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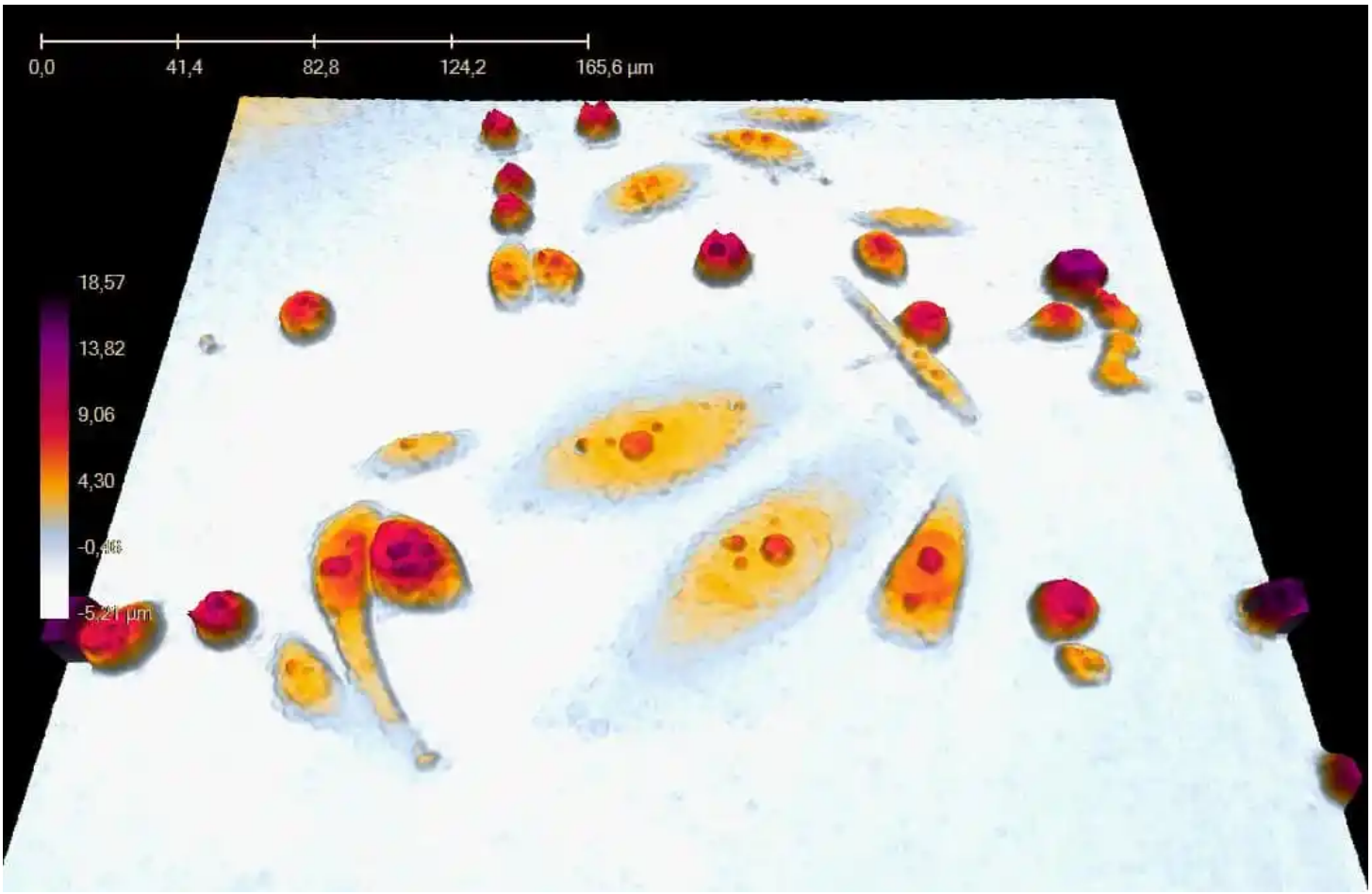
Onco-this-Week

February 17, 2019(https://sciwri.club/archives/date/2019/02/17)



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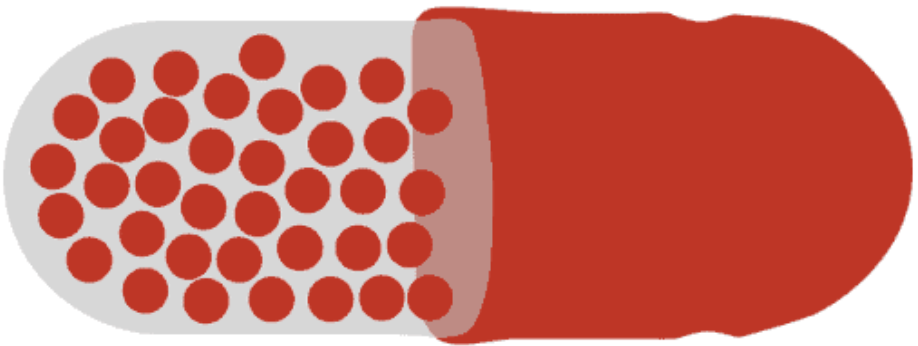

OTW in a Capsule

HIGHLIGHTS

1. **Priority review granted to two immunotherapies in RCC.** Axitinib became part of two priority reviews in RCC when it showed encouraging responses in 1L RCC patients in Ph III KEYNOTE-426 trial in combination with Pembrolizumab; and with Avelumab, based on Phase III JAVELIN Renal 101 trial. The frontline battle in RCC intensified post KEYNOTE-426 data announcement and it would be interesting to see how these two combinations fare against Nivoumab-Ipilimumab which is already approved in this setting.
2. **Pembrolizumab's performance in mCRPC settings.** After announcement of promising Ph Ib/II KEYNOTE-365 data, Merck announced initiation of three pivotal Ph III trials of Pembrolizumab, in combination with Olaparib or Decetaxel + Prednisone or Enzalutamide to be initiated in mCRPC patients. Big deal is inclusion with OS as a co-primary endpoint!
3. **Novel radiotherapy, LuPSMA, showed encouraging efficacy in heavily pretreated mCRPC** Delivering radiation to specific cells is an effective approach to target specific cancer cells while minimizing damage to normal cells, especially for aggressive and difficult-to-treat mCRPC. For people with prostate cancer cells that express PSMA, a membrane antigen on the surface of the cancer cells, LuPSMA may become a new treatment option as per the results announced in ASCO GU 2019 conference.

DRUG APPROVALS

FDA Approves Split-Dosing Regimen of Daratumumab for Multiple Myeloma (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-us-fda-approval-darzalexr-daratumumab-split)

> . @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) approves split-dosing of daratumumab for patients with multiple myeloma. Read more here: https://t.co/YQtCEtC3hh (https://t.co/YQtCEtC3hh) including expert opinion from Ajai Chari, MD of @MountSinaiNYC (https://twitter.com/MountSinaiNYC?ref_src=twsrc%5Etfw) #mmsm (https://twitter.com/hashtag/mmsm?src=hash&ref_src=twsrc%5Etfw) #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw) #drugupdate (https://twitter.com/hashtag/drugupdate?src=hash&ref_src=twsrc%5Etfw) #fda (https://twitter.com/hashtag/fda?src=hash&ref_src=twsrc%5Etfw) #daratumumab (https://twitter.com/hashtag/daratumumab?src=hash&ref_src=twsrc%5Etfw) #darzalex (https://twitter.com/hashtag/darzalex?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/Ns1N6cyyi9 (https://t.co/Ns1N6cyyi9)
>
> — Multiple Myeloma Hub (@MM_Hub) February 13, 2019 (https://twitter.com/MM_Hub/status/1095685654774775809?ref_src=twsrc%5Etfw)

"The first infusion of daratumumab is an important first step in a patient's course of therapy, and this approval provides added flexibility for how patients may receive initial treatment," Craig Tendler, MD, vice president, clinical development and global medical affairs, Janssen Research & Development, LLC, which codevelops daratumumab with Genmab, said in a press release. "We are committed to exploring options that may improve the overall treatment experience for patients."

EU approval granted to CD30-targeting ADC brentuximab vedotin in CD30+ 1L HL patients, based on Ph III ECHELON-1 trial results (https://www.takeda.com/newsroom/newsreleases/2019/european-commission-approves-adcetris-with-avd-for-adults-with-previously-untreated-cd30-stage-iv-hodgkin-lymphoma/)

> Seattle Genetics Achieves $30 Million Milestone Payment for European Commission Approval of ADCETRIS® (Brentuximab Vedotin) in Frontline Hodgkin Lymphoma https://t.co/KwOiitHBBk (https://t.co/KwOiitHBBk) pic.twitter.com/BRfZQJOCTr (https://t.co/BRfZQJOCTr)
>
> — Stocks News Feed (@feed_stocks) February 12, 2019 (https://twitter.com/feed_stocks/status/1095167148211597312?ref_src=twsrc%5Etfw)

"The decision by the European Commission is a welcomed advancement for patients with previously untreated Stage IV Hodgkin lymphoma – a population that has not been offered a new treatment option in decades," 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. "Patients with Stage IV disease carry a higher risk of progression following their first therapy and experience poorer outcomes as a result. The approval of this regimen may help address this unmet need by providing European physicians and their patients with a new option that showed significant benefit compared to ABVD along with a safety profile consistent with when ADCETRIS is used as a single agent."

Dasatinib + chemotherapy approved by EU in 1L pediatric Ph+ ALL patients based on Ph II CA180-372 trial results (https://news.bms.com/press-release/corporatefinancial-news/european-commission-approves-bristol-myers-squibbs-sprycel-das)

> #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) approves #dasatinib (https://twitter.com/hashtag/dasatinib?src=hash&ref_src=twsrc%5Etfw) for kids with Ph+ ALL https://t.co/0ADBlcPya7 (https://t.co/0ADBlcPya7) #Sprycel (https://twitter.com/hashtag/Sprycel?src=hash&ref_src=twsrc%5Etfw) #acutelymphoblasticleukemia (https://twitter.com/hashtag/acutelymphoblasticleukemia?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/jK6GIoOENo (https://t.co/jK6GIoOENo)
>
> — MDedge Hematology & Oncology (@MDedgeHemOnc) January 3, 2019 (https://twitter.com/MDedgeHemOnc/status/1080877923870130178?ref_src=twsrc%5Etfw)

"We are proud that the approval by the European Commission brings children with Ph+ acute lymphoblastic leukemia a new treatment option, including a powder formulation developed as part of our commitment to addressing the unique needs of children with cancer," said Fouad Namouni, M.D., head, oncology development, Bristol-Myers Squibb.

REGULATORY NEWS

Pembrolizumab + Axitinib got priority review in 1L RCC patients based on Ph III KEYNOTE-426 and Ph Ib KEYNOTE-035 trials data; PDUFA: Jun 20, 2019 (https://www.mrknewsroom.com/news-release/oncology/fda-grants-priority-review-mercks-supplemental-biologics-license-application-2)

> #Keynote426 (https://twitter.com/hashtag/Keynote426?src=hash&ref_src=twsrc%5Etfw) : Axitinib + pembrolizumab improves OS in #KidneyCancer (https://twitter.com/hashtag/KidneyCancer?src=hash&ref_src=twsrc%5Etfw) patients in the first line metastatic setting with a record HR of 0.53. efficazcy accross all IMDC risk groups #GU19 (https://twitter.com/hashtag/GU19?src=hash&ref_src=twsrc%5Etfw) @EAU_Uroonco (https://twitter.com/EAU_Uroonco?ref_src=twsrc%5Etfw) @Uroweb (https://twitter.com/Uroweb?ref_src=twsrc%5Etfw) pic.twitter.com/e2REuPC2kX (https://t.co/e2REuPC2kX)
>
> — Idir ouzaid (@IdirOuzaid) February 16, 2019 (https://twitter.com/IdirOuzaid/status/1096894770163511296?ref_src=twsrc%5Etfw)

"Many patients with advanced renal cell carcinoma face a poor prognosis and there remains a need for new and effective treatment options in the first-line setting," said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. "KEYNOTE-426 demonstrated that an anti-PD-1 combination therapy significantly improved

overall survival and progression-free survival versus sunitinib in the first-line treatment of advanced renal cell carcinoma. We look forward to working with the FDA to bring this KEYTRUDA combination to patients."

CTA approval granted for initiation of Ph I/II trial of clonal neoantigen T cells (cNeT) in metastatic or recurrent melanoma patients in UK (https://achillestx.com/achilles-therapeutics-receives-cta-approval-for-phase-i-ii-study-in-metastic-or-recurrent-melanoma-second-cta-approval-in-2019-the-first-was-for-a-nsclc-study/)

> #BioIT (https://twitter.com/hashtag/BioIT?src=hash&ref_src=twsrc%5Etfw) #BioInformatics (https://twitter.com/hashtag/BioInformatics?src=hash&ref_src=twsrc%5Etfw) Achilles Therapeutics receives CTA Approval for Phase I/II Study in Metastatic or Recurrent Melanoma – BioSpace https://t.co/oJp2MtiSIO (https://t.co/oJp2MtiSIO)
>
> — SeqComplete (@SeqComplete) February 14, 2019 (https://twitter.com/SeqComplete/status/1095957668399853568?ref_src=twsrc%5Etfw)

"To have received our second CTA approval in as many weeks is highly encouraging," said Dr Iraj Ali, CEO of Achilles Therapeutics. "We look forward to bringing this potentially transformative treatment option into the clinic later this year."

Approval to STAT3 inhibitor, WP1220, to begin trial for the topical treatment of CTCL (https://ir.moleculin.com/press-releases/detail/114/moleculin-announces-approval-for-third-drug-to-commence)

> Moleculin Announces Approval for Third Drug to Commence Clinical Trials: MBRX will now have three distinctive oncology drugs in clinic in four ongoing clinical trials WP1220 a STAT3 inhibitor to begin clinical trials in Poland for the treatment of... https://t.co/XtH1fldsoz (https://t.co/XtH1fldsoz) pic.twitter.com/FyoADL63kh (https://t.co/FyoADL63kh)
>
> — Drug Approvals (@DrugApprovalBio) February 7, 2019 (https://twitter.com/DrugApprovalBio/status/1093497746009468930?ref_src=twsrc%5Etfw)

"This marks an important milestone for Moleculin. We now have three unique drug candidates in four ongoing clinical trials for the potential treatment of rare and difficult cancers," commented Walter Klemp, Moleculin's Chairman and CEO. "We are committed to the strategy of what we call 'multiple shots on goal,' and this latest approval to begin trials means we now have three distinctly different therapies in clinical trials for the potential treatment of rare and difficult cancers."

FDA Accepts sBLA and grants Priority Review for Avelumab + Axitinib in advanced RCC based on data from the pivotal Phase III JAVELIN Renal 101 trial; PDUFA: Jun 2019 (https://www.merckgroup.com/en/news/rcc-2019-02-11.html?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)

> Pivotal Phase III Data for BAVENCIO® (avelumab) Plus INLYTA® (axitinib) in Advanced Renal Cell Carcinoma Published in the New England Journal of Medicine https://t.co/0PKeotghd1 (https://t.co/0PKeotghd1) pic.twitter.com/04eNKvOYKT (https://t.co/04eNKvOYKT)
>
> — ShareHRnews (@ShareHRnews) February 17, 2019 (https://twitter.com/ShareHRnews/status/1096925862421622784?ref_src=twsrc%5Etfw)

"The combination of BAVENCIO with INLYTA builds on Pfizer's significant heritage in advancing standards of care for patients with advanced RCC and has the potential to make a meaningful impact for the lives of patients," said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology, Pfizer Global Product Development. "We look forward to working with the FDA to bring this potential new treatment option to patients as quickly as possible."

Priority review granted to Pembrolizumab in 1L SCCHN patients on the basis of Ph III KEYNOTE-048 trial data; PDUFA: Jun 10, 2019 (https://www.mrknewsroom.com/news-release/oncology/fda-grants-priority-review-mercks-supplemental-biologics-license-application-1)

> ICYMI: #Pembrolizumab (https://twitter.com/hashtag/Pembrolizumab?src=hash&ref_src=twsrc%5Etfw) extended OS compared with standard #chemotherapy (https://twitter.com/hashtag/chemotherapy?src=hash&ref_src=twsrc%5Etfw) for patients with relapsed or metastatic head and neck squamous cell carcinoma, according to study results from KEYNOTE 040 presented at #AACR18 (https://twitter.com/hashtag/AACR18?src=hash&ref_src=twsrc%5Etfw). https://t.co/uyVa7L2yQS (https://t.co/uyVa7L2yQS) #HNSCC (https://twitter.com/hashtag/HNSCC?src=hash&ref_src=twsrc%5Etfw) #SCCHN (https://twitter.com/hashtag/SCCHN?src=hash&ref_src=twsrc%5Etfw) @Merck (https://twitter.com/Merck?ref_src=twsrc%5Etfw) #Keytruda (https://twitter.com/hashtag/Keytruda?src=hash&ref_src=twsrc%5Etfw) @AACR (https://twitter.com/AACR?ref_src=twsrc%5Etfw)
>
> — HemOnc Today (@HemOncToday) May 9, 2018 (https://twitter.com/HemOncToday/status/994025660711559168?ref_src=twsrc%5Etfw)

"Head and neck cancer remains a challenging and devastating disease, and newly diagnosed patients are in need of improved treatment options," said Dr. Jonathan Cheng, vice president, clinical research, Merck Research Laboratories. "Merck continues to make meaningful advances in the treatment of head and neck cancer, and we look forward to working with the FDA to bring these important new options to patients in the first-line setting."

IND approved of anti-PD-1 x anti-TAA bispecific antibody IBI318 to initiate trials in patients with hematological and advanced solid tumors (http://innoventbio.com/en/#/news/129)

> Bravo #IBI318 (https://twitter.com/hashtag/IBI318?src=hash&ref_src=twsrc%5Etfw)! China's National Medical Products Administration (NMPA) has approved its IND application for hematological and advanced #solidtumors (https://twitter.com/hashtag/solidtumors?src=hash&ref_src=twsrc%5Etfw)
>
> IBI318 is a recombinant fully human #bispecific (https://twitter.com/hashtag/bispecific?src=hash&ref_src=twsrc%5Etfw) antibody targeting #PD1 (https://twitter.com/hashtag/PD1?src=hash&ref_src=twsrc%5Etfw) & undisclosed target for a tumor-associated antigen (TAA) pic.twitter.com/08HdYiQfPi (https://t.co/08HdYiQfPi)
>
> — Beacon Intelligence (@BeaconIntel) February 13, 2019 (https://twitter.com/BeaconIntel/status/1095616066762559488?ref_src=twsrc%5Etfw)

"IBI318 is one of the exciting, innovative anti-cancer programs that Innovent has pursued. We have a few bispecific antibody product candidates that have reached the clinical stage of development in both oncology and ophthalmology therapeutic areas. Many of these projects have the potential to be global first-in-class assets that could help large numbers of patients in need. The IND approval by NMPA of the bispecific antibody IBI318 has confirmed Innovent's ability to innovate and encouraged us to continue our pursuit of global innovation," said Michael Yu, Founder, Chief Executive Officer and Chairman of Innovent.

IND filed for PD-L1 inhibitor CS1001+PARP inh IMP4297 combination therapy for trial in patients with solid tumors (https://www.prnewswire.com/news-releases/cstone-and-impact-therapeutics-clinical-collaboration-progresses-to-ind-filing-acceptance-for-cs1001imp4297-combination-therapy-300791944.html)

> CStone and IMPACT Therapeutics' clinical collaboration progresses to IND filing acceptance for CS1001IMP4297 combination therapy: SUZHOU China Feb. 8 2019 PRNewswire CStone Pharmaceutical "CStone" and IMPACT Therapeutics Inc. "IMPACT"... https://t.co/SWYivcQzUf (https://t.co/SWYivcQzUf)
>
> — Renal Cell Carcinoma (@Renal_Bio) February 8, 2019 (https://twitter.com/Renal_Bio/status/1093708755429056512?ref_src=twsrc%5Etfw)

CStone's Chairman and CEO Dr. Frank Jiang commented: "Combination therapy is CStone's core R&D strategy. CS1001 is one of our backbone IO pipeline candidates, while IMP4297 has the potential to be the best-in-class. We are thrilled that IMPACT chose us as a strategic partner in 2018 and happy to see our collaboration moving forward. We look forward to achieving positive results in clinical studies and benefiting more Chinese patients."

TRIAL RESULTS

Data from Ph II Pracinostat + Azacitidine trial in 1L unfit AML patients published (https://www.helsinn.com/news-and-events/helsinn-and-mei-pharma-announce-publication-of-phase-ii-data-for-pracinostat-in-combination-with-azacitidine-in-the-frontline-treatment-of-older-aml-patients-unfit-for-intensive-chemotherapy-in-blood-advance/)

> Pracinostat plus azacitidine in older patients with newly diagnosed acute myeloid leukemia: results of a phase 2 study #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) https://t.co/s4YjXREfgz (https://t.co/s4YjXREfgz) pic.twitter.com/ipVbBaYdSo (https://t.co/ipVbBaYdSo)
>
> — Blood Advances (@BloodAdvances) February 14, 2019 (https://twitter.com/BloodAdvances/status/1096062781474910213?ref_src=twsrc%5Etfw)

Dr. Guillermo Garcia-Manero, MD Professor, Department of Leukemia, at MD Anderson Cancer Center in Houston, Texas, US, said: "We are thrilled to be in a position to outline the encouraging results of this Phase II study in Blood Advances, as the data is highly encouraging for older patients suffering from acute myeloid leukemia, and who cannot be treated with intensive chemotherapy. We look forward to continuing with our ongoing Phase III study with pacinostat to show improvement of the pracinostat combination vs azacitidine with placebo, in this difficult-to-treat AML patients population."

Nivolumab/Ipilimumab combo demonstrates continued survival benefit at 30-month follow-up in Ph III CheckMate-214 trial (https://news.bms.com/press-release/corporatefinancial-news/opdivo-nivolumab-plus-low-dose-yervoy-ipilimumab-demonstrate-0)

> Nivolumab 3 mg/kg + ipilimumab 1 mg/kg is the first regimen approved by the European Commission as a first-line treatment for advanced renal cell carcinoma (RCC) patients. The decision was based on results from Checkmate-214 trial.#renalcancer (https://twitter.com/hashtag/renalcancer?src=hash&ref_src=twsrc%5Etfw) #nivolumab (https://twitter.com/hashtag/nivolumab?src=hash&ref_src=twsrc%5Etfw) #ipilimumab (https://twitter.com/hashtag/ipilimumab?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/TXzGLl2AgS (https://t.co/TXzGLl2AgS)
>
> — Beacon Intelligence (@BeaconIntel) January 22, 2019 (https://twitter.com/BeaconIntel/status/1087711485109981184?ref_src=twsrc%5Etfw)

"The results from this 30-month follow-up from the CheckMate -214 study are meaningful as they continue to demonstrate that in patients with advanced renal cell carcinoma, a population with considerable unmet treatment needs, there is potential for long-term survival benefits with the combination of nivolumab and ipilimumab," said CheckMate -214 investigator Nizar M. Tannir, M.D., FACP, Department of Genitourinary Medical Oncology, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center.

Neoadjuvant anti-PD-1 immunotherapy promotes a survival benefit with intratumoral and systemic immune responses in rGBM patients (https://www.statnews.com/2019/02/11/immunotherapy-brain-cancer-glioblastoma-surgery/)

> Finally a study that at least suggest survival benefit in GBM! Looking forward to the randomised study! Neoadjuvant anti-PD-1 immunotherapy promotes a survival benefit with intratumoral and systemic immune responses in recurrent glioblastoma | Nature Med https://t.co/seoFUHD3lq (https://t.co/seoFUHD3lq)
>
> — Beatrice Melin (@beatrice_melin) February 13, 2019 (https://twitter.com/beatrice_melin/status/1095551731428192256?ref_src=twsrc%5Etfw)

“It’s exciting because up to now, immunotherapies looked like they were going down the road for everything else — ‘Oh, they work in peripheral tumors, but not in the brain,’” said Dr. Frederick Lang, the chair of neurosurgery at MD Anderson Cancer Center, who was not involved in the research. “This study really infuses hope back into the field, that these checkpoint inhibitors may be effective if we use them in the correct way,” he added, referring to the type of immunotherapy used in the trial.

TRIAL STATUSES

Ph II FUZE trial of FGFR inh Debio 1347 initiated in patients with FGFR fusion+ solid tumors (https://www.debiopharm.com/debiopharm-international/press-releases/debiopharm-international-sa-initiates-fuze-a-clinical-trial-phase-ii-study-evaluating-debio-1347-in-advanced-solid-tumors-harboring-an-fgfr-fusion/)

> We initiates #FUZE (https://twitter.com/hashtag/FUZE?src=hash&ref_src=twsrc%5Etfw), a Clinical Trial Phase II study evaluating #Debio1347 (https://twitter.com/hashtag/Debio1347?src=hash&ref_src=twsrc%5Etfw) in advanced solid tumors harboring an #FGFR (https://twitter.com/hashtag/FGFR?src=hash&ref_src=twsrc%5Etfw) fusion https://t.co/2JWDqt1UrC (https://t.co/2JWDqt1UrC) pic.twitter.com/T995PlnEzB (https://t.co/T995PlnEzB)
>
> — Debiopharm (@DebiopharmNews) February 14, 2019 (https://twitter.com/DebiopharmNews/status/1096046415250444288?ref_src=twsrc%5Etfw)

“Historically, cancer therapies have been approved for use on the basis of the tumor’s location and stage of cancer. The FUZE clinical trial has been designed on the basis of a specific tumor’s genetic alteration, rather than its location. This tissue-agnostic approach could therefore benefit cancer patients with a rare genetic alteration, such as an FGFR fusion, irrespective of tumor type. We are committed to using innovative treatment approach guided by advanced technologies to meet unmet needs with the intent to improve outcomes and quality of life for cancer patients.”

First patient enrolled in Ph I/II trial of cancer-type specific immunotherapy ADXS-503 in NSCLC patients under ADXS-HOT program (https://ir.advaxis.com/press-release/advaxis-announces-enrollment-first-patient-its-phase-12-trial-adxs-hot-treatment-non)

> Advaxis Announces Enrollment of the First Patient in its Phase 12 Trial for ADXSHOT in the Treatment of NonSmall Cell Lung Cancer: Advaxis Inc.&160;NASDAQADXS a latestage biotechnology company focused on the discovery development and commercialization of... https://t.co/UNVx742heR (https://t.co/UNVx742heR)
>
> — Renal Cell Carcinoma (@Renal_Bio) February 14, 2019 (https://twitter.com/Renal_Bio/status/1096039494002761729?ref_src=twsrc%5Etfw)

“Coming on the heels of the presentation of data from our immunotherapy platform at the I/O 360 conference last week, we are excited to announce the enrollment of the first ADXS-HOT patient in our Phase 1/2 trial evaluating ADXS-503 for the treatment of NSCLC. The data presented at I/O 360 suggest that our neoantigen-directed constructs from both our ADXS-NEO and ADXS-HOT programs have the potential to demonstrate best-in-class CD+8 T cell response for neoantigen therapies,” said Kenneth A. Berlin, President and Chief Executive

Officer of Advaxis. He continued, “We believe our ADXS-HOT drug constructs have significant advantages compared to certain other neoantigen-focused therapies in development as our ADXS-HOT drug constructs are off-the-shelf and immediately available to administer to the patient and have a favorable cost to manufacture.” He concluded, “The ADXS-HOT program supports our goal of leveraging the significant experience we have gained from our proprietary platform in order to advance programs in the fight against cancer for patients in need of new therapeutic options and we look forward to studying these constructs in the clinic.”

Three pivotal Ph III trials of Pembrolizumab + Olaparib/Decetaxel + Prednisone/Enzalutamide to be initiated in mCRPC patients with OS as a co-primary endpoint after promising Ph Ib/II KEYNOTE-365 data (https://www.mrknewsroom.com/news-release/oncology/merck-increases-focus-advanced-prostate-cancer-expanding-immuno-oncology-progr)

> @ASCO (https://twitter.com/ASCO?ref_src=twsrc%5Etfw) #GU19 (https://twitter.com/hashtag/GU19?src=hash&ref_src=twsrc%5Etfw) presented by Evan Yu:KEYNOTE 365 Cohort A Pembrolizumab Plus Olaparib Treatment for Docetaxel-Pretreated mCRPC Patients
> coverage by: @TheRealJasonZhu (https://twitter.com/TheRealJasonZhu?ref_src=twsrc%5Etfw)https://t.co/519gk9jV59 (https://t.co/519gk9jV59) pic.twitter.com/2frmPezDbE (https://t.co/2frmPezDbE)
>
> — UroToday.com (@urotoday) February 16, 2019 (https://twitter.com/urotoday/status/1096763684272201730?ref_src=twsrc%5Etfw)

“At the core of our research program is a commitment to investigate the potential of KEYTRUDA – both as combination and monotherapy – to serve as a foundational treatment, especially for cancers where additional therapies are needed,” said Dr. Roy Baynes, senior vice president, head of global clinical development, and chief medical officer, Merck Research Laboratories. “These promising data presented at ASCO GU coupled with the significant unmet medical need in patients with metastatic castration-resistant prostate cancer, propelled us to initiate three new Phase 3 trials to further evaluate these KEYTRUDA combination regimens.”

Updates on development of galinpepimut-S (GPS) and nelipepimut-S (NPS) announced (https://www.sellaslifesciences.com/investors/news/News-Details/2019/SELLAS-Life-Sciences-Provides-Galinpepimut-S-and-Nelipepimut-S-Program-Update/default.aspx)

> SELLAS Life Sciences Provides GalinpepimutS and NelipepimutS Program Update: Dr. Richard Maziarz and Dr. Roisin O’Cearbhaill Named CoPrincipal Investigators for GalinpepimutS GPS Pembrolizumab Phase 12 Basket Trial Immune Response Data from the Phase 2b... https://t.co/DMY2QdSymK (https://t.co/DMY2QdSymK)
>
> — Bioscience (@BioscienceBio) February 12, 2019 (https://twitter.com/BioscienceBio/status/1095331579235168258?ref_src=twsrc%5Etfw)

“We are thrilled to announce that Drs. Maziarz and O’Cearbhaill will serve as co-principal investigators of this important study,” said Dr. Angelos M. Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “Both Rich and Roisin will be indispensable in overseeing the scientific rigor of the investigation, helping to interpret both clinical and correlative immuno-response data, and guiding us to optimally advance the development of GPS as a uniquely positioned active immunizer of the peptide vaccine type for the treatment of recalcitrant malignancies in the presence of measurable disease.”

Ph I/II trial of TLR3 agonist rintatolimod + Pembrolizumab started in recurrent ovarian cancer patients (http://ir.hemispherx.net/profiles/investor/ResLibraryView.asp?ResLibraryID=89674&BzID=2265&g=980&Nav=0&LangID=1&s=0)

> Hemispherx Biopharma $HEB (https://twitter.com/search?q=%24HEB&src=ctag&ref_src=twsrc%5Etfw) Announces Commencement of a New 45 Subject Clinical Trial Combining Ampligen and Merck's Keytruda in the Treatment of Recurrent Ovarian Cancer https://t.co/WnN5gvdu4b (https://t.co/WnN5gvdu4b) pic.twitter.com/VKj1BJblQY (https://t.co/VKj1BJblQY)
>
> — Mike Elliott (@mikeelliott) February 12, 2019 (https://twitter.com/mikeelliott/status/1095332046677987328?ref_src=twsrc%5Etfw)

"At Hemispherx we are determined to pursue a comprehensive R&D program focused on improved immune therapies for lethal malignancies such as recurrent ovarian cancer. We at Hemispherx are deeply grateful for the attention and support we are getting from Merck and the world-class ovarian cancer team at UPMC in this important major clinical trial," said Hemispherx CEO Thomas K. Equels. "We believe this clinical study at UPMC is an important step in Hemispherx' overall clinical plan in immuno-oncology and just one of the major milestones we have recently announced. We believe that the clinical trials that are now underway are very important to our company. We have seen a clear synergistic effect in our animal laboratory studies in several different solid tumors. Data from human tumor explants indicate this phenomenon may extend to humans. In addition to the already existing large IV safety profile, we have established that Ampligen is generally well tolerated intraperitoneally. To the extent this follows through in vivo with humans in these clinical trials, we believe the expected synergy with the checkpoint inhibitors in humans has the potential to position Ampligen as a medical translational breakthrough in immuno-oncology. We believe the Ampligen clinical data are important first and foremost to those in need of such enhanced immuno-therapeutic response in recurrent cancers as well as a long-term driver for stockholder value."

Devimistat (CPI-613) to be explored in a new combination for T-Cell Lymphoma treatment (http://www.globenewswire.com/news-release/2019/02/07/1712195/0/en/Devimistat-CPI-613-to-be-Explored-in-a-New-Combination-for-T-Cell-Lymphoma-Treatment-as-Part-of-Stand-Up-To-Cancer-s-T-Cell-Lymphoma-Dream-Team-Research-Grant.html)

> T-cell Lymphoma 'Dream Team' to Study Devimistat Combo Therapy https://t.co/qQPOZKatBo (https://t.co/qQPOZKatBo)#lymphoma (https://twitter.com/hashtag/lymphoma?src=hash&ref_src=twsrc%5Etfw) #CancerResearch (https://twitter.com/hashtag/CancerResearch?src=hash&ref_src=twsrc%5Etfw) 4x #cancersurvivor (https://twitter.com/hashtag/cancersurvivor?src=hash&ref_src=twsrc%5Etfw)
>
> — Ryan HamNer (@ryanhamner) February 14, 2019 (https://twitter.com/ryanhamner/status/1096051444095045633?ref_src=twsrc%5Etfw)

According to Dr. Zanetta Lamar, a lymphoma specialist and an investigator on the grant, "We must develop better treatments for those with T-Cell Lymphomas. Although treatments are available, many patients who achieve remission will, unfortunately, experience a relapse. In addition, there is no consensus treatment for patients with

this recurrent and difficult to treat disease." She added that this new combination therapy of devimistat is a unique way to treat cancer and does not have some of the common chemotherapeutic side effects such as hair loss.

Ph I trial of multi TKI, XL092, to be initiated in patients with advanced solid tumors (http://ir.exelixis.com/phoenix.zhtml?c=120923&p=irol-newsArticle&ID=2387164)

> Exelixis to Initiate Phase 1 Clinical Development of XL092, First New Compound to Enter the Clinic from Reinitiated Discovery Efforts https://t.co/wjHjz8ujEj (https://t.co/wjHjz8ujEj) pic.twitter.com/x16vZvw6Xl (https://t.co/x16vZvw6Xl)
>
> — Stocks News Feed (@feed_stocks) February 13, 2019 (https://twitter.com/feed_stocks/status/1095486855456251904?ref_src=twsrc%5Etfw)

"Exelixis is building a pipeline of diverse investigational medicines behind cabozantinib through in-house drug discovery activities and targeted in-licensing," said Peter Lamb, Ph.D., Executive Vice President of Scientific Strategy and Chief Scientific Officer of Exelixis. "XL092 is a novel compound that targets key signal transduction pathways in tumors, while potentially addressing tumor-induced immune suppression. Data from the upcoming phase 1 clinical trial will be used to determine the potential for further development of XL092."

First patient dosed in Ph I trial of CD19-targeting ADC, ADCT-402 (loncastuximab tesirine) and Durvalumab in DLBCL, MCL or FL (https://adctherapeutics.com/)

> Trial available now at Sylvester. Physician in chief @CraigMoskMD (https://twitter.com/CraigMoskMD?ref_src=twsrc%5Etfw) is investigator: First Patient Dosed In Phase I Clinical Trial Of ADCT-402 (Loncastuximab Tesirine) And IMFINZI® (Durvalumab) In Multiple Types Of Advanced Non-Hodgkin #Lymphoma (https://twitter.com/hashtag/Lymphoma?src=hash&ref_src=twsrc%5Etfw) #LymSM (https://twitter.com/hashtag/LymSM?src=hash&ref_src=twsrc%5Etfw) https://t.co/ha8jJpqr67 (https://t.co/ha8jJpqr67)
>
> — Sylvester Cancer (@SylvesterCancer) February 14, 2019 (https://twitter.com/SylvesterCancer/status/1096132159205720064?ref_src=twsrc%5Etfw)

Jay Feingold, MD, PhD, Chief Medical Officer and Senior Vice President of Clinical Development at ADC Therapeutics, said, "Data from our 183-patient first-in-human clinical trial of ADCT-402, which were presented at the 60th American Society of Hematology (ASH) Annual Meeting, demonstrated its acceptable safety profile and promising anti-tumor activity as a single agent in patients with relapsed or refractory B-cell non-Hodgkin lymphomas. We are now excited to explore the possible impact of ADCT-402 plus durvalumab in patient populations that would greatly benefit from new treatment options."

Patient enrollment completed in Ph I trial of controlled IL-12 monotherapy Ad-RTS-hIL-12 plus veledimex in rGBM patients (https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-completes-enrollment-controlled-il-12)

.@Regeneron (https://twitter.com/Regeneron?ref_src=twsrc%5Etfw) to provide Libtayo to @ziopharm (https://twitter.com/ziopharm?ref_src=twsrc%5Etfw) for Ph2 #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) vs recurrent glioblastoma in H1 2019

Anti-PD-1 to be combined w/ #GeneTherapy (https://twitter.com/hashtag/GeneTherapy?src=hash&ref_src=twsrc%5Etfw) lead Ad-RTS-hIL-12 + veledimex https://t.co/Hxf8AiS4lG (https://t.co/Hxf8AiS4lG)#oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #biopharma (https://twitter.com/hashtag/biopharma?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/tCQd5PECPb (https://t.co/tCQd5PECPb)

— DDNews Online (@DDNewsOnline) November 12, 2018 (https://twitter.com/DDNewsOnline/status/1062072329440739328?ref_src=twsrc%5Etfw)

"Glioblastoma is a difficult-to-treat brain cancer, with very few therapeutic options at recurrence and there is a significant need to develop new treatment options," said Rimas Lukas, M.D., associate professor of Neurology at Feinberg School of Medicine, Northwestern University. "This investigational therapy designed to stimulate and control expression of interleukin 12, a very powerful immuno-stimulant, has shown promise in treating brain cancer, especially when minimizing the use of immune-suppressive steroids. This substudy accrued quite rapidly, and we look forward to the results from treating these additional patients with rGBM."

First patient dosed in Ph I trial of STING pathway inhibitor ADU-S100 (MIW815) + ipilimumab in R/R melanoma patients (http://investors.aduro.com/phoenix.zhtml?c=242043&p=irol-newsArticle&ID=2386898)

. @LillyPad (https://twitter.com/LillyPad?ref_src=twsrc%5Etfw), Aduro Biotech ($ADRO) to Develop STING Pathway Inhibitors for Autoimmune Diseases: https://t.co/HWWj1bm2no (https://t.co/HWWj1bm2no) pic.twitter.com/pWX7fdJuwj (https://t.co/pWX7fdJuwj)

— GEN (@GENbio) December 19, 2018 (https://twitter.com/GENbio/status/1075416181849382912?ref_src=twsrc%5Etfw)

"We are pleased to initiate this study evaluating ADU-S100 with ipilimumab in a homogeneous patient population. Despite recent advancements in treating earlier stages of melanoma, the relapsed and refractory patient segment remains underserved due to a lack of therapeutic options. Based on their potential synergistic activity, ADU-S100 in combination with an anti-CTLA-4 antibody could generate a systemic adaptive immune response in patients with late-stage melanoma," commented Stephen Isaacs, chairman, president and chief executive officer of Aduro Biotech. "As demonstrated leaders in the STING pathway, we are committed to build upon the growing body of data we've generated thus far, including encouraging clinical signals demonstrated by ADU-S100 as a single agent and in combination with spartalizumab, an investigational anti-PD-1 antibody."

First patient treated in Ph Ib/II ILIAD combination trial of dendritic cell therapy ilixadencel with Pembrolizumab/Avelumab in head and neck cancer, non-small cell lung cancer and gastric cancer (http://immunicum.se/investors/press-releases/press/?xml_id=2234280&xml_date=201902)

> Today we announced the first patient treated in the Phase Ib/II ILIAD combination trial. Click here for the full details of the announcement: https://t.co/hWBa2VkSTI (https://t.co/hWBa2VkSTI) pic.twitter.com/VXzg9WeiUV (https://t.co/VXzg9WeiUV)
>
> — Immunicum AB (@Immunicum) February 11, 2019 (https://twitter.com/Immunicum/status/1094854925853622273?ref_src=twsrc%5Etfw)

"The start of the ILIAD clinical trial is a positive and important step in the development of ilixadencel, testing its ability to prime a patient's immune system to fight the cancer. This study will give us the opportunity to further evaluate its potential as a backbone component in combination therapies to treat solid tumors, and we look forward to exploring the synergistic effects of the immune activity of ilixadencel together with CPIs," said Peter Suenaert, Chief Medical Officer at Immunicum.

COLLABORATIONS & LICENSING DEALS

Combination of Tumor Targeting Superantigen Naptumomab estafenatox and Durvalumab to be tested in Ph Ib/II trial in patients with solid tumor (https://www.activebiotech.com/en/media/pressreleases/?id=2234350&date=1549890000)

> NeoTX Therapeutics enters clinical collaboration with AstraZeneca's global biologics R&D arm, MedImmune, to evaluate naptumomab estafenatox #naptumomab (https://twitter.com/hashtag/naptumomab?src=hash&ref_src=twsrc%5Etfw) in combination with IMFINZI® #durvalumab (https://twitter.com/hashtag/durvalumab?src=hash&ref_src=twsrc%5Etfw). These studies are expected to begin in 2019.https://t.co/ALXAU0AvLb (https://t.co/ALXAU0AvLb)
>
> — Beacon Intelligence (@BeaconIntel) February 13, 2019 (https://twitter.com/BeaconIntel/status/1095623623203639296?ref_src=twsrc%5Etfw)

"We are very pleased with NeoTX's progress in the ANYARA project. The collaboration with AstraZeneca validates the project and is an important step towards start of the clinical study" says Helén Tuvesson, CEO, Active Biotech AB.

Clinigens aquires US rights to Novartis' rIL2 Aldesleukin (https://www.clinigengroup.com/news/news-container/2019/clinigen-to-acquire-us-rights-to-proleukin/)

> British pharmaceutical and services company Clinigen Group PLC has inked an agreement with Swiss peer Novartis to buy the U.S. rights to Proleukin, aldesleukin, human recombinant interleukin-2. @Clinigen (https://twitter.com/Clinigen?ref_src=twsrc%5Etfw) @Novartis (https://twitter.com/Novartis?ref_src=twsrc%5Etfw) #Proleukin (https://twitter.com/hashtag/Proleukin?src=hash&ref_src=twsrc%5Etfw) #Pharmaceutical (https://twitter.com/hashtag/Pharmaceutical?src=hash&ref_src=twsrc%5Etfw) https://t.co/DlR8UVX1pN (https://t.co/DlR8UVX1pN)
>
> — A. Ersin Bilgin (@aersinbilgin) February 14, 2019 (https://twitter.com/aersinbilgin/status/1095969843654942720?ref_src=twsrc%5Etfw)

Shaun Chilton, Group Chief Executive Officer, Clinigen, said: “This highly earnings enhancing acquisition of US rights to Proleukin is significant to the whole Group not just the Commercial Medicines division. As part of Commercial Medicines, Proleukin is an excellent fit within our oncology and infectious disease medicines as well as diversifying our wider portfolio – it will be the largest product in the portfolio in terms of current sales. The product has significant potential for revitalisation, which will provide further breadth and diversity to the portfolio and material increases in revenues.”

AbbVie and Teneobio to develop TNB-383B, a BCMA-targeting immunotherapeutic, for Multiple Myeloma (https://markets.businessinsider.com/news/stocks/abbvie-and-teneobio-announce-a-strategic-transaction-to-develop-a-new-treatment-for-multiple-myeloma-1027940891)

> #Biopharma (https://twitter.com/hashtag/Biopharma?src=hash&ref_src=twsrc%5Etfw) @abbvie (https://twitter.com/abbvie?ref_src=twsrc%5Etfw) has agreed a deal with #Teneobio (https://twitter.com/hashtag/Teneobio?src=hash&ref_src=twsrc%5Etfw) to develop a B-cell maturation antigen (#BCMA (https://twitter.com/hashtag/BCMA?src=hash&ref_src=twsrc%5Etfw))-targeting bispecific antibody for multiple #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw), a type of #bloodcancer (https://twitter.com/hashtag/bloodcancer?src=hash&ref_src=twsrc%5Etfw). AbbVie will pay $90 m upfront to develop Teneobio’s #immunotherapeutic (https://twitter.com/hashtag/immunotherapeutic?src=hash&ref_src=twsrc%5Etfw) TNB-383B. https://t.co/DVRNnUbzEe (https://t.co/DVRNnUbzEe) pic.twitter.com/iXaRWHmVFg (https://t.co/iXaRWHmVFg)
>
> — CHEManager International (@CHEManager_EU) February 16, 2019 (https://twitter.com/CHEManager_EU/status/1096678092964278277?ref_src=twsrc%5Etfw)

Roland Buelow, CEO of Teneobio, Inc. and TeneoOne, Inc. added, “We are excited to partner with AbbVie on our first clinical candidate, TNB-383B, which targets BCMA using our unique T-cell redirecting platform. Combined with AbbVie’s commitment to scientific advancement and bringing oncology products to the world-wide commercial market, we will be able to quickly progress the development of TNB-383B for patients in need.”

3SBio and Verseau to develop first-in-class class macrophage checkpoint modulators (MCMs) (https://www.prnewswire.com/news-releases/3sbio-and-verseau-establish-global-clinical-development-collaboration-for-first-in-class-immuno-oncology-therapies-300793012.html)

> 3SBio and Verseau Partners in Immuno-Oncology Field – https://t.co/LqawNPhNig (https://t.co/LqawNPhNig) pic.twitter.com/cuviO0jKXS (https://t.co/cuviO0jKXS)
>
> — GMPnews.Net (@GMPnewsNet) February 12, 2019 (https://twitter.com/GMPnewsNet/status/1095323937301504000?ref_src=twsrc%5Etfw)

“Recent advances in immuno-oncology have produced unprecedented benefit to patients; however, many people with cancer still require more effective treatment options,” said Dr. Jing Lou, Chief Executive Officer of 3SBio. “Our collaboration with Verseau provides 3SBio with access to novel and differentiated immune-modulating antibodies that will complement our growing innovative oncology portfolio. We look forward to partnering with the Verseau team.”

Bayer exercised option to obtain full licensing rights for larotrectinib and BAY 2731954 (LOXO-195) (https://media.bayer.com/baynews/baynews.nsf/id/Bayer-exercised-option-to-obtain-full-licensing-rights-for-larotrectinib-and-BAY-2731954-LOXO-195?OpenDocument&sessionID=1550249287)

> Bayer to obtain full rights to global development and commercialization of oncology compounds Vitrakvi® (larotrectinib) and BAY 2731954 (LOXO-195) https://t.co/FvvhJ65LLn (https://t.co/FvvhJ65LLn)
>
> — Miles Collier (@MilesCollier) February 17, 2019 (https://twitter.com/MilesCollier/status/1097077448376836096?ref_src=twsrc%5Etfw)

"Bayer is dedicated to improving the lives of cancer patients, and precision oncology is a promising area that has the potential to redefine the way cancer patients are treated. Our partnership with Loxo Oncology was an important milestone and with the opportunity to exercise our option on larotrectinib and BAY 2731954, we are taking the next step in our efforts to advance the future of cancer care and strengthen our leadership in this field," said Robert LaCaze, Member of the Executive Committee of Bayer's Pharmaceuticals Division and Head of the Oncology Strategic Business Unit at Bayer. "With the first-ever approved TRK inhibitor, larotrectinib, and BAY 2731954 progressing through clinical development, we have two very promising compounds in our precision oncology portfolio and we are committed to expanding this portfolio by bringing forward highly differentiated and promising additional projects."

CONFERENCE COVERAGE: ASCO GU 2019

> Not able to join us in #SanFrancisco (https://twitter.com/hashtag/SanFrancisco?src=hash&ref_src=twsrc%5Etfw) at @ASCO (https://twitter.com/ASCO?ref_src=twsrc%5Etfw) #GU19 (https://twitter.com/hashtag/GU19?src=hash&ref_src=twsrc%5Etfw) , or just need to catch up on : we have you covered w/ written coverage coverage! click the link below, we will be updating all #ascogu2019 (https://twitter.com/hashtag/ascogu2019?src=hash&ref_src=twsrc%5Etfw) long!! @zklaassen_md (https://twitter.com/zklaassen_md?ref_src=twsrc%5Etfw) @tchandra_uromd (https://twitter.com/tchandra_uromd?ref_src=twsrc%5Etfw) @GoldbergHanan (https://twitter.com/GoldbergHanan?ref_src=twsrc%5Etfw) @FCUroOnc (https://twitter.com/FCUroOnc?ref_src=twsrc%5Etfw) https://t.co/SAPSBpnjoh (https://t.co/SAPSBpnjoh) pic.twitter.com/Zqs7OnkodJ (https://t.co/Zqs7OnkodJ)
>
> — UroToday.com (@urotoday) February 14, 2019 (https://twitter.com/urotoday/status/1096180507480608769?ref_src=twsrc%5Etfw)

1. Statistically significant improvement in MFS observed in Ph III ARAMIS trial of ARi Darolutamide in nmCRPC patients; mOS not reached (https://www.bayer.us/en/newsroom/press-releases/article/?id=123278)
2. Nivolumab + Ipilimumab show response in pre-treated mCRPC patients in Ph II CheckMate-650 trial (https://news.bms.com/press-release/corporatefinancial-news/opdivo-nivolumab-plus-yervoy-ipilimumab-shows-response-pre-tre)
3. Promising response rates observed in interim analysis of Ph II GALAHAD trial of Niraparib in mCRPC patients with DRD (https://www.janssen.com/janssen-announces-preliminary-results-phase-2-galahad-study-adults-metastatic-castration-resistant)
4. Encouraging SM-88 results observed without typical hormone-related AEs in Ph II trial of patients with

biomarker recurrent Prostate Cancer (https://www.tymeinc.com/investors/news-releases/press-release-details/2019/TYME-Reports-Encouraging-SM-88-Clinical-Results-without-Typical-Hormone-Related-Side-Effects-in-Phase-II-Study-of-Patients-with-Biomarker-Recurrent-Prostate-Cancer/default.aspx)

5. Safety lead-in data presented from Ph II trial of PLK1 inh Onvansertib + abiraterone acetate/prednisone in mCRPC patients (http://trovageneoncology.investorroom.com/2019-02-14-Trovagene-Presents-Update-on-Phase-2-Study-of-Onvansertib-in-Combination-with-Zytiga-in-Patients-with-mCRPC-at-ASCO-GU-Conference)
6. Trial design of Ph Ib/II trial of tubulin inhibitor VERU-111 in mCRPC patients presented (https://verupharma.com/investors/press-releases/press-release/?releaseid=2387077)
7. Data from Ph I/II PIVOT-02 trial of CD122-biased agonist NKTR-214 + nivolumab in 1L advanced/metastatic urothelial carcinoma patients presented (https://ir.nektar.com/news-releases/news-release-details/nektar-therapeutics-webcast-conference-call-urothelial-cancer)
8. Immunomedics presented trial design of Ph II TROPHY U-01 and longer follow-up data on TRPO2-targeting SN38 ADC sacituzumab govitecan in mUC patients from Ph I/II trial (https://www.immunomedics.com/our-company/news-and-events/immunomedics-announces-oral-presentation-at-the-2019-genitourinary-cancers-symposium/)
9. Merck highlighted clinical updates from KEYNOTE-199, -365, -057, -0426, -427 and PROPEL trials (https://www.mrknewsroom.com/news-release/oncology/merck-highlights-breadth-immuno-oncology-research-program-genitourinary-cancer)
10. Data from Ph II CALYPSO trial of c-MET inh Savolitinib + Durvalumab in papillary RCC patients presented (https://www.chi-med.com/calypso-pres-at-2019-asco-gu-sym/)
11. LuPSMA treatment provides high response rates in mCRPC patients (https://www.asco.org/about-asco/press-center/news-releases/phase-ii-trial-shows-novel-radiolabeled-psma-targeted)
12. Pembrolizumab + Axitinib extended OS and PFS in 1L RCC patients in Ph III KEYNOTE-426 trial (https://www.asco.org/about-asco/press-center/news-releases/pembrolizumab-plus-axitinib-extended-overall-survival-and)
13. Ph III ARCHES trial shows enzalutamide significantly improved radiographic PFS in mCSPC patients (https://newsroom.astellas.us/2019-02-11-Phase-3-ARCHES-Trial-Shows-XTANDI-R-enzalutamide-Significantly-Improved-Radiographic-Progression-Free-Survival-in-Men-with-Metastatic-Hormone-Sensitive-Prostate-Cancer)
14. Results from Ph II trial of FGFR3 inh Vofatamab in FGFR3 mutation positive patients with locally advanced or metastatic bladder cancer presented (https://www.rainierrx.com/wp-content/uploads/2019/02/Final-2.15.19-ASCO_GU-data-Release-Rainier.pdf)

OTW Trivia

WOO Trials

Q: What are Window of opportunity (WOO) trials?

A: Window of opportunity (WOO) studies are the ones, in which treatment-naïve patients are briefly exposed to therapy to observe tumor biology.

Q: What is the objective of WOO trials?

A: WOO trials are being positioned as a strategy to identify biomarkers. WOO trials also allow for assessment of different therapies combined with, or instead of, standard of care treatments that are crucial to understand the pharmacodyamics of new therapies and classify biomarkers.

Q: How to WOO trials help?

A: Appropriate biomarker selection can be the tool to identify which subgroup of patients should be included in later stage testing and ultimately treated with targeted agents to avoid a cost-intensive approach. WOO studies allow assessment of changes in a known target following exposure to brief therapy, this enabling more efficient application of this knowledge of the main drug target.

(Source: https://www.ncbi.nlm.nih.gov/pubmed/30301582 (https://www.ncbi.nlm.nih.gov/pubmed/30301582))

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 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: Single screenshot of "A time-lapse series using digital holographic microscopy presented as a movie. The movie shows living human prostate cancer cells (DU 145) induced to undergo of apoptosis following treatment with etoposide. The images were created by Phase Holographic Imaging AB (PHIAB), Lund, Sweden." Source (http://cellimagelibrary.org/images/43705)

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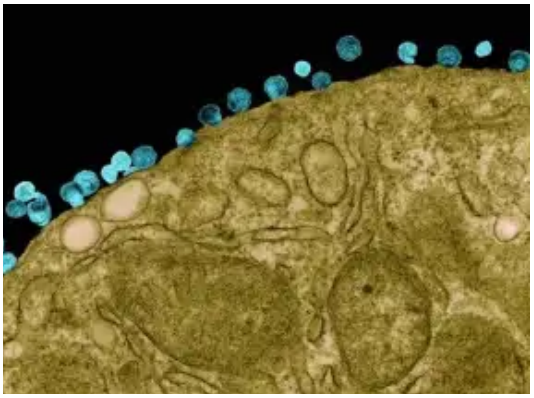

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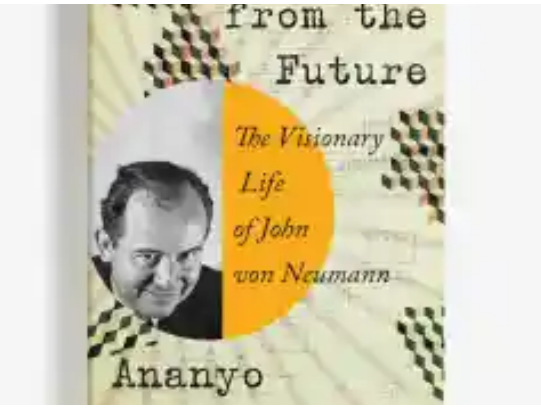

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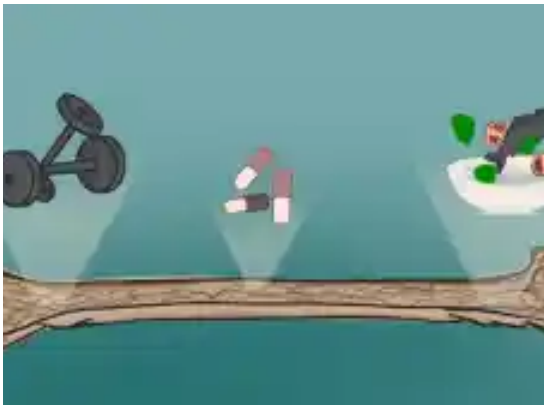

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