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Onco-this-Week

September 15, 2018(https://sciwri.club/archives/date/2018/09/15)

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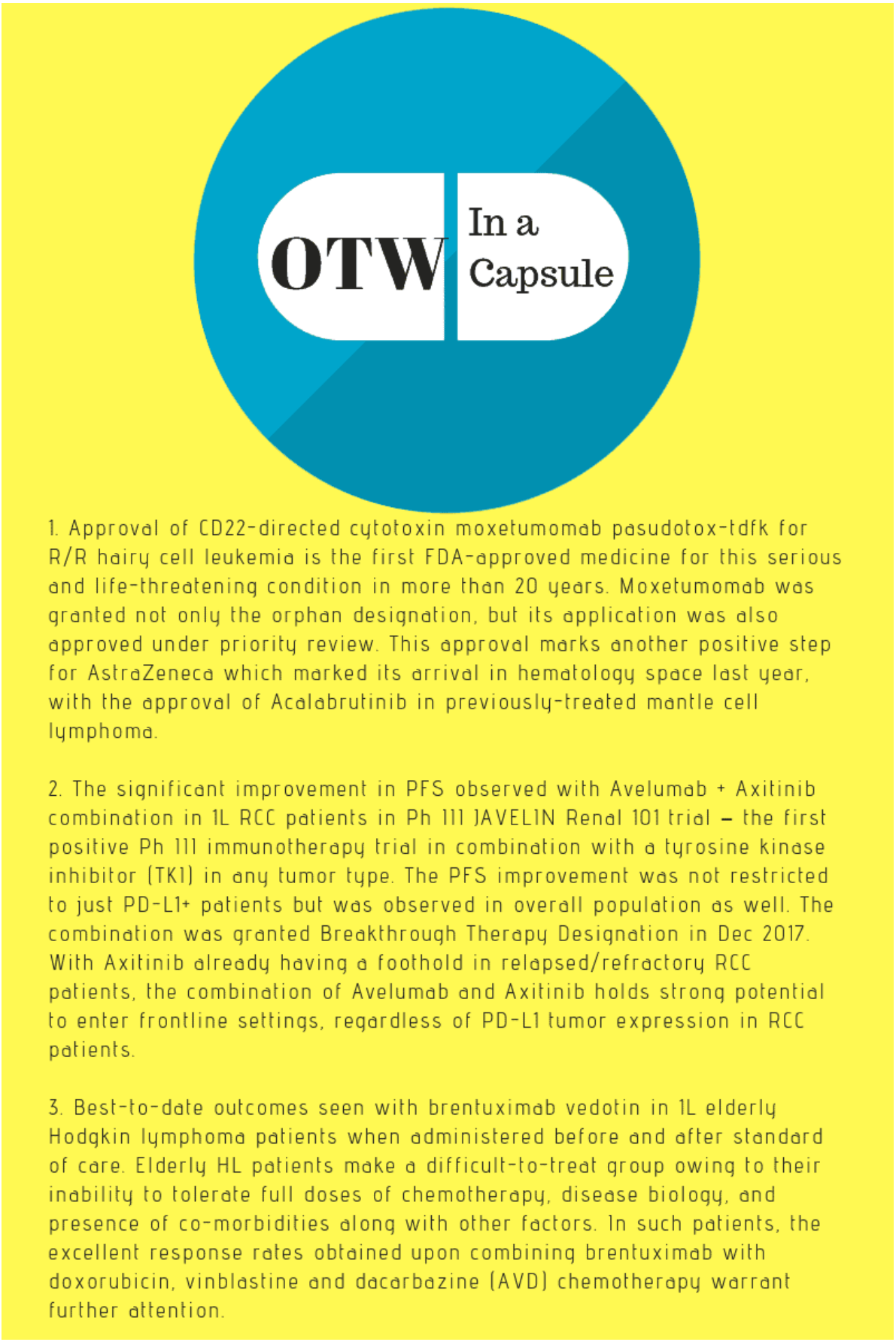
We are back with Richa Tewari's Onco-this-Week (OTW), who has added a special news analysis section OTW-In a Capsule for a quick view of the highlights of this week! In this edition, check out the news about the bacterial toxin-based drug, moxetumomab, which was discovered by NCI researchers, and has been FDA-approved for hairy cell leukemia. Also making headlines is Keytruda with a Chemotherapy Combo is now approved for 1st-Line Treatment for Advanced NSCLC in EU. In the clinical trial updates, read up about a randomized phase II study of

anti-PD-1 antibody (pembrolizumab) alone versus anti-PD1 antibody plus stereotactic body radiation therapy in advanced Merkel cell carcinoma. We have all this and much more for your weekly dose of Oncology news. Our regular Onco-this-Week Trivia features infographics on the stages of Melanoma. – Abhi Dey (https://www.linkedin.com/in/abhinavdey/)



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DRUG APPROVALS

FDA approves CD22-directed cytotoxin moxetumomab pasudotox-tdfk for R/R hairy cell leukemia based on Ph III Study 1053 results (https://www.astrazeneca.com/media-centre/press-releases/2018/us-fda-approves-lumoxiti-moxetumomab-pasudotox-tdfk-for-certain-patients-with-relapsed-or-refractory-hairy-cell-leukaemia.html)

Dave Fredrickson, Executive Vice-President, Global Head Oncology Business Unit, said: "Today's FDA approval of Lumoxiti represents a significant milestone for people living with hairy cell leukaemia, a rare blood cancer that can result in serious and life-threatening conditions. For patients, this approval provides the first FDA-approved medicine for this condition in more than 20 years."

> The bacterial toxin-based drug moxetumomab, which was discovered by NCI researchers, has been approved for hairy cell #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw): https://t.co/TZvcg6eoMO (https://t.co/TZvcg6eoMO) @NCIResearchCtr (https://twitter.com/NCIResearchCtr?ref_src=twsrc%5Etfw) pic.twitter.com/iJhlsbkiF5 (https://t.co/iJhlsbkiF5)
>
> — National Cancer Institute (@theNCI) September 14, 2018 (https://twitter.com/theNCI/status/1040594786477113344?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Robert J. Kreitman, MD, Senior Investigator, Head of Clinical Immunotherapy Section, Laboratory of Molecular Biology, Center for Cancer Research, National Cancer Institute, and Principal Investigator of the Phase III clinical trial, said: "While many patients with hairy cell leukaemia experience a remission with current treatments, 30% to 40% will relapse five to ten years after their first treatment.4 With subsequent treatments, durations of

response diminish and toxicities accumulate, and few approved treatment options exist. Moxetumomab pasudotox represents a promising non-chemotherapeutic agent for HCL, addressing an unmet medical need for physicians and their patients."

Pembrolizumab + chemo get EU approval in 1L non-sq. ALK WT/EGFR WT mNSCLC patients on the basis of KEYNOTE-189 data (https://www.mrknewsroom.com/news-release/oncology/european-commission-approves-mercks-keytruda-pembrolizumab-combination-pemetre)

"We are very pleased that the European Commission has approved KEYTRUDA in combination with chemotherapy based on the significant survival benefit demonstrated in the KEYNOTE-189 trial," said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. "This approval is a first in Europe and adds to the rapidly growing role of KEYTRUDA as a foundation for the treatment of lung cancer."

> New Post: Keytruda and Chemotherapy Combo Now 1st-Line Treatment for Advanced NSCLC in EU https://t.co/xar4R1C8Ux (https://t.co/xar4R1C8Ux) pic.twitter.com/rsXusp0712 (https://t.co/rsXusp0712)
>
> — Immuno-Oncology News (@immunooncnews) September 14, 2018 (https://twitter.com/immunooncnews/status/1040571049614749697?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Lung cancer is the leading cause of cancer death in Europe, and we are committed to doing everything in our power to help address it," said Frank Clyburn, president, Merck Oncology. "Today KEYTRUDA is now approved across Europe for the treatment of appropriate patients with metastatic nonsquamous non-small cell lung cancer as both a monotherapy and in combination with chemotherapy."

REGULATORY NEWS

Priority review to Pembrolizumab monotherapy in 1L PD-L1+ve NSCLC patients based on Ph III KEYNOTE-042 trial; PDUFA: Jan 11, 2019 (https://www.mrknewsroom.com/news-release/oncology/fda-grants-priority-review-mercks-application-keytruda-pembrolizumab-monothera)

"KEYTRUDA is already a foundation for the treatment of metastatic non-small cell lung cancer," said Dr. Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, Merck Research Laboratories. "We are pleased that the FDA is reviewing this sBLA and we look forward to potentially extending the monotherapy indication for KEYTRUDA to locally advanced or metastatic patients whose tumors express PD-L1, with a tumor proportion score of one percent or more."

> "Keytruda is already a foundation for the treatment of metastatic NSCLC," an expert said in response to the FDA's priority review for frontline use in patients with locally advanced or metastatic nonsquamous or squamous NSCLC. Read on https://t.co/CbsOqfK03Y (https://t.co/CbsOqfK03Y) #lcsm (https://twitter.com/hashtag/lcsm?src=hash&ref_src=twsrc%5Etfw) #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/pGQK79Qx1H (https://t.co/pGQK79Qx1H)
>
> — Targeted Oncology (@TargetedOnc) September 13, 2018 (https://twitter.com/TargetedOnc/status/1040087704694910976?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
MRD negativity data from Ph III MURANO trial added to Venetoclax's label (https://news.abbvie.com/news/minimal-residual-disease-negativity-data-measure-undetectable-disease-added-to-venclexta-venetoclax-

tablets-label.htm)

> Minimal residual disease data from the phase III MURANO trial has been added to the label for venetoclax by the FDA for its approved use in combination with rituximab for previously-treated patients with chronic lymphocytic leukemia: https://t.co/SV8ZeIYTHv (https://t.co/SV8ZeIYTHv) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/g1crIkkLly (https://t.co/g1crIkkLly)
>
> — Targeted Oncology (@TargetedOnc) September 13, 2018 (https://twitter.com/TargetedOnc/status/1040269144640372736?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"With this label expansion for VENCLEXTA, physicians now have additional information on MRD-negativity, which is becoming an increasingly important goal when caring for their previously-treated CLL patients," said Michael Severino, M.D., executive vice president, research and development, and chief scientific officer, AbbVie. "VENCLEXTA plus rituximab is the first chemotherapy-free combination for previously-treated CLL that allows patients the ability to stop treatment after approximately two years. This label expansion is another important milestone in our efforts to advance care for patients with difficult-to-treat blood cancers."

rPFS added as an alternative primary endpoint in addition to OS in Ph III VISION trial of 177Lu-PSMA-617 in mCRPC patients (http://investor.endocyte.com/news-releases/news-release-details/endocyte-announces-fda-acceptance-radiographic-progression-free)

> Endocyte Announces FDA Acceptance of Radiographic Progression Free Survival rPFS as an Alternative Primary Endpoint of the VISION Trial in Addition to Overall Survival OS: Demonstrating benefit in rPFS versus control with no detriment to OS sufficient... https://t.co/7iz3QIFMzW (https://t.co/7iz3QIFMzW)
>
> — Opthalmology News (@Opthalmol_bio) September 10, 2018 (https://twitter.com/Opthalmol_bio/status/1039127326267564033?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are very pleased with the FDA's support of the rPFS endpoint as the basis for a submission for full approval of ^{177}Lu-PSMA-617. This change provides an opportunity to obtain a full approval sooner than we previously anticipated and highlights the Agency's commitment to addressing the urgent need for a new mechanism of action to treat mCRPC," said Mike Sherman, president and CEO of Endocyte. "Under the updated protocol, we now expect the analysis of rPFS for potential full approval to occur before the end of 2019. We also retained the final, fully powered OS analysis, which is expected to occur near the end of 2020. This provides two potential paths for approval and preserves a robust OS analysis to support a potential label."

PDUFA date on Atezolizumab's sBLA in 1L mNSCLC pts extended by three months; revised date: Dec 05, 2018 (https://www.roche.com/investors/updates/inv-update-2018-09-06b.htm)

> Last week, the FDA announced that they extended the review period for atezolizumab for metastatic nonsquamous non–small cell lung cancer. What did you think of this news?https://t.co/kcTilDMBJD (https://t.co/kcTilDMBJD)#LungCancer (https://twitter.com/hashtag/LungCancer?src=hash&ref_src=twsrc%5Etfw) #nsclc (https://twitter.com/hashtag/nsclc?src=hash&ref_src=twsrc%5Etfw) #lcsm (https://twitter.com/hashtag/lcsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/ozayRr52iH (https://t.co/ozayRr52iH)
>
> — Targeted Oncology (@TargetedOnc) September 10, 2018 (https://twitter.com/TargetedOnc/status/1038970369846243329?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
The review period for Roche's sBLA for combination of TECENTRIQ® (atezolizumab) and Avastin® (bevacizumab), carboplatin and paclitaxel in frontline metastatic non-squamous non-small cell lung cancer (NSCLC) has been extended by three months. This additional time would be required to review further information in support of the sBLA. The revised PDUFA date is December 05, 2018 for TECENTRIQ + Avastin + carboplatin + paclitaxel combination, which was granted Priority Review from the FDA based on results from the Phase III IMpower150 study.

Priority review granted to Pembrolizumab in MCC on the basis of Ph II KEYNOTE-017 trial results; PDUFA: Dec 28, 2018 (https://www.mrknewsroom.com/news-release/oncology/fda-grants-priority-review-mercks-supplemental-biologics-license-application-0)

> #NCTN (https://twitter.com/hashtag/NCTN?src=hash&ref_src=twsrc%5Etfw) #MCC (https://twitter.com/hashtag/MCC?src=hash&ref_src=twsrc%5Etfw) Trial Activation: (A091605) A randomized phase II study of anti-PD-1 antibody (pembrolizumab) alone versus anti-PD1 antibody plus stereotactic body radiation therapy in advanced Merkel cell carcinoma, led by @ALLIANCE_org (https://twitter.com/ALLIANCE_org?ref_src=twsrc%5Etfw) https://t.co/Rbu9l7hmES (https://t.co/Rbu9l7hmES) pic.twitter.com/G1ijsLlyEp (https://t.co/G1ijsLlyEp)
>
> — NCI CTEP Clinical Research (@NCICTEP_ClinRes) February 5, 2018 (https://twitter.com/NCICTEP_ClinRes/status/960612274091282432?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Merkel cell carcinoma, a rare type of skin cancer, is an aggressive and fast-growing disease that has been associated with mortality rates higher than other types of skin cancer, including melanoma," said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. "KEYNOTE-017 represents the longest observation to date of patients with advanced Merkel cell carcinoma receiving anti-PD-1 therapy in the first-line setting, and demonstrated durable tumor control in these patients. We look forward to working closely with the FDA throughout the review process and to bringing KEYTRUDA to patients with Merkel cell carcinoma."

SPECIAL STATUSES

Galinpepimut-S gets orphan designation in Europe by EMA for MM patients (https://www.sellaslifesciences.com/investors/news/News-Details/2018/SELLAS-Receives-Orphan-Medicinal-Product-Designation-Approval-by-the-Committee-for-Orphan-Medicinal-Products-of-the-European-Medicines-Agency-for-Galinpepimut-S-for-the-Treatment-of-Patien)

"This OMPD endorsement by the COMP of the EMA for GPS in MM complements the orphan designation

awarded by the US FDA for this product in the same indication," said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS.

> Last night, SELLAS Life Sciences Group, Inc. announced that the @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) granted orphan drug designation to galinpepimut-S (#GPS (https://twitter.com/hashtag/GPS?src=hash&ref_src=twsrc%5Etfw)) for the treatment of multiple #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw).
>
> READ: https://t.co/zMR1PfITLG (https://t.co/zMR1PfITLG) pic.twitter.com/KFFhTCrODU (https://t.co/KFFhTCrODU)
>
> — Rare Disease Report (@RareDR) May 13, 2018 (https://twitter.com/RareDR/status/995468741013114880?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The results from our open-label Phase 2 study reinforce the potential of GPS to serve as a therapy for high-risk MM patients in the post-autotransplant maintenance setting. The innovative nature and unique mechanism of action for GPS provide a promising potential addition to the current arsenal of therapies in this indication. We continue to work closely with the FDA and EMA, as well as multiple myeloma KOLs to further advance the clinical development of GPS in this malignancy and look forward to gaining further insights on the potential therapeutic role of GPS in high-risk MM patients."

FLT3 Inhibitor Quizartinib Receives Orphan Drug Designation from Japanese MHLW for FLT3-Mutated AML (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006902.html)

"There is a critical need for new treatment options for patients with *FLT3*-ITD AML, especially given the poor prognosis associated with this subtype of AML," said Koichi Akahane, PhD, MBA, Executive Officer, Head of Oncology Function, R&D Division, Daiichi Sankyo.

> Orphan Drug Designation granted for quizartinib in Japan for the treatment of FLT3-mutated acute myeloid leukemia. https://t.co/Rth40AcRh2 (https://t.co/Rth40AcRh2) #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/dB6OYrmgh7 (https://t.co/dB6OYrmgh7)
>
> — AML Global Portal (@AGP_hematology) September 13, 2018 (https://twitter.com/AGP_hematology/status/1040369794896343046?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Following the recent U.S. FDA Breakthrough Therapy designation for quizartinib, receiving Orphan Drug designation is another important regulatory milestone that will help accelerate the development of quizartinib in Japan. We look forward to working closely with the Japan MHLW to bring quizartinib to patients as quickly as possible."

Ph II JASPER Trial of Niraparib + PD-1 inh TSR-042 in 1L NSCLC pts expanded to second stage (http://ir.tesarobio.com/news-releases/news-release-details/tesaro-announces-expansion-second-stage-jasper-trial-zejular)

"These JASPER data provide preliminary evidence that the combination of ZEJULA and an anti-PD-1 antibody could be active as a first-line treatment for patients with non-small cell lung cancer and high levels of PD-L1

expression," said Mary Lynne Hedley, Ph.D., President and COO of TESARO.

> "ZEJULA and an anti-PD-1 antibody could be 1st Line treatment for patients with NSCLC & high levels of PD-L1 expression"$TSRO (https://twitter.com/search?q=%24TSRO&src=ctag&ref_src=twsrc%5Etfw)
>
> 40's coming next pic.twitter.com/GsbWpuQAok (https://t.co/GsbWpuQAok)
>
> — S Manian (@DrSManian) September 4, 2018 (https://twitter.com/DrSManian/status/1037096677419540480?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"In the second stage of the trial, 36 additional patients will be enrolled and treated with ZEJULA in combination with TSR-042, our anti-PD-1 antibody. TSR-042 is the foundation of our lung cancer strategy, and is also being studied as a monotherapy in our GARNET trial in anti-PD-(L)1 naïve patients who have progressed on chemotherapy, and in combination with TSR-022, our anti-TIM-3 antibody, in AMBER, a study in late-line NSCLC patients that have progressed after anti-PD-(L)1 therapy. We look forward to sharing lung cancer data from both GARNET and AMBER at the Society for the Immunotherapy of Cancer (SITC) Annual Meeting in November."

Priority review to LOXO-292 for RET fusion+ PD-(L)1 progressors NSCLC pts and RET m+ MTC pts based on data from ongoing Ph I/II LIBRETTO-001 trial (https://ir.loxooncology.com/press-releases/2366070-Loxo-oncology-announces-receipt-of-breakthrough-therapy-designation-from-u.s.-food-and-drug-administration-for-loxo-292)

"We look forward to working with FDA to streamline the development of LOXO-292 in the two patient populations that have comprised the bulk of our initial clinical trial enrollment," said Josh Bilenker, M.D., chief executive officer at Loxo Oncology.

> The FDA has granted the RET inhibitor LOXO-292 a breakthrough therapy designation for the treatment of RET fusion-positive NSCLC or RET-mutant MTC: https://t.co/FlgYQpOS9r (https://t.co/FlgYQpOS9r). Also see this Review by @alexdrilon (https://twitter.com/alexdrilon?ref_src=twsrc%5Etfw) et al. on targeting RET-driven cancers: https://t.co/gHxwadOvq6 (https://t.co/gHxwadOvq6) pic.twitter.com/65lAm8ZwP4 (https://t.co/65lAm8ZwP4)
>
> — NatureRevClinOncol (@NatRevClinOncol) September 7, 2018 (https://twitter.com/NatRevClinOncol/status/1038069150046924800?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Given the many available therapies for non-small cell lung cancer and medullary thyroid cancer, we are pleased that LOXO-292 has shown encouraging data in refractory patients, and hope to demonstrate the full potential of this treatment in additional populations over time."

TRIAL RESULTS

Anti-ROR mAb Cirmtuzumab shows encouraging preliminary results in Ph I CLL trial (http://www.oncternal.com/news/oncternal-announces-publication-of-data-from-phase-1-trial-of-cirmtuzumab-in-cll-in-cell-stem-cell)

According to Dr. Choi, first author on the paper, "The patients who enrolled on the trial had leukemia that was getting worse and disrupting normal blood production or causing other symptoms. For most patients, after receiving four doses of cirmtuzumab, the disease stopped progressing, and stayed under control without needing any other treatment for approximately 8 months."

> Our researchers are testing a novel drug combination against the toughest breast cancers: https://t.co/HlAfCxKBxE (https://t.co/HlAfCxKBxE)
>
> Phase Ib clinical trial will combine standard chemotherapy with cirmtuzumab, a monoclonal antibody developed here with suppport from @CIRMnews (https://twitter.com/CIRMnews?ref_src=twsrc%5Etfw)
>
> — UC San Diego School of Medicine (@UCSDMedSchool) August 27, 2018 (https://twitter.com/UCSDMedSchool/status/1034172745792217090?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are thrilled that the results from the Phase 1 study of cirmtuzumab were published in *Cell Stem Cell*, a prestigious, peer-reviewed journal in the field," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "These important data formed the basis of our Phase 2 development program, including the Phase 1b/2 CIRLL trial that is now underway in collaboration with UC San Diego and CIRM to evaluate cirmtuzumab in combination with ibrutinib in the treatment of CLL and other B-cell malignancies. We are encouraged that cirmtuzumab may have the potential to bring deeper, more durable responses to these patients who are in urgent need of new treatment options."

HRQoL maintained with addition of Apalutamide to ADT in nmCRPC patients enrolled in Ph III SPARTAN trial (https://www.janssen.com/health-related-quality-life-maintained-addition-erleada-androgen-deprivation-therapy-patients-non)

"Prostate cancer treatment can often result in unwelcome side effects that can impact or disrupt patients' everyday lives," said Fred Saad, M.D., FRCS, Professor and Chairman of Urology, University of Montreal Hospital Center, and SPARTAN investigator and author of the study.

> Apalutamide Preserves HRQoL in Nonmetastatic CRPC https://t.co/IJf603VpqS (https://t.co/IJf603VpqS)
>
> — Amer. Urol. Assn. (@AmerUrological) September 14, 2018 (https://twitter.com/AmerUrological/status/1040691782349205504?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"As clinicians, we want to monitor and measure the impact of new treatments to see if there is an effect on patients' overall health and well-being. The fact that a treatment such as apalutamide can be added to current standard of care, prolonging metastasis-free survival without significantly impacting HRQoL, is a significant advance for patients with nmCRPC and for clinicians who treat them."

Avelumab + Axitinib significantly improved PFS in 1L RCC patients in Ph III JAVELIN Renal 101 trial (https://www.merckgroup.com/en/news/positive-phase-III-studie-bavencio-plus-inlyta-11-09-2018.html?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)

"JAVELIN Renal 101 is the first positive Phase III study combining an immune checkpoint blocker with a TKI, supporting the potential of BAVENCIO and INLYTA as a new cancer treatment approach for patients with advanced RCC," said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-Oncology, Early Development and Translational Oncology, Pfizer Global Product Development. "These positive results reinforce Pfizer's long-standing heritage in advancing standards of care for people with RCC, and we look forward to discussing these data in greater detail with health authorities."

> Combination of avelumab & axitinib is the first IO/TKI Ph III trial to meet PFS endpoint regardless of PD-L1 status https://t.co/YGt4Efmhl8 (https://t.co/YGt4Efmhl8) pic.twitter.com/JBRfUMLYfw (https://t.co/JBRfUMLYfw)
>
> — DAVA Oncology (@DAVAOnc) September 12, 2018 (https://twitter.com/DAVAOnc/status/1039882649639235584?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are encouraged by these data which illustrate the impact of BAVENCIO in combination with INLYTA as a potential first-line treatment for people with advanced RCC, a serious and life-threatening cancer," said Luciano Rossetti, M.D., Executive Vice President, Global Head of Research & Development at the Biopharma business of Merck. "They also support our firm belief in the promise of combining BAVENCIO with currently approved therapies and novel agents, a strong focus of the overall JAVELIN clinical development program."

65% CR/PR observed in HIV-associated Kaposi's sarcoma patients treated with Pembrolizumab/ Nivolumab (https://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1217)

"Despite the successful and prevalent use of antiretroviral medications to treat human immunodeficiency virus (HIV)-positive patients, about 15 percent of this population still develops Kaposi's sarcoma, which is an incurable malignancy with significant morbidity," said Natalie Galanina, MD, oncologist at Moores Cancer Center at UC San Diego Health. "Due to a paucity of novel therapeutic options for this disease in recent decades, we wanted to investigate if immune checkpoint inhibition was effective in treating this virally mediated cancer."

> The fact that PD-1 blockade antibodies have limited drug interactions makes them an appealing treatment option for patients receiving ART, according to researchers. https://t.co/sucRHfEjUc (https://t.co/sucRHfEjUc)
>
> — Randi Hernandez (@RandiMHernandez) September 12, 2018 (https://twitter.com/RandiMHernandez/status/1039872506474242048?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
1L elderly HL patients show best outcomes to date with brentuximab vedotin given before and after doxorubicin, vinblastine and dacarbazine (AVD) chemotherapy in Ph II trial (http://cinj.org/clinical-trial-shows-best-outcomes-date-older-hodgkin-lymphoma-patients)

"Historically, survival rates for older patients with Hodgkin lymphoma, typically defined as 60 years and older, have been shown to be disproportionately and markedly inferior compared with younger patients. Compounding this has been the underrepresentation of older Hodgkin lymphoma patients in clinical trials over the past several decades. In this current study, the survival rates are among the best reported compared with prior Hodgkin lymphoma studies," notes Andrew M. Evens, DO, MSc, FACP, associate director for clinical services and director of the Lymphoma Program at Rutgers Cancer Institute of New Jersey.

> "Pulmonary Toxicity Increased in Pediatric Hodgkin Lymphoma Treated With Brentuximab Vedotin" https://t.co/ZUbkiyOe9d (https://t.co/ZUbkiyOe9d)
>
> — Meagan Bryan, RN (@M_Bryan_AHC) September 13, 2018 (https://twitter.com/M_Bryan_AHC/status/1040248718350589952?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Importantly, this regimen was well tolerated, eliminating bleomycin to avoid pulmonary toxicity and with only 4 percent of patients experiencing grade 3 neuropathy, compared to 27 to 33 percent in other frontline

brentuximab vedotin studies in older patients," adds co-senior author Paul A. Hamlin, MD, medical oncologist and member of the Lymphoma Service at Memorial Sloan Kettering Cancer Center.

TTFs + SoC Chemotherapy significantly extends mOS by 6.1 months in STELLAR Ph II registration trial in Mesothelioma (https://www.novocure.com/tumor-treating-fields-plus-standard-of-care-chemotherapy-significantly-extends-median-overall-survival-by-6-1-months-in-stellar-phase-2-registration-trial-in-mesothelioma-compared-to-historical-contro/)

"The final results of the STELLAR trial demonstrate an impressive extension of median overall survival in the treatment of malignant pleural mesothelioma with no increase in systemic toxicity," said Giovanni Luca Ceresoli, MD, Head of Pulmonary Oncology at the Humanitas Gavazzeni Hospital in Bergamo, Italy, and an investigator in the STELLAR trial.

> ICYMI, $NVCR (https://twitter.com/search?q=%24NVCR&src=ctag&ref_src=twsrc%5Etfw) issued a release about final STELLAR results in #mesothelioma (https://twitter.com/hashtag/mesothelioma?src=hash&ref_src=twsrc%5Etfw) being presented at #WCLC2018 (https://twitter.com/hashtag/WCLC2018?src=hash&ref_src=twsrc%5Etfw). Primary investigator in the trial, Dr. Ceresoli discusses the need for additional treatment options for #mesothelioma (https://twitter.com/hashtag/mesothelioma?src=hash&ref_src=twsrc%5Etfw) patients. See more here: https://t.co/FBzki69RKg (https://t.co/FBzki69RKg) pic.twitter.com/AjlBWAhvpZ (https://t.co/AjlBWAhvpZ)
>
> — Novocure (@Novocure) September 11, 2018 (https://twitter.com/Novocure/status/1039561787262332930?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Mesothelioma patients face an urgent unmet need for additional therapies that improve survival. Based on these data, I believe Tumor Treating Fields represent an extremely promising therapeutic option that, if approved, should be added to standard of care chemotherapy for the treatment of malignant pleural mesothelioma."

75% ORR observed with EGFRi CK-101 in 1L EGFR+ NSCLC patients (http://ir.checkpointtx.com/Cache/1001242927.PDF?O=PDF&T=&Y=&D=&FID=1001242927&iid=4660467)

"These preliminary data demonstrate CK-101 is well-tolerated at the doses tested while also demonstrating encouraging anti-tumor activity, particularly in treatment-naïve EGFR mutation-positive lung cancer patients," said Melissa L. Johnson, M.D., Associate Director, Lung Cancer Research, Sarah Cannon Research Institute at Tennessee Oncology, PLLC, and study chair of the Phase 1/2 trial.

"The data to date demonstrate CK-101's potential to be a highly effective mutant-selective EGFR inhibitor with the potential for a differentiated safety profile," said James F. Oliviero, President and Chief Executive Officer of Checkpoint Therapeutics. "We look forward to continuing to advance CK-101 towards a pivotal Phase 3 trial next year, positioning CK-101 to potentially be only the second third-generation EGFR inhibitor to enter the market."

CR obtained with ET140202 T-cell therapy in AFP-positive mHCC patients (https://www.eurekatherapeutics.com/media/press-releases/090518/)

"We are encouraged by the safety profile and the potential efficacy of ET140202 for AFP-positive liver cancer," said Cheng Liu, Ph.D., President and Chief Executive Officer of Eureka Therapeutics.

> Eureka Therapeutics announced a proof-of-concept study of its ET140202 T cell therapy for patients with AFP-positive hepatocellular carcinoma (HCC) with positive results.
>
> Sinoway always focuses on human health, and provides you best solution. Visit us at https://t.co/xLKf7jbyjX (https://t.co/xLKf7jbyjX) pic.twitter.com/wvUs4L46Wi (https://t.co/wvUs4L46Wi)
>
> — Sinoway Industrial (@sinowaychem) September 7, 2018 (https://twitter.com/sinowaychem/status/1037951148055908352?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Combining T-cell therapy with a TCR-mimic antibody to target intracellular antigens is a novel approach and can potentially represent a powerful way to treat solid tumors, and in particular, liver cancer, an area of significant unmet medical need. The initial results represent an important milestone in T-cell therapy against solid tumors, and we intend to continue to study and rapidly advance ET140202 into Phase 1 clinical trials in the United States."

TRIAL STATUSES

First patient dosed in Ph I trial of STAT3 inhibitor WP1066 in GBM patients (https://ir.moleculin.com/press-releases/detail/98/moleculins-brain-cancer-drug-candidate-begins-patient)

"Treating the first brain tumor patient with WP1066 is the start of a very exciting and encouraging program for doctors treating the worst types of brain cancers. There has been very little progress in recent years toward improved therapies for glioblastoma and other aggressive primary or metastatic brain tumors.

> Moleculin Reports Dosing of Novel Brain Cancer Drug WP1066 in P-I trial for the treatment of Brain Tumor
> Shots:
> •The P-I trial is assessing WP1066 in 15 patients with relapsed brain tumor for 6 to 8mos, testing its safety and tolerability in patients at...https://t.co/OcHhiTJYaQ (https://t.co/OcHhiTJYaQ)
>
> — PharmaShots (@Pharmashot) September 14, 2018 (https://twitter.com/Pharmashot/status/1040566280422612992?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
WP1066 has shown extremely promising results based on animal studies where we have seen inhibition of tumor growth and improvements in survival," said Dr. Sandra Silberman, a world-renowned oncologist and Moleculin's Chief Medical Officer. "This is based on the fact that although STAT3 has long been identified as an important target for treating tumors, for years most efforts have focused on attempts to indirectly inhibit STAT3 from upstream signaling, not from within the cancer cell itself. WP1066 appears to be unique in its ability in vitro and in animal models to consistently and directly inhibit the activated form of STAT3 and produce significant anticancer effects, including tumor growth inhibition and increased life span of treated animals."

Enrollment started in second last cohort in Ph I L-DOS47 + pemetrexed + carboplatin study in NSCLC patients (http://www.helixbiopharma.com/wp-content/uploads/2018/07/201800725-HBP-Press-Release-LDOS001-Cohort5-Enrollment-FINAL.pdf)

> Helix BioPharma Corp. Initiates Enrollment of the Second Last Cohort in U.S. Combination Treatment Study of Its Lung Cancer Drug Candidate LDOS47: RICHMOND HILL Ontario Sept. 13 2018 GLOBE NEWSWIRE Helix BioPharma Corp. TSX FSE HBP “Helix” or the... https://t.co/RLm5JdUToL (https://t.co/RLm5JdUToL) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw)
>
> — Cancer News (@Cancer_bio) September 13, 2018 (https://twitter.com/Cancer_bio/status/1040211026938015744?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“The Company has made good progress in advancing this trial, the FDA approved amendment helped to accelerate dose escalation and the completion of the last two cohorts will provide additional important clinical data,” said Heman Chao, Helix’s Chief Executive Officer.

First patient enrolled in Ph I STELLAR-001 trial of anti-C5aR antibody IPH5401 + Durvalumab in solid tumors (https://www.innate-pharma.com/en/news-events/press-releases/innate-pharma-announces-enrollment-first-patient-phase-i-study-iph5401-combination-durvalumab-imfinzir-solid-tumors)

> INNATE PHARMA first patient in the Phase I study of IPH5401 in combination with durvalumab: Innate PHARMA announces enrollment of first patient in the phase i study of IPH5401 in combination with durvalumab IMFINZIÂ in solid tumors IPH5401 is a... https://t.co/mA1cXgboUU (https://t.co/mA1cXgboUU)
>
> — Antibody News (@AntibodyNews) September 12, 2018 (https://twitter.com/AntibodyNews/status/1039773304893128704?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
”We are pleased to have started the first clinical study for IPH5401,” commented Pierre Dodion, Chief Medical Officer of Innate Pharma. “Despite significant recent advances in immunotherapy, immune escape of tumor cells remains a major challenge. We believe that IPH5401 has a high potential for cancer patients in multiple indications and could play an important role in PD-1/PD-L1 combination strategies for patients who are non-responsive, have a poor response or who have stopped responding to PD-1/PD-L1 immunotherapies.”

Ph II NSCLC study of EGFR TKI Poziotinib expanded to include two new cohorts for 1L NSCLC patients with EGFR or HER2 exon 20 insertion mutations (http://investor.sppirx.com/news-releases/news-release-details/spectrum-pharmaceuticals-expands-poziotinib-clinical-trial-first)

“Given the exciting preliminary poziotinib clinical data in NSCLC patients with EGFR exon 20 mutations who have received prior systemic therapy, we are happy to extend our participation in Spectrum’s trial to explore poziotinib’s activity in the first-line setting,” said Jonathan Goldman, M.D., Associate Professor of Hematology and Oncology, Associate Director of Drug Development and Director of Clinical Trials in Thoracic Oncology at UCLA Health.

> After #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) failed to control her #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw), Deanna Brinkman found hope with a #CancerMoonshot (https://twitter.com/hashtag/CancerMoonshot?src=hash&ref_src=twsrc%5Etfw) clinical trial studying poziotinib: https://t.co/Y2N4d7tzZn (https://t.co/Y2N4d7tzZn) #LCSM (https://twitter.com/hashtag/LCSM?src=hash&ref_src=twsrc%5Etfw) #endcancer (https://twitter.com/hashtag/endcancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/4VTSCw8qod (https://t.co/4VTSCw8qod)
>
> — MD Anderson Cancer Center (@MDAndersonNews) September 14, 2018 (https://twitter.com/MDAndersonNews/status/1040706253406838784?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“Current available therapies for NSCLC patients with exon 20 insertion mutations have been shown to be minimally effective. We do not have good options for these patients as we do in other settings with actionable mutations. This clinical trial expansion is a welcome milestone for patients and physicians battling this disease.”

Ph IIa trial of LSD inhibitor, Ladademstat, in combination with Azacitidine to start in elderly AML patients not fit for intensive chemotherapy (https://www.oryzon.com/en/news/oryzon-receives-approval-start-alice-phase-iia-clinical-trial-aml-iadademstat-ory-1001)

Roger Bullock, Oryzon’s Chief Medical Officer, commented: “The approval of ALICE, the first Phase IIa clinical trial of Iadademstat (ORY-1001) in combination, is the next logical step in the clinical development of this drug. The response to cancer is on the combinations of different drugs. In preclinical studies, the combination of Iadademstat with Azacitidine has shown promising results”.

> ORYZON receives approval to start ALICE a Phase IIa clinical trial in AML with Iadademstat ORY1001: The study will be done in elderly Acute Myeloid Leukemia AML patients not eligible for intensive chemotherapyIt is the first Phase II study of Iadademstat... https://t.co/4KlbXGJ9z0 (https://t.co/4KlbXGJ9z0) pic.twitter.com/nBbt9QYRKo (https://t.co/nBbt9QYRKo)
>
> — Clinical Approvals (@ClinicalApprova) September 11, 2018 (https://twitter.com/ClinicalApprova/status/1039486992549965825?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“Iadademstat is a first-in-class, best-in-class LSD1i, a molecule with a clear potential that only now we begin to master and understand” said Carlos Buesa, president and CEO of Oryzon. “Particularly, the possibilities of combination with various epigenetic drugs and the ones from the IO arena are very interesting. This is the first of a set of trials planned with Iadademstat after regaining fully its rights in January 2018 and this ambitious clinical plan demonstrates our commitment to the development of this drug”.

Ph II basket trial to evaluate DPX-Survivac + Pembrolizumab in five solid tumors (bladder, HCC, ovarian, or NSCLC cancers as well as MSI-H+ve tumors) (http://ir.imvaccine.com/news-releases/news-release-details/imv-inc-announces-phase-2-basket-trial-collaboration-merck)

“The clinical data from our recent ASCO meeting presentation demonstrated for the first time the unique potential of DPX-Survivac to generate solid tumor regressions in ovarian cancer,” said Frederic Ors, Chief Executive Officer, IMV Inc. “We are delighted to expand our clinical program and collaboration with Merck across multiple cancer indications, and look forward to investigating the potential added benefit of combining DPX-Survivac and KEYTRUDA®.”

> IMV (NASDAQ:IMV, TSX:IMV) and Merck (NYSE:MRK) announced a collaboration to develop IMV’s lead candidate DPX-Survivac with Merck’s Keytruda for five solid tumor indications. This marks the third Phase 2 trial for both drugs. https://t.co/RgzoCoAdyh (https://t.co/RgzoCoAdyh) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #investing (https://twitter.com/hashtag/investing?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/XuR3bEsz9w (https://t.co/XuR3bEsz9w)
>
> — INN Life Science (@INN_LifeScience) September 12, 2018 (https://twitter.com/INN_LifeScience/status/1039924860221304835?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
“With this new study evaluating the combination of IMV and Merck immunotherapies, our goal is to expand the patient impact and market potential of our lead candidate across a broad range of cancers,” said Joseph Sullivan, Senior Vice President, Business Development, IMV Inc. “The Merck team has significant experience in the field,

and we are very enthusiastic about exploring this combination with them in multiple solid tumor indications."

Ph I Safety Lead-In completed and global registrational Ph III trial of Bemarituzumab in 1L advanced Gastric and Gastroesophageal Junction Cancers started (http://investor.fiveprime.com/news-releases/news-release-details/five-prime-therapeutics-completes-phase-1-safety-lead-and)

"We are very pleased to have completed the safety lead-in and move into the Phase 3 registrational portion of the bemarituzumab trial in patients with gastric cancer," said Helen Collins, M.D., Senior Vice President and Chief Medical Officer of Five Prime.

> Five Prime begins phase III portion of bemarituzumab + ... https://t.co/VoR8Ky9ble (https://t.co/VoR8Ky9ble) #FivePrime (https://twitter.com/hashtag/FivePrime?src=hash&ref_src=twsrc%5Etfw) #gastriccancer (https://twitter.com/hashtag/gastriccancer?src=hash&ref_src=twsrc%5Etfw) #bemarituzumab (https://twitter.com/hashtag/bemarituzumab?src=hash&ref_src=twsrc%5Etfw) #FIGHTtrial (https://twitter.com/hashtag/FIGHTtrial?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/KyugznYvVM (https://t.co/KyugznYvVM)
>
> — TRM Oncology (@TRMoncology) September 13, 2018 (https://twitter.com/TRMoncology/status/1040359624178905089?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Patients with advanced gastric cancer are in dire need of new treatment options. Bemarituzumab is a targeted therapy and we are using state-of-the-art diagnostic tools to help us identify patients with FGFR2b overexpression, which is associated with a worse prognosis. Bemarituzumab has demonstrated encouraging monotherapy activity as a late-line treatment for gastric cancer and we believe that combining with chemotherapy in the front-line setting should provide the greatest patient benefit."

Patient enrollment completed in randomized Ph II SHERLOC study of MM-121 (seribantumab) in HER3+ve NSCLC patients (http://investors.merrimack.com/node/11801)

"We believe the robust clinical interest we have seen in the SHERLOC study reflects the significant unmet medical need among this patient population," said J. Marc Pipas, M.D., Merrimack's Senior Medical Director and Project Leader for MM-121.

> Merrimack Completes Enrollment in Randomized Phase II SHERLOC Study of MM-121 (Seribantumab) in Non-Small Cell #LungCancer (https://twitter.com/hashtag/LungCancer?src=hash&ref_src=twsrc%5Etfw) @MerrimackPharma (https://twitter.com/MerrimackPharma?ref_src=twsrc%5Etfw) https://t.co/UVsdCxdDBs (https://t.co/UVsdCxdDBs)
>
> — Pulmonary Cell News (@pulmonary_news) September 9, 2018 (https://twitter.com/pulmonary_news/status/1038597870218342400?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"With gratitude to our team and, of course, to investigators and patients for their commitment to advancing cancer care, we are pleased to have achieved this clinical milestone and look forward to reporting the results from this event-driven study in the coming months."

First patient randomized in the gene-mediated immunotherapy (GEN-1) Ph I/II OVATION II study of 1L stage III/IV Ovarian Cancer patients (http://investor.celsion.com/news-releases/news-release-details/celsion-announces-first-patient-randomized-gene-mediated)

"In previous studies, GEN-1 was shown to be well tolerated at doses up to 79 mg/m² with meaningful, dose-dependent, pro-immune clinical activity," said Dr. Nicholas Borys, Celsion's senior vice president and chief medical officer. "The overall median progression-free survival (PFS) in the first OVATION Study recently reached 24 months among patients treated per protocol. These data compare favorably to the historical median PFS of 12 months for newly diagnosed patients with Stage III and IV ovarian cancer who undergo neoadjuvant chemotherapy followed by interval debulking surgery. We continue to follow these patients and expect to report the final median PFS in the second half of 2018. GEN-1's safety profile and evident dose response have led us to initiate this new trial at a higher dose of 100 mg/m². We believe that GEN-1 dosing before and after debulking surgery in combination with neoadjuvant chemotherapy will maximize the therapeutic effect of GEN-1. We are looking forward to ongoing data readouts as the OVATION II Study progresses."

Verastem Oncology Announces Investigator Sponsored Study of PI3K inhibitor Duvelisib + Bcl-2 inhibitor Venetoclax in R/R CLL and SLL patients (http://investor.verastem.com/phoenix.zhtml?c=250749&p=irol-newsArticle&ID=2366298)

> @VSTMOncology (https://twitter.com/VSTMOncology?ref_src=twsrc%5Etfw) Verastem Oncology Announces Investigator Sponsored Study on #Duvelisib (https://twitter.com/hashtag/Duvelisib?src=hash&ref_src=twsrc%5Etfw) in Combination with #Venetoclax (https://twitter.com/hashtag/Venetoclax?src=hash&ref_src=twsrc%5Etfw)https://t.co/D7uVDr70Nf (https://t.co/D7uVDr70Nf) pic.twitter.com/l5iG7HFIDG (https://t.co/l5iG7HFIDG)
>
> — Verastem Oncology (@VerastemOncolog) September 6, 2018 (https://twitter.com/VerastemOncolog/status/1037780700609490944?ref_src=twsrc%5Etfw)

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"Duvelisib and venetoclax target different pathways fundamental to CLL biology and have distinct mechanisms of action. We have found that CLL cells from duvelisib-treated patients are primed for apoptosis in response to treatment with agents such as venetoclax. We now have the opportunity to explore whether this combination may be an effective therapy for the treatment of patients with CLL," said Matthew Davids, MD, MMSc, Assistant Professor of Medicine, Harvard Medical School, and Associate Director, Center for Chronic Lymphocytic Leukemia, Dana-Farber Cancer Institute and the study's principal investigator. "We are excited to conduct this trial, as these new, targeted agents in development have the potential to improve patients' response through combination therapies."

Enrolment completed for pivotal Ph III OPTIMA study of thermodox, heat-activated liposomal encapsulation of doxorubicin, in HCC patients (http://investor.celsion.com/news-releases/news-release-details/celsion-announces-enrollment-completion-pivotal-phase-iii-optima)

"Completion of enrollment in the OPTIMA Study is yet another important milestone for Celsion and marks the conclusion of the execution phase in this multi-year study," said Michael H. Tardugno, Celsion's chairman, president and chief executive officer. "We believe ThermoDox® has enormous potential in combination with heat-based treatment modalities that are an increasingly important subject of research for controlling malignancy.

> Celsion Announces Enrollment Completion for Pivotal Phase III OPTIMA Study of ThermoDox® in Primary Liver Cancer https://t.co/o8Ff2BlTPH (https://t.co/o8Ff2BlTPH)
>
> — Connie Hampton (@BioRecruiter) September 13, 2018 (https://twitter.com/BioRecruiter/status/1040249781354995712?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
With over 850,000 new cases of HCC each year worldwide, we believe the addressable market opportunity for ThermoDox® is conservatively over 200,000 patients with intermediate-stage HCC. On a global basis, the incidence of HCC is growing at 5% annually. For the United States, HCC is a particular problem. Recent reports from the Center for Disease Control and Prevention indicate that rates of new liver cancer cases rose 38% from 2003 to 2012, and the death rate from liver cancer has increased 56% since 2003. We believe that ThermoDox® has the potential to be a meaningful new treatment option in HCC, with the potential to change these grim trajectories. We look forward to the study's outcome, and to continuing our efforts — in anticipation of potential success — to advance our regulatory, commercial, clinical and manufacturing strategies."

Top line results of A3AR inhibitor, Namodenoson, in Ph II HCC patients expected by year end (https://ir.canfite.com/press-releases/detail/831/top-line-results-of-the-namodenoson-phase-ii-advanced-liver-cancer-trial-expected-by-end-of-year)

> Can-Fite to Present the Anti-Fibrogenic Effects of Namodenoson at the Hepatic Fibrosis Conference of the American Association for the Study of Liver Diseases (AASLD) https://t.co/tYHarrUYta (https://t.co/tYHarrUYta) pic.twitter.com/XzoeAYCPn3 (https://t.co/XzoeAYCPn3)
>
> — Latest News from Business Wire (@NewsFromBW) September 12, 2018 (https://twitter.com/NewsFromBW/status/1039833578152976385?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Can-Fite' CEO, Dr. Pnina Fishman, commented, "We are pleased with the progress so far in our clinical trial for Namodenoson for the treatment of advanced HCC, the third leading cause of cancer deaths worldwide, and look forward to data release. We believe a major advantage of Namodenoson stems from its favorable safety profile demonstrated thus far, in which Namodenoson selectively targets diseased cells while sparing normal cells which express very low levels of the A3 receptor.

First patient dosed in Ph I trial of HER2-targeting IO drug PRS-343 + Atezolizumab in a study with advanced or metastatic HER2-positive solid tumors (https://www.pieris.com/news-and-events/press-releases/detail/600/pieris-pharmaceuticals-announces-dosing-of-first-patient-in)

"The initiation of the combination trial of PRS-343 with an anti-PD-L1 immunotherapy marks the beginning of Pieris' investigation into the potential synergistic effects of its 4-1BB-targeted therapy with PD-1/L1 blockade," said Louis Matis, M.D., Senior Vice President and Chief Development Officer of Pieris.

> $PIRS (https://twitter.com/search?q=%24PIRS&src=ctag&ref_src=twsrc%5Etfw) Pieris Pharmaceuticals Announces Dosing of First Patient in Phase I Combination Trial for PRS-343 Plus Anti-PD-L1 Immunotherapy https://t.co/eg9ipM1iP9 (https://t.co/eg9ipM1iP9)
>
> — Stock News Now (@StockNewsNow) September 4, 2018 (https://twitter.com/StockNewsNow/status/1037090043062624256?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Given evidence from multiple preclinical studies demonstrating synergistic anti-tumor activity from concurrent 4-1BB activation and PD-(L)1 pathway blockade, we believe that combination therapy with PRS-343 and atezolizumab has the potential to provide significant clinical benefit for patients. We are enthusiastic to be initiating this trial and look forward to reporting our findings from this combination study next year."

Ph II trial of Pembrolizumab planned in Prostate cancer patients (PERSEUS1, NCT03506997) based on research on biopsies revealing mismatch repair mutations in 8.1% patients (https://www.pcf.org/news/immunotherapy-could-offer-hope-for-some-men-with-aggressive-prostate-cancers/)

Study leader Professor Johann de Bono, Regius Professor of Cancer Research at The Institute of Cancer Research, London, and Consultant Oncologist at The Royal Marsden NHS Foundation Trust, said: "Our study found that some men with advanced prostate cancers have genomic mutations in their tumours that make the disease unstable, aggressive and resistant to standard therapies. These men with 'mismatch' repair mutations only live about half as long as others who also have advanced prostate cancer but whose tumours don't carry such mutations.

"We made an exciting step forward in working out how to treat men with such aggressive, unstable tumours. We discovered that tumours with mismatch repair mutations have key hallmarks which make them particularly likely to respond to checkpoint inhibitor immunotherapy. We are now developing tests that could pick out patients with these mutations, and we're running new clinical trials to see if immunotherapy can offer new hope for these men."

COLLABORATIONS

TLR9 agonist CMP-001 + PD-L1 inhibitor Avelumab combination to be tested in Ph Ib/II trial in PD-1/PD-L1-Refractory Advanced SCCHN patients (https://checkmatepharma.com/pdf/release8.pdf)

"This collaboration is an important next step in advancing our clinical development program for CMP-001 into indications beyond melanoma, where we already have demonstrated proof-of-concept," said Art Krieg, CEO of Checkmate. "Merck KGaA, Darmstadt, Germany, and Pfizer are ideal partners for Checkmate given their commitment to developing avelumab broadly in the immuno-oncology field."

Efficacy of Imprime PGG + Durvalumab to be tested in a Ph II neoadjuvant study for patients with head and neck cancer (https://www.biothera.com/biothera-pharmaceuticals-announces-immuno-oncology-clinical-trial-collaboration-with-astrazeneca/)

"We are pleased to work with AstraZeneca in hopes of addressing the high unmet clinical needs of patients with head and neck cancer," said Barry Labinger, Biothera Pharmaceuticals' President and Chief Executive Officer. "Previous clinical and pre-clinical studies demonstrated that Imprime PGG consistently repolarized the immunosuppressive tumor microenvironment and increased T cell infiltration and activation, which we believe will have a synergistic effect with durvalumab's targeting of PD-L1."

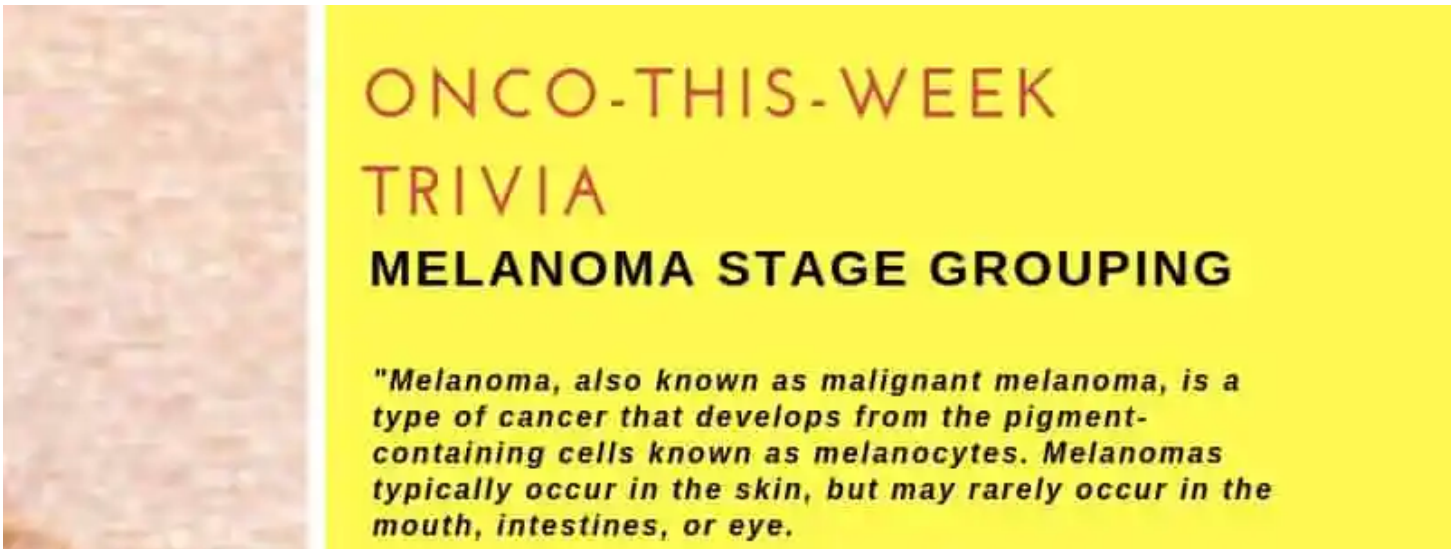

IMAGE SOURCE

Melanoma on a patient's skin. For additional resource, see the following web site:http://www.cancer.gov/cancertopics/wyntk/melanoma

In women, they most commonly occur on the legs, while in men they are most common on the back. Sometimes they develop from a mole with changes such as an increase in size, irregular edges, change in color, itchiness, or skin breakdown." *- Wikipedia*

• Stage 0: Melanoma in situ; only in the outer layer of skin or epidermis.

• Stage I: Still only in the skin. Divided into two subgroups, IA or IB, depending on the thickness of the melanoma and presence of ulceration under a microscope

• Stage II: Thicker than stage I, extending through the epidermis and further into the dermis. Slightly higher chance of spreading. Divided into 3 subgroups—A, B, or C —depending on thickness of melanoma and presence of ulceration.

• Stage III: Locally advanced or spread through the lymphatic system, as a satellite lesion near the primary tumor, to a regional lymph node located near where the cancer started, or to a skin site on the way to a lymph node (in-transit metastasis, satellite metastasis, or microsatellite disease). Divided into 4 subgroups—A, B, C, or D—depending on the size and number of lymph nodes involved with melanoma, whether the primary tumor has satellite lesions, and presence of ulceration.

• Stage IV: Metastasized to distant locations on the skin or soft tissue, distant lymph nodes, or other organs like the lung, liver, brain, bone, or gastrointestinal tract. Further evaluated based on the location of distant metastasis:
M1a: Spread only to distant skin and/or soft tissue sites
M1b: Spread to the lung.
M1c: Spread to non-CNS location
M1d: Spread to CNS

Reference:
1. https://en.wikipedia.org/wiki/Melanoma
2.https://www.cancer.net/cancer-types/melanoma/stages

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

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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: (Cell Image Library)This scanning electron micrograph shows the internal structure of liver tissue from an adult mouse. The sinusoids (vascular channels lined with endothelial cells) can be seen as pink structures running through the tissue. These contain red blood cells and Kupffer cells (specialized macrophages of the liver). Hepatocytes, shown in brown, are arranged in plates surrounding the sinusoids. Bile is secreted into the canaliculi, shown as green channels. These are dilated intercellular spaces between adjacent hepatocytes and bile flows through them en route to the small intestine.- Source (http://www.cellimagelibrary.org/images/39088)

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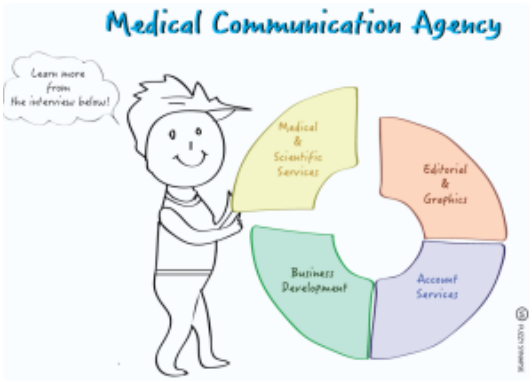

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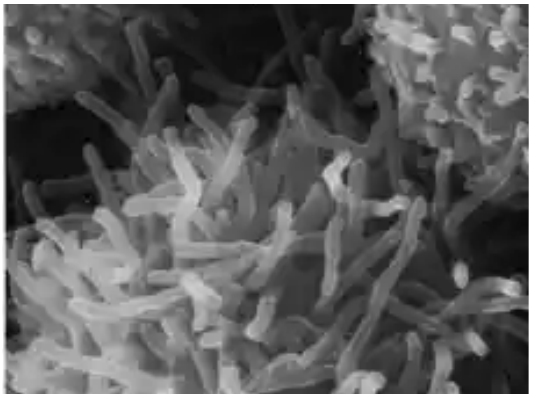

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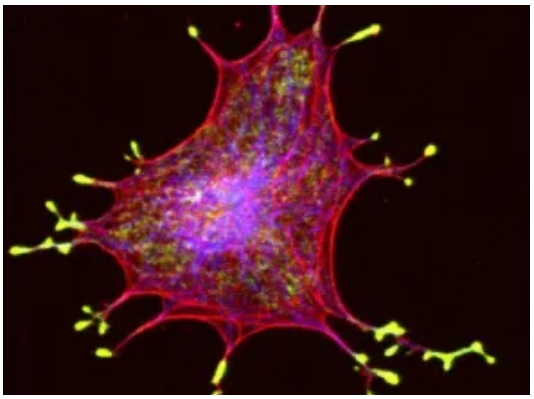

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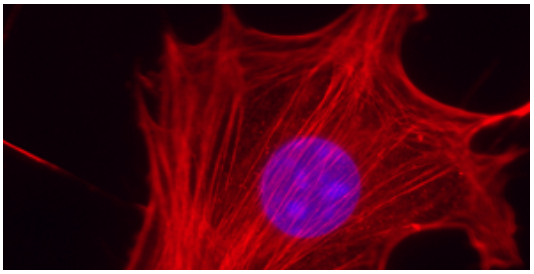

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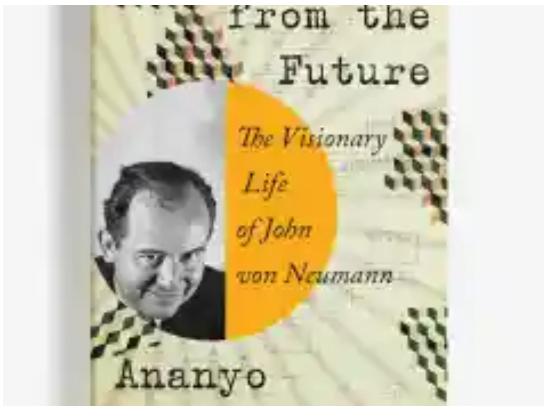

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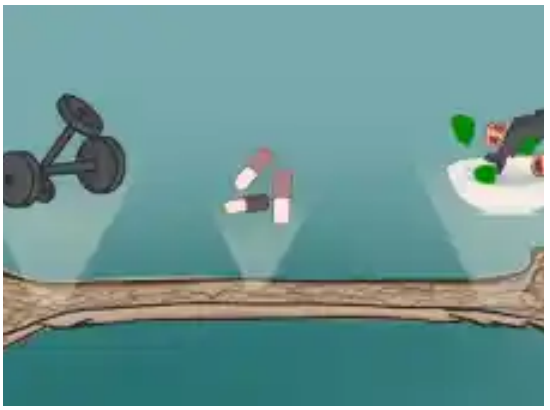

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