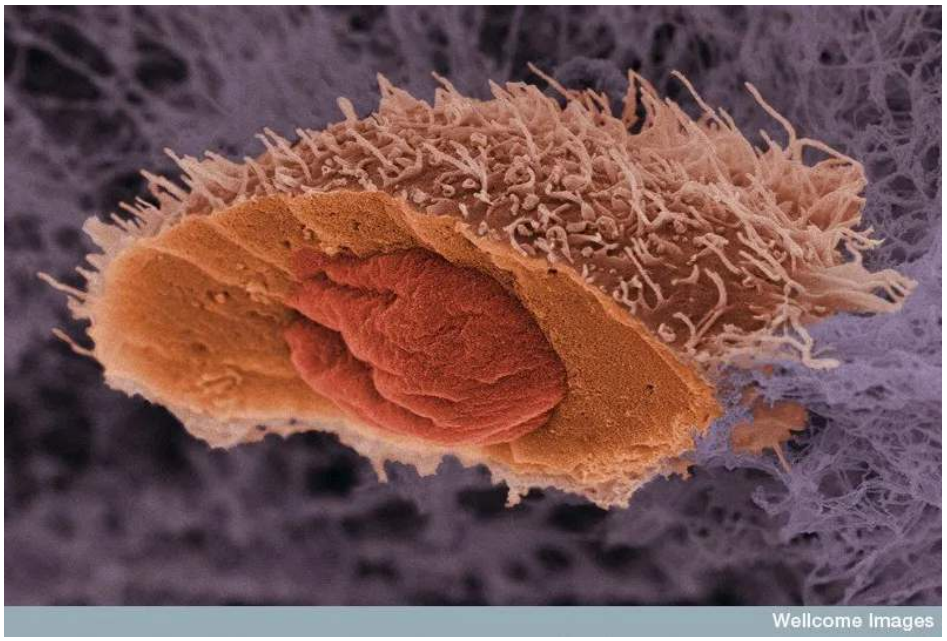
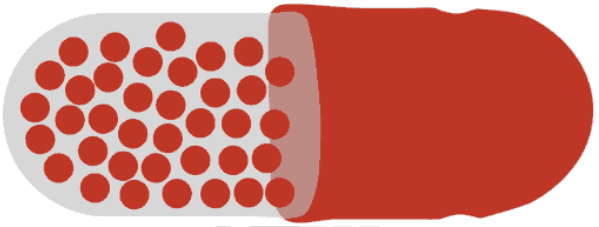
Onco-this-Week

December 15, 2018(https://sciwri.club/archives/date/2018/12/15)



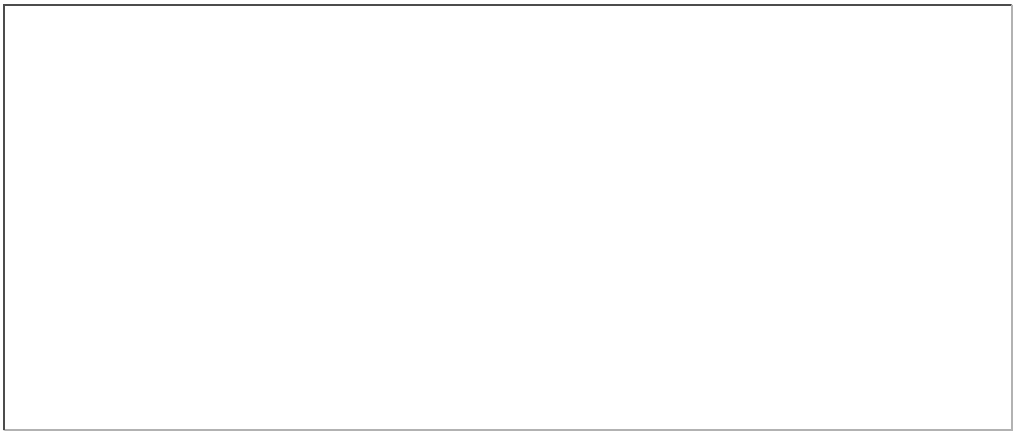


OTW in a Capsule

HIGHLIGHTS

1. **Positive CHMP opinion for brentuximab vedotin in CD30+ 1L HL patients**. Following the FDA approval in March this year based on Ph III ECHELON-1 trial data, brentuximab vedotin in combination with AVD (Adriamycin, Vinblastine and Dacarbazine) hopes to become the first new treatment option available for adult, previously untreated CD30+ stage III or IV Hodgkin Lymphoma patients in almost four decades in Europe. The physician community too would heartily welcome an improved regimen, which is less toxic and more effective.
2. **Decreased ORR than previously reported with tilsotolimod-ipilimumab combination in metastatic melanoma patients**. Compared to ASCO 2018 results, where Idera Pharmaceuticals showed ORR in nine patients at 44%, these recent results in 34 patients yielded an ORR of 29.4%. Though the responses are better when seen in the context of disease control rate (DCR, improved to 76% from previously reported 67%), they could not keep Idera's shares from tumbling. However, in PD-1 refractory patients, these responses are much better anything seen so far thus keeping the hope in this treatment regimen alive.
3. **Roche and Merck developing companion Dx for use with Pembrolizumab in dMMR positive solid tumor**

patients. In May 2017, Pembrolizumab became the first cancer treatment approved by the FDA for the treatment of pediatric and adult patients with unresectable or metastatic, 2L+ MSI-high or MMR deficient solid tumors, or CRC that progressed on chemotherapy. This episode was just a beginning of era of tumor-agnostic drugs, and it also substantiated the need of choosing the right patients for such therapies. Roche and Merck are collaborating to develop an IHC-based test to identify those patients likely to benefit the most.



(https://goo.gl/XM63s6)

TRIAL RESULTS

Updated tumor responses announced from Ph IIb KEYNOTE-695 trial of Tavo + Pembrolizumab in metastatic melanoma patients (https://ir.oncosec.com/press-releases/detail/1974/oncosec-reports-updated-tumor-responses-in-keynote-695)

"Complete responses in this patient population are rare. One of the first partial responses to be observed in this study now being assessed by the investigator at six months as a complete response is exciting. Durable responses reaching the six-month mark demonstrate that the benefits of TAVO are clinically meaningful," said Daniel J. O'Connor, President and CEO of OncoSec. "The evidence of the potential of TAVO™ in conjunction with PD-1 inhibition to improve outcomes in this patient population is mounting and we look forward to providing updates as necessary regarding the progress of this trial."

> Will tiny OncoSec break out with promising melanoma immunotherapy study results? @adamfeuerstein (https://twitter.com/adamfeuerstein?ref_src=twsrc%5Etfw) Is the patient with CR reported today validating the thesis that TAVO could increase the % of anti-PD1 checkpoint inhibitors? #oncs (https://twitter.com/hashtag/oncs?src=hash&ref_src=twsrc%5Etfw) #keytruda (https://twitter.com/hashtag/keytruda?src=hash&ref_src=twsrc%5Etfw) #merck (https://twitter.com/hashtag/merck?src=hash&ref_src=twsrc%5Etfw)
>
> — El Nino (@NNotteau) December 12, 2018 (https://twitter.com/NNotteau/status/1072964219732135938?ref_src=twsrc%5Etfw)

Positive second cohort results of Ph Ib trial of Paclitaxel's oral formulation, Oraxol + Ramucirumab in gastric cancer patients announced (http://ir.athenex.com/phoenix.zhtml?c=254495&p=irol-newsArticle&ID=2380288)

"We are pleased by the strong positive signals of efficacy together with a good safety profile in this Phase 1b clinical trial of Oraxol plus ramucirumab in the second-line treatment of gastric cancer patients so far and look forward to further results from the continuation of this study. The results also echoed the strong positive signal that we have observed in other clinical studies of Oraxol as monotherapy for the treatment of metastatic breast cancer," stated Dr. Rudolf Kwan, Athenex's Chief Medical Officer.

> Athenex $ATNX (https://twitter.com/search?q=%24ATNX&src=ctag&ref_src=twsrc%5Etfw) Announces Positive Second Cohort Results of Oraxol-plus-Ramucirumab Phase 1b Clinical Trial in Gastric Cancerhttps://t.co/wIsIAJECSW (https://t.co/wIsIAJECSW)
>
> — LifeSci Advisors (@LifeSciAdvisors) December 11, 2018 (https://twitter.com/LifeSciAdvisors/status/1072603527074209798?ref_src=twsrc%5Etfw)

Dabrafenib + Trametinib show promise in Ph II ROAR trial in BRAF V600E- Mutated BTC patients and in HCL patients (https://www.cancer.gov/news-events/cancer-currents-blog/2018/biliary-tract-cancer-dabrafenib-trametinib?cid=eb_govdel)

"The response rate they describe is certainly very encouraging," commented Tim Greten, M.D., head of the gastrointestinal malignancy section of NCI's Center for Cancer Research. He noted that other genetic features found in some cases of biliary tract cancer—mutations in the IDH1 and IDH2 genes and FGFR fusion gene—are also under investigation as potential molecular targets for treatment, with ongoing clinical trials at various stages.

> Targeted #Treatment (https://twitter.com/hashtag/Treatment?src=hash&ref_src=twsrc%5Etfw) for Rare #Digestive (https://twitter.com/hashtag/Digestive?src=hash&ref_src=twsrc%5Etfw) Tract #Cancers (https://twitter.com/hashtag/Cancers?src=hash&ref_src=twsrc%5Etfw) May Extend #Survival (https://twitter.com/hashtag/Survival?src=hash&ref_src=twsrc%5Etfw)
> National Cancer Institute (NCI) #Dabrafenib (https://twitter.com/hashtag/Dabrafenib?src=hash&ref_src=twsrc%5Etfw) (#Tafinlar (https://twitter.com/hashtag/Tafinlar?src=hash&ref_src=twsrc%5Etfw)) plus #Trametinib (https://twitter.com/hashtag/Trametinib?src=hash&ref_src=twsrc%5Etfw) (#Mekinist (https://twitter.com/hashtag/Mekinist?src=hash&ref_src=twsrc%5Etfw)) https://t.co/KupOIbt70e (https://t.co/KupOIbt70e)
>
> — Eduardo García-Toledano (@EduardGToledano) December 13, 2018 (https://twitter.com/EduardGToledano/status/1073124601033564160?ref_src=twsrc%5Etfw)

"This study adds to our knowledge and reinforces that patients with biliary tract cancers should have their tumors sequenced or analyzed for molecular changes," Dr. Greten said. "This work adds a molecular change that we may be able to target therapeutically."

Updated data from Ph II ILLUMINATE trial of tilsotolimod + ipilimumab in metastatic melanoma patients presented (http://ir.iderapharma.com/news-releases/news-release-details/idera-pharmaceuticals-presents-clinical-safety-and-efficacy)

"The continued positive results from this trial, a response rate substantially higher than expected with ipilimumab alone, and anti-tumor activity in both injected and uninjected lesions are exciting. These reinforce our conviction that tilsotolimod may overcome an immunosuppressive tumor microenvironment and, in combination with ipilimumab, could provide a treatment option when anti PD-1 therapy fails these patients," stated Dr. Joanna Horobin, Idera's Chief Medical Officer. "These data, along with the translational data, bolster our confidence in both the Phase 3 trial and taking tilsotolimod beyond melanoma."

> Dr. Adi Diab, M.D., discusses the Idera Pharmaceuticals, Inc. presentation of data from the ongoing ILLUMINATE-204 trial investigating tilsotolimod in combination with ipilimumab (Yervoy®). https://t.co/c9DRoOl9BO (https://t.co/c9DRoOl9BO) pic.twitter.com/iUedzAVtUG (https://t.co/iUedzAVtUG)
>
> — Health Radio Online (@HealthProRadio) November 28, 2018 (https://twitter.com/HealthProRadio/status/1067908495939387392?ref_src=twsrc%5Etfw)

REGULATORY NEWS

Positive CHMP opinion for CD30-targeting ADC brentuximab vedotin in CD30+ 1L HL patients, based on Ph III ECHELON-1 trial results (https://www.takeda.com/newsroom/newsreleases/2018/takeda-receives-positive-chmp-opinion-for-adcetris/)

"For a large number of previously untreated Hodgkin lymphoma patients diagnosed with Stage IV disease, progression will occur with current treatments, highlighting a true unmet need in this population," said Anna Sureda, M.D., Ph.D., Head of the Hematology Department and Hematopoietic Stem Cell Transplant Programme, Institut Català d'Oncologia – Hospital Duran i Reynals. "In the ECHELON-1 clinical trial, ADCETRIS in combination with AVD reduced the risk of progression, death or need for subsequent anticancer therapy in patients with Stage IV disease by 29 percent versus ABVD, a standard of care. If approved in this indication, ADCETRIS may offer an important novel treatment option for previously untreated patients with Stage IV Hodgkin lymphoma in Europe."

> Our Angioimmunoblastic Lymphoma clinical tool has been updated to reflect @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) approval of brentuximab vedotin for certain patients #MedUpdate (https://twitter.com/hashtag/MedUpdate?src=hash&ref_src=twsrc%5Etfw) #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/2Ote8fTlHK (https://t.co/2Ote8fTlHK) pic.twitter.com/hVd7FE6jiL (https://t.co/hVd7FE6jiL)
>
> — Medscape (@Medscape) December 15, 2018 (https://twitter.com/Medscape/status/1073903247834914816?ref_src=twsrc%5Etfw)

Positive CHMP opinion for Rucaparib as maintenance therapy based on Ph III ARIEL3 trial (https://ir.clovisoncology.com/investors-and-news/news-releases/press-release-details/2018/CHMP-Grants-Positive-Opinion-for-New-Indication-of-Clovis-Oncologys-Rubraca-rucaparib-Tablets-as-Maintenance-Treatment-for-Women-with-Relapsed-Ovarian-Cancer/default.)

"The CHMP recommendation represents an important step forward for women with recurrent ovarian cancer, for whom additional treatment options are needed. The ARIEL3 trial demonstrated rucaparib to be effective across all patient types, regardless of their BRCA mutation status, and is the only PARP-inhibitor trial in which independent radiological review reported a median progression-free survival of more than one year across the entire population studied," said Professor Jonathan Ledermann, MD, Professor of Medical Oncology, UCL Cancer Institute and UCL Hospitals, London, global Principal Investigator for non-US sites in the ARIEL3 study. "The meaningful efficacy data and tolerable safety profile offers women diagnosed with relapsed ovarian cancer a new therapy option."

> CHMP Grants Positive Opinion for New Indication of Clovis Oncology's Rubraca®▼ (rucaparib) Tablets as Maintenance Treatment for Women with Relapsed Ovarian Cancer https://t.co/s99HY6zNlF (https://t.co/s99HY6zNlF)
>
> — cache update (@cacheupdate) December 14, 2018 (https://twitter.com/cacheupdate/status/1073608659375218688?ref_src=twsrc%5Etfw)

sNDA submitted for Daratumumab in 1L MM in Japan based on data from the Ph III ALCYONE study (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-submission-supplemental-new-drug-application)

"We are extremely pleased that daratumumab in front line multiple myeloma has now been submitted in Japan. Should this submission be approved, it would bring an exciting new therapeutic option to Japanese multiple myeloma patients in need," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

> Genmab Submits sNDA for Daratumumab in Front Line Multiple Myeloma in Japan $GEN (https://twitter.com/search?q=%24GEN&src=ctag&ref_src=twsrc%5Etfw) httpsglobenewswire.comnewsrelease20181214166707 60enGenmabAnnouncesSubmissionofSupplementalNewDrugApplicationforDaratumumabi Genmab Submits sNDA for... https://t.co/5D5DLtslVY (https://t.co/5D5DLtslVY)
>
> — Multiple Sclerosis (@MS_Bio) December 14, 2018 (https://twitter.com/MS_Bio/status/1073529289625071617?ref_src=twsrc%5Etfw)

SPECIAL STATUSES

Orphan Drug Designation granted to anti-TGFbeta x anti-PD-L1 bifunctional immunotherapy M7824 in Biliary Tract Cancer (https://www.merckgroup.com/content/dam/web/corporate/non-images/press-releases/2018/dec/en/M7824-ODD-FDA-Press-Release-EN.pdf?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)

"Biliary tract cancer is a rare, notoriously hard-to-treat tumor where existing treatment approaches, such as surgery or chemotherapy, are either not viable or simply don't deliver acceptable patient outcomes," said Luciano Rossetti, Head of Global Research & Development at the Biopharma business of Merck. "As the first regulatory designation for M7824, Merck is excited about the potential of this new class of immunotherapy in a number of challenging cancers and settings."

> .@US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) grants orphan drug designation to M7824 for biliary tract cancer, with reporting from our sister publication @HemOncToday (https://twitter.com/HemOncToday?ref_src=twsrc%5Etfw) https://t.co/ePnijJWn90 (https://t.co/ePnijJWn90)
>
> — Healio Gastroenterology (@HealioGastro) December 11, 2018 (https://twitter.com/HealioGastro/status/1072530468686442497?ref_src=twsrc%5Etfw)

TRIAL STATUSES

Ph III and and another trial of Bevacizumab biosimilar IBI305 met primary endpoint (http://innoventbio.com/en/#/news/121)

"Lung cancer is the highest incidence cancer in China, and bevacizumab is an important treatment for non-small lung cancer patients. The launch of a high quality bevacizumab biosimilar will improve drug accessibility and benefit more patients," said Professor Li Zhang from Cancer Hospital of Sun Yat-sen University.

> ICYMI, a proposed bevacizumab biosimilar, IBI305, met its primary endpoints in 2 clinical trials. https://t.co/veWvnl3Z8v (https://t.co/veWvnl3Z8v)
>
> — CenterForBiosimilars (@BiosimCenter) December 15, 2018 (https://twitter.com/BiosimCenter/status/1073996143787421696?ref_src=twsrc%5Etfw)

"The current morbidity and mortality of malignant tumors in China are high, and anti-tumor treatment is a significant economic burden for millions of families. Anti-angiogenic drugs are effective anti-tumor treatments, but as of yet there are no approved bevacizumab biosimilars in China. The clinical studies of IBI305, a potential biosimilar of bevacizumab, are encouraging. I hope that IBI305 will be launched soon into China market, so more cancer patients and their families can benefit from the use of this important medicine," said Michael Yu, Founder, Chief Executive Officer and Chairman of Innovent.

First patient dosed in Ph I/Ib trial of anti-CD123 x anti-CD3 bispecific antibody in AML and high grade MDS patients (https://aptevotherapeutics.gcs-web.com/news-releases/news-release-details/aptevo-therapeutics-doses-first-patient-phase-1b-clinical-trial)

"Today's news represents an important milestone for Aptevo and for AML and MDS patients," said Dr. Scott Stromatt, Chief Medical Officer for Aptevo. "There is a strong unmet medical need for novel targeted biological therapies to treat patients with relapsed or refractory AML or MDS. Chemotherapy, which is the standard of care for these patients, is generally poorly tolerated in the elderly, and patients are still confronted with high relapse rates after treatment. Recent clinical data has demonstrated that CD123 is a validated target for AML therapy. We are particularly excited to begin clinical evaluation of APVO436 as our preclinical data suggest that it possesses best-in-class attributes and could offer benefits compared to current investigational therapies."

> $APVO (https://twitter.com/search?q=%24APVO&src=ctag&ref_src=twsrc%5Etfw) Aptevo Therapeutics Doses First Patient in Phase 1/1b Clinical Trial of Lead Next-Generation Bispecific Antibody APVO436 https://t.co/2pL6w1fU09 (https://t.co/2pL6w1fU09)
>
> — Stocks News Feed (@feed_stocks) December 13, 2018 (https://twitter.com/feed_stocks/status/1073244334097612802?ref_src=twsrc%5Etfw)

Ph I study of pelareorep + carfilzomib + nivolumab initiated in RRMM patients (https://www.oncolyticsbiotech.com/press-releases/detail/444/oncolytics-biotech-announces-first-patient-treated-in)

"Having worked with pelareorep in multiple myeloma and understanding its ability to act as a potentiator of checkpoint blockade, I'm very excited to work with the Oncolytics team on this study," said Dr. Craig Hofmeister, Associate Professor, Department of Hematology and Medical Oncology Emory University School of Medicine. "Pelareorep has proven its ability to create an inflamed phenotype and its potential for upregulation of PD-1 on tumor-infiltrating lymphocytes. My hope is this study leads not only to an effective combination dosing schedule but provides quantitative data describing the expression of PD-1, along with correlative studies that reveal the roles of both immune-mediated and direct cytotoxic myeloma cell killing."

> Excited to announce the first patient treated in our study combining pelareorep, carfilzomib and ICI Opdivo® in multiple myeloma https://t.co/yfpJsDpquX (https://t.co/yfpJsDpquX). Big thanks to @EagleMyeloma (https://twitter.com/EagleMyeloma?ref_src=twsrc%5Etfw) and @WinshipAtEmory (https://twitter.com/WinshipAtEmory?ref_src=twsrc%5Etfw) pic.twitter.com/hNpR8yQlcB (https://t.co/hNpR8yQlcB)
>
> — Oncolytics Biotech (@Oncolytics) December 12, 2018 (https://twitter.com/Oncolytics/status/1072914590021824512?ref_src=twsrc%5Etfw)

Ph III AVENGER 500 trial of metabolic regulator CPI-613 (devimistat) + mFOLFIRINOX initiated in 1L metastatic pancreatic cancer patients (http://www.globenewswire.com/news-release/2018/12/11/1665069/0/en/Rafael-Pharmaceuticals-Announces-Initiation-of-Pivotal-Phase-3-Trial-AVENGER-500-of-CPI-613-devimistat-in-Combination-with-Modified-FOLFIRINOX-as-First-Line-Treatment-for-Patients-.html)

Howard Jonas, Chairman of Rafael Pharmaceuticals, commented: "It is our goal not only to prolong life but ultimately to develop cures for pancreatic cancer and other difficult-to-treat cancers. We have great hope both for the success of this trial and for our follow-on compounds in the years to come. We are optimistic that cancer metabolism drugs will create a new paradigm in oncology treatment."

> Researchers are looking for patients with pancreatic cancer who are eligible for their study on using a chemotherapy mFOLFIRINOX to see if it's more effective than standard chemo. Interested patients, researchers or sponsors call 845-483-6825 or email research@health-quest.org pic.twitter.com/HxYyI6YkoN (https://t.co/HxYyI6YkoN)
>
> — My Health Quest (@my_healthquest) November 18, 2018 (https://twitter.com/my_healthquest/status/1064247019399757824?ref_src=twsrc%5Etfw)

Ph Ib portion of Ph Ib/II trial of GAS6 inhibitor AVB-S6-500 initiated in platinum-resistant recurrent ovarian cancer patients (https://markets.businessinsider.com/news/stocks/aravive-biologics-initiates-phase-1b-portion-of-phase-1b-2-clinical-trial-of-avb-s6-500-in-platinum-resistant-recurrent-ovarian-cancer-1027798241)

"We are very pleased to initiate this first trial of AVB-S6-500 in patients with ovarian cancer," said Gail McIntyre Ph.D., DABT, Senior Vice President of R&D at Aravive. "Our initial Phase 1 clinical trial of this agent in healthy volunteers showed a favorable safety and tolerability profile, with no reported serious adverse events and no adverse events that limited dosing in the trial. We also suppressed circulating free GAS6 across all dose levels and higher doses suppressed circulating free GAS6 for a longer duration than lower doses. We anticipate the measurement of circulating free GAS6 will be highly useful as a biomarker of drug activity in this new trial. A reduction in this biomarker has correlated to anti-tumor activity in preclinical studies."

> Aravive Biologics initiates Phase 1b/2 Clinical Trial of AVB-S6-500 in Platinum-Resistant Recurrent Ovarian Cancer https://t.co/3X1nLgYOgX (https://t.co/3X1nLgYOgX) #biotechnology (https://twitter.com/hashtag/biotechnology?src=hash&ref_src=twsrc%5Etfw) #biopharma (https://twitter.com/hashtag/biopharma?src=hash&ref_src=twsrc%5Etfw) #pharma (https://twitter.com/hashtag/pharma?src=hash&ref_src=twsrc%5Etfw) #lifescience (https://twitter.com/hashtag/lifescience?src=hash&ref_src=twsrc%5Etfw) #science (https://twitter.com/hashtag/science?src=hash&ref_src=twsrc%5Etfw) #biology (https://twitter.com/hashtag/biology?src=hash&ref_src=twsrc%5Etfw) #research (https://twitter.com/hashtag/research?src=hash&ref_src=twsrc%5Etfw) #healthcare (https://twitter.com/hashtag/healthcare?src=hash&ref_src=twsrc%5Etfw) #medtech (https://twitter.com/hashtag/medtech?src=hash&ref_src=twsrc%5Etfw) #medicaldevice (https://twitter.com/hashtag/medicaldevice?src=hash&ref_src=twsrc%5Etfw) #cl (https://twitter.com/hashtag/cl?src=hash&ref_src=twsrc%5Etfw)… pic.twitter.com/DWuXhBabGu (https://t.co/DWuXhBabGu)
>
> — NewDartagnan (@New_Dartagnan) December 15, 2018 (https://twitter.com/New_Dartagnan/status/1073885922033319936?ref_src=twsrc%5Etfw)

Triple combination arm (CXCR4 antagonist BL-8040, Pembrolizumab and chemotherapy) initiated in Ph IIa COMBAT/KEYNOTE-202 trial in pancreatic cancer patients (http://www.biolinerx.com/default.asp?pageid=16&itemid=642)

"We are pleased to commence this triple combination arm of our Phase 2a pancreatic study, under the framework of our immuno-oncology collaboration with MSD," stated Philip Serlin, Chief Executive Officer of BioLineRx. "We believe that the addition of chemotherapy may be synergistic with BL-8040 and KEYTRUDA, as chemotherapy has been shown to reduce overall tumor burden while inducing immunogenic cell death, leading to activation and expansion of new tumor-reactive T-cells. Based on its mechanism of action, we believe that BL-8040 may facilitate the infiltration of these T-cells into the tumor core, alongside the restoration of T-cell activity within the tumor by KEYTRUDA. We look forward to results of the study expected in the second half of 2019."

> BioLineRx $BLRX (https://twitter.com/search?q=%24BLRX&src=ctag&ref_src=twsrc%5Etfw) Announces Initiation of Triple Combination Arm of Phase 2a COMBAT/KEYNOTE-202 Study in Pancreatic Cancer Under Immuno-Oncology Collaborationhttps://t.co/wIsIAJECSW (https://t.co/wIsIAJECSW)
>
> — LifeSci Advisors (@LifeSciAdvisors) December 11, 2018 (https://twitter.com/LifeSciAdvisors/status/1072602796464201734?ref_src=twsrc%5Etfw)

Ph II portion of ProSTAR trial of EZH2 inhibitor CPI-1205 initiated in mCRPC patients; CPI-1205 + abiraterone arm added in 2L setting (http://ir.constellationpharma.com/news-releases/news-release-details/constellation-pharmaceuticals-initiates-phase-2-portion-prostar)

"We are pleased that CPI-1205 achieved its Phase 1b endpoints in ProSTAR, demonstrating an encouraging safety profile and evidence of clinical activity in both arms," said Adrian Senderowicz, Chief Medical Officer of Constellation Pharmaceuticals. "As we advance into the Phase 2 portion of the study, we believe combination therapy with CPI-1205 may provide a meaningful second-line treatment option to patients with metastatic castration-resistant prostate cancer, an area of significant unmet medical need. We are excited about expanding our opportunity to include an arm evaluating CPI-1205 in combination with abiraterone in the second-line setting, given that very few patients experience a 50% reduction in PSAs on second-line treatment with abiraterone and that time to progression in this setting is typically short."

> Constellation Pharmaceuticals Initiates Phase 2 Portion of ProSTAR Clinical Trial in Patients: Constellation PharmaceuticalsÂNasdaqCNST a clinicalstage biopharmaceutical company using its expertise in epigenetics to discover and develop novel... https://t.co/afN10aoREg (https://t.co/afN10aoREg)
>
> — CRO Contract Res. (@cro_bio) December 11, 2018 (https://twitter.com/cro_bio/status/1072570171150217216?ref_src=twsrc%5Etfw)

Nivolumab + rationally-defined human bacterial consortium VE800 to be evaluated in patients with advanced or metastatic cancers (https://news.bms.com/press-release/rd-news/bristol-myers-squibb-and-vedanta-biosciences-announce-new-clinical-collaborati)

"Our lead, microbiome-based immuno-oncology candidate, VE800, is based on work conducted in collaboration with our co-founder, Dr. Kenya Honda, showing in preclinical models that certain gut-dwelling bacterial strains potentiate cytotoxic CD8+ T cells and enhance infiltration into tumors," said Bernat Olle, Ph.D., Co-founder and Chief Executive Officer of Vedanta Biosciences. "Through this collaboration our goal is to determine whether VE800 in combination with Opdivo can improve outcomes for patients with advanced or metastatic cancers."

> #BMS (https://twitter.com/hashtag/BMS?src=hash&ref_src=twsrc%5Etfw), #VedantaBiosciences (https://twitter.com/hashtag/VedantaBiosciences?src=hash&ref_src=twsrc%5Etfw) to evaluate #Opdivo (https://twitter.com/hashtag/Opdivo?src=hash&ref_src=twsrc%5Etfw) – #VE800 (https://twitter.com/hashtag/VE800?src=hash&ref_src=twsrc%5Etfw) combo in #metastaticcancers (https://twitter.com/hashtag/metastaticcancers?src=hash&ref_src=twsrc%5Etfw) https://t.co/tkWwoL1l4b (https://t.co/tkWwoL1l4b) via @Pharma_BR (https://twitter.com/Pharma_BR?ref_src=twsrc%5Etfw) @bmsnews (https://twitter.com/bmsnews?ref_src=twsrc%5Etfw) @Bristol_Myers (https://twitter.com/Bristol_Myers?ref_src=twsrc%5Etfw) @VedantaBio (https://twitter.com/VedantaBio?ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw)
>
> — Plexus Ventures (@PlexusVentures) December 12, 2018 (https://twitter.com/PlexusVentures/status/1072951886507139072?ref_src=twsrc%5Etfw)

"We are continuing to explore the novel mechanisms of new assets in combination with our oncology portfolio," said Fouad Namouni, M.D., head of development, oncology, Bristol-Myers Squibb. "Vedanta Biosciences is a leading company focused on the characterization of immunomodulatory human gut commensals and the development of live bacterial products for the potential treatment of human diseases. Our collaboration with Vedanta Biosciences will allow us to gain a deeper understanding about the emerging microbiome landscape, its role in oncology, and the potential to improve outcomes for patients with advanced or metastatic cancer."

U.S. registrational pathway and updated clinical development plan announced for tetravalent, bispecific NK cell engager AFM13 (http://www.affimed.com/affimed-announces-u-s-registrational-pathway-and-updated-clinical-development-plan-for-afm13-at-rd-day/)

"We believe that the clinical development plan shared today for AFM13 provides potential for accelerated approval and helps to lay the groundwork for further investigations of CD16A innate immune engagers," said Dr. Adi Hoess, Affimed's CEO. "Through our fit-for-purpose ROCK® platform, we continue to generate novel engagers, like AFM13, to broaden our leadership in innate immunity. We look forward to continuing this important work to enhance current immuno-oncology approaches, with the ultimate goal of giving patients back the body's innate ability to fight cancer."

COLLABORATIONS

Ph I/II trial of PD-L1i durvalumab + VEGFR-TKi tivozanib to start in 1L HCC patients (https://investor.aveooncology.com/news-releases/news-release-details/aveo-oncology-announces-immuno-oncology-clinical-collaboration)

"We are thrilled to collaborate with AstraZeneca to explore another tivozanib-immunotherapy combination and look forward to understanding the potential of combining tivozanib with durvalumab in liver cancer," said Michael Bailey, president and chief executive officer of AVEO. "TKI-immunotherapy combinations have demonstrated important clinical potential across multiple tumor types, though toxicities associated with these combinations have limited their potential use. Our goal is to establish tivozanib as the TKI of choice for use with immunotherapies by demonstrating efficacy with reduced toxicity."

> $AVEO (https://twitter.com/search?q=%24AVEO&src=ctag&ref_src=twsrc%5Etfw) Announces ImmunoOncology Clinical Collab with $AZN (https://twitter.com/search?q=%24AZN&src=ctag&ref_src=twsrc%5Etfw). Ph 12 Study will Evaluate Combination of IMFINZIÂ durvalumab and FOTIVDAÂ tivozanib in FirstLine HCC... https://t.co/2wLk5OK03D (https://t.co/2wLk5OK03D) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #cancertreatment (https://twitter.com/hashtag/cancertreatment?src=hash&ref_src=twsrc%5Etfw) #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) #braincancer (https://twitter.com/hashtag/braincancer?src=hash&ref_src=twsrc%5Etfw)
>
> — Cancer News (@Cancer_bio) December 12, 2018 (https://twitter.com/Cancer_bio/status/1072834387614478336?ref_src=twsrc%5Etfw)

COMPANION Dx

Blood-based CDx tests to be developed for Durvalumab and Osimertinib; breakthrough device designation to GuardantOMNI test used for TMB analysis (https://guardanthealth.gcs-web.com/news-releases/news-release-details/guardant-health-partners-astrazeneca-develop-blood-based)

"Precision medicine is at the heart of our ambition to eliminate cancer as a cause of death," said Ruth March, PhD, Senior Vice President of Precision Medicine and Genomics for AstraZeneca's Innovative Medicines and Early Development (IMED) Biotech Unit. "We are committed to matching life-changing medicines to patients most likely to benefit, and we believe our partnership with Guardant Health will help us achieve this."

"AstraZeneca's work in targeted therapy and immuno-oncology has already benefited thousands of advanced cancer patients," said Guardant Health Co-Founder and COO AmirAli Talasaz, PhD. "The data presented today at ESMO's IO congress builds on other recent data that show Guardant's liquid biopsy technology can increase the number of patients who are tested for important biomarkers relative to tissue. We are proud to support these programs using the Guardant platform and help more patients access these important treatments."

> 💎 In pursuit of its goal to manage cancer across all stages of the disease, @guardanthealth (https://twitter.com/GuardantHealth?ref_src=twsrc%5Etfw) has launched liquid biopsy tests, Guardant360 and GuardantOMNI, for advanced stage cancer. pic.twitter.com/mcqjphpjoS (https://t.co/mcqjphpjoS)
>
> — Nasdaq (@Nasdaq) October 4, 2018 (https://twitter.com/Nasdaq/status/1047852730801410049?ref_src=twsrc%5Etfw)

Roche and Merck to develop companion Dx for use with Pembrolizumab in dMMR positive solid tumor patients (https://www.prnewswire.com/news-releases/roche-to-develop-companion-diagnostic-test-to-help-identify-patients-eligible-for-anti-pd-1-therapy-based-on-biomarker-expression-not-location-of-solid-tumors-300762953.html)

"We are excited to collaborate with Merck to develop a pan-cancer companion diagnostic test panel to detect mismatch repair deficiency," said Jill German, Head of Roche Tissue Diagnostics. "This new development could help change the way we identify patients best suited for immunotherapy treatment."

> Roche partners with Merck to develop companion diagnostic test: Roche will develop companion diagnostic for use with Keytruda pembrolizumab Merck&8217;s antiPD1 therapy in advanced solid tumors with mismatch repair deficiency dMMR. Roche tissue... https://t.co/uyl2eduIcI (https://t.co/uyl2eduIcI)
>
> — HIV/AIDS News (@HIV_AIDS_Bio) December 13, 2018 (https://twitter.com/HIV_AIDS_Bio/status/1073307339803901952?ref_src=twsrc%5Etfw)

"A key element of our strategy at Merck is focused on identifying those patients likely to benefit most from our medicines," said Dr. Eric Rubin, senior vice president, oncology clinical development, Merck Research Laboratories. "We look forward to working with Roche to develop a diagnostic test for mismatch repair deficiency."

CONFERENCE COVERAGE: San Antonio Breast Cancer Symposium (SABCS) Annual Meeting

> Check out our coverage of #SABCS18 (https://twitter.com/hashtag/SABCS18?src=hash&ref_src=twsrc%5Etfw), the 2018 San Antonio Breast Cancer Symposium:https://t.co/VeUlQveRuw (https://t.co/VeUlQveRuw)#breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/xoSnT6J6vF (https://t.co/xoSnT6J6vF)
>
> — Physician's Weekly (@physicianswkly) December 10, 2018 (https://twitter.com/physicianswkly/status/1072179044526014466?ref_src=twsrc%5Etfw)

1. One-year follow up EFS data of Trastuzumab biosimilar SB3 vs Trastuzumab presented (http://www.samsungbioepis.com/en/newsroom/detail/Samsung-Bioepis-Announces-Results-of-Additional-One-Year-Follow-Up-Study.html)
2. Ph I data of HER2-targeting ADC DS-8201 in HER2-low metastatic breast cancer patients presented (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006943.html)
3. Subgroup analyses of three pivotal Ph III MONALEESA trials showed Ribociclib plus endocrine therapy extended PFS in all patients with and without visceral involvement (https://www.novartis.com/news/media-releases/novartis-data-demonstrates-consistent-efficacy-and-tolerability-kisqali-combination-therapy-hrher2-advanced-breast-cancer-patients-difficult-treat-visceral)
4. Clinical updates with Sacituzumab govitecan presented (https://www.nasdaq.com/press-release/immunomedics-provides-clinical-updates-on-breast-cancer-programs-with-sacituzumab-govitecan-20181206-00458)
5. Initial safety data presented from Ph IIa trial of Bria-IMT + pembrolizumab in advanced breast cancer patients (http://briacell.com/2018/12/06/briacell-presents-positive-efficacy-data-with-lead-cancer-drug-candidate-in-phase-iia-monotherapy-and-excellent-initial-safety-data-in-combination-with-keytruda-at-a-major-breast-cancer-conferen/)
6. Puma Biotechnology presents results from Ph II SUMMIT trial (http://www.pumabiotechnology.com/pr20181206summit.html)
7. Puma Biotechnology presents results from Ph II CONTROL trial (http://www.pumabiotechnology.com/pr20181206control.html)
8. Puma Biotechnology presents results from Ph III ExteNET trial (http://www.pumabiotechnology.com/pr20181206extenet.html)
9. Improved PFS observed with alpelisib + fulvestrant in Ph III SOLAR-1 trial of PI2KCA mutated HR+/HER2- advanced breast cancer patients (https://www.novartis.com/news/media-releases/novartis-investigational-byl719-alpelisib-plus-fulvestrant-consistently-improved-pfs-patients-pik3ca-mutated-hrher2-advanced-breast-cancer-new-solar-1-analyses)
10. Updated Ph I data for HER3-targeting ADC U3-1402 presented in HER3-expressing metastatic Breast Cancer patients (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006938.html)
11. Ph III GEICAM/CIBOMA trial of adjuvant capecitabine failed – didn't meet primary endpoint of DFS improvement (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1250)
12. Ph III KATHERINE trial of adjuvant trastuzumab emtansine met primary endpoint of iDFS reduction in early stage HER2+ breast cancer patients (http://hugin.info/174806/R/2227754/874660.pdf)
13. Lilly presented clinical data for abemaciclib and Real-World Evidence across HR+, HER2- Metastatic Breast Cancer (https://investor.lilly.com/news-releases/news-release-details/lilly-present-clinical-data-verzenior-abemaciclib-and-real-world)

OTW Trivia

Q: What are companion diagnostic tests?

A: According to the FDA, a companion diagnostic is a medical tool, like an *in vitro* device, to be used to provide important information for the safe and effective use of a corresponding drug or biological product.

Q: How are companion diagnostic tests important?

A: Companion diagnostic tests ensure that clinically meaningful patient benefit is provided to the right patient by delivering the right therapy at the right time. They become all the more important in the era of personalized medicine where selected patients derive maximum benefit from a certain kind of therapy.

Q: How would one know if a companion diagnostic test is recommended for a particular drug?

A: Use of a companion diagnostic test with a particular therapeutic drug is recommended in the label instructions for use of both corresponding drug and the test. Any biosimilar equivalents or generic versions of the drug also have the information mentioned in their labels.

Q: What are common companion diagnostic tests in use in oncology?

A: The following list has examples of some common companion diagnostic tests along with the indication and drug

they are recommended for:

Diagnostic Name	Trade Name (Generic) – NDA/BLA
BRACAnalysis CDx	***Breast Cancer:*** Lynparza (olaparib); Talzenna (talazoparib) ***Ovarian Cancer:*** Lynparza (olaparib); Rubraca (rucaparib)
therascreen EGFR RGQ PCR Kit	***NSCLC:*** Iressa (gefitinib); Gilotrif (afatinib); Vizimpro (dacomitinib)
FoundationOne CDx	***NSCLC:*** Gilotrif (afatinib); Iressa (gefitinib); Tarceva (erlotinib); Tagrisso (osimertinib); Alecensa (alectinib); Xalkori (crizotinib); Zykadia (ceritinib); Tafinlar (dabrafenib) in combination with Mekinist (trametinib) ***Melanoma:*** Tafinlar (dabrafenib); Zelboraf (vemurafenib); Mekinist (trametinib) or Cotellic (cobimetinib) in combination with Zelboraf (vemurafenib) ***Breast cancer:*** Herceptin (trastuzumab); Perjeta (pertuzumab); Kadcyla (ado-trastuzumab emtansine) ***Colorectal cancer:*** Erbitux (cetuximab); Vectibix (panitumumab) ***Ovarian cancer:*** Rubraca (rucaparib)

Source: https://www.fda.gov/medicaldevices/productsandmedicalprocedures/invitrodiagnostics/ucm301431.htm

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.

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

Image Sources: Wikipedia and Twitter

Cover image: "Scanning electron micrograph of the inside of a cancer cell. This cell originates from a squamous cell carcinoma, a type of skin cancer. The cell has been frozen and split open to reveal its nucleus." Source (http://flagella.crbs.ucsd.edu/images/38938)

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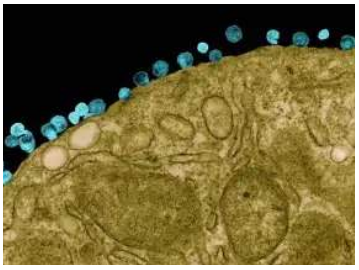

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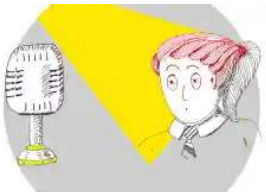

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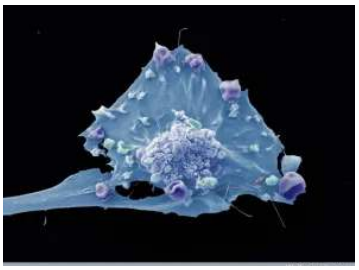

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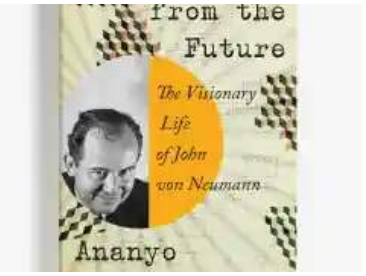

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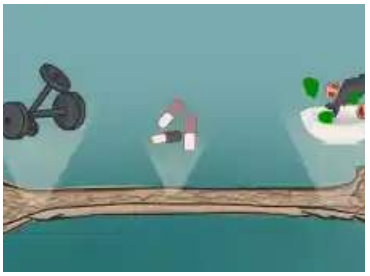

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