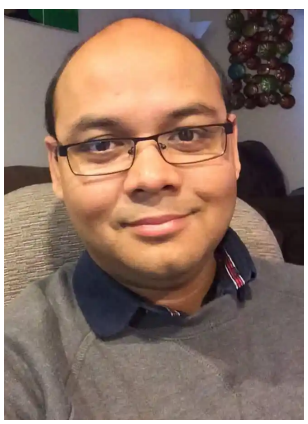
Source: https://www.biteantibodies.com/ (https://www.biteantibodies.com/), http://www.amgenoncology.com/science/bite-immunotherapy.html (http://www.amgenoncology.com/science/bite-immunotherapy.html)

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)

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)A z-projection of an osteosarcoma cell, stained with phalloidin to visualise actin filaments. The image was taken on a confocal microscope, and the subsequent deconvolution was done using an experimentally derived point spread function.– Source (https://commons.wikimedia.org/wiki/File:Depth_Coded_Phalloidin_Stained_Actin_Filaments_Cancer_Cell.png#filelinks)

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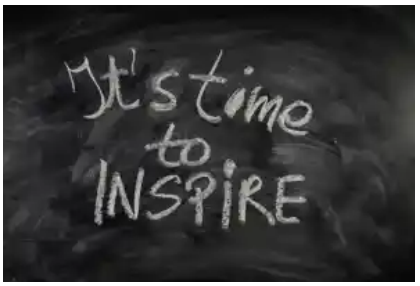

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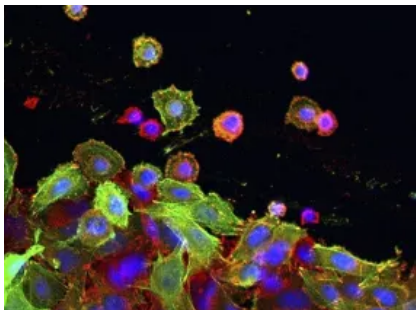

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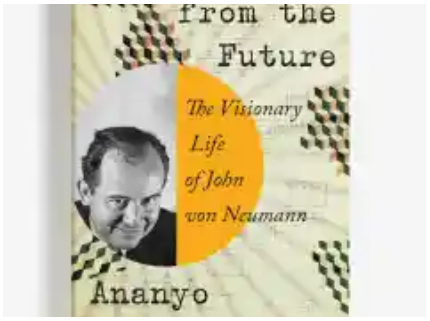

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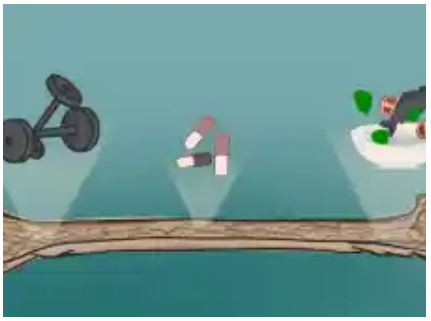

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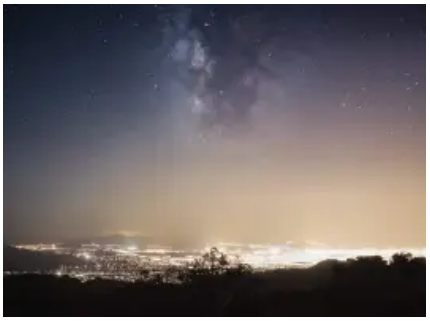

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