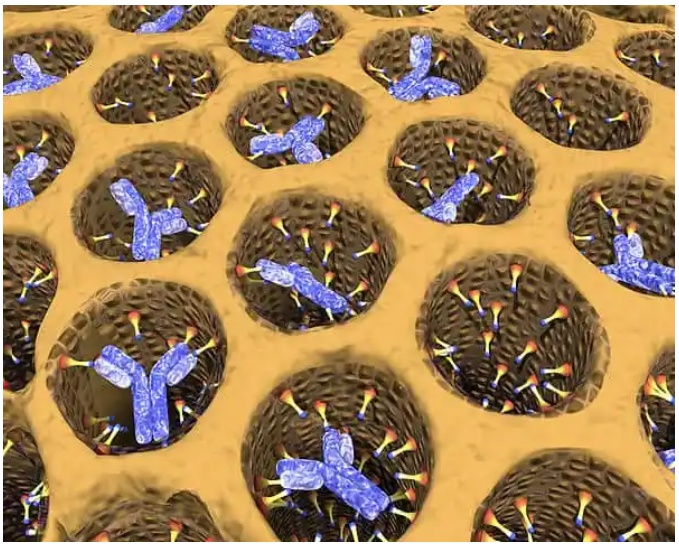
Onco-this-Week

April 1, 2018(https://sciwri.club/archives/date/2018/04/01)



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Editor's Note- In Onco-this-Week, Richa Tewari updates us about the FDA approval of Blinatumomab for Minimal Residual Disease-positive Acute Lymphoblastic Leukemia. In addition, find out which drug/combinations received FDA's Breakthrough Therapy designations and which compound caused tumor shrinkage in ovarian cancer patients. Also in this edition, we have updates about the story of a drug-candidate that is inspiring others to develop drugs for both adult and pediatric patients on the basis of tumor genetics rather than tumor site of origin. But that is not the end, we have several other updates on clinical trails in NSCLC, Endometrial Cancer, Ovarian Cancer. And if you are still trying to make sense of this avalanche of information, check out the YouTube videos that talk about the basics of the FDA approval process and the overview of the Clinical Trials process. – Abhi Dey (https://www.linkedin.com/in/abhinavdey/)

(For detailed info, click on the headline of each story to get directed to the original news source)

FDA APPROVALS

This hand drawn white board video illustrates the 5 important stages of drug approval by the FDA. Discovery and Screening, IND Application Submission, Clinical Trials, Application Review and Inspections, and Safety Monitoring.

FDA Approves Blinatumomab for MRD+ ALL (https://www.prnewswire.com/news-releases/fda-expands-approval-of-blincyto-for-treatment-of-a-type-of-leukemia-in-patients-who-have-a-certain-risk-factor-for-relapse-300621847.html)

"This is the first FDA-approved treatment for patients with MRD-positive ALL," said Richard Pazdur, M.D., director of the FDA's Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "Because patients who have MRD are more likely to relapse, having a treatment option that eliminates even very low amounts of residual leukemia cells may help keep the cancer in remission longer. We look forward to furthering our understanding about the reduction in MRD after treatment with Blincyto. Studies are being conducted to assess how Blincyto affects long-term survival outcomes in patients with MRD."

> The Food and Drug Administration expands approval of blinatumomab (Blincyto) for some adults and children with a type of leukemia https://t.co/lb2UrLIzbg (https://t.co/lb2UrLIzbg) pic.twitter.com/KN878yba6t (https://t.co/KN878yba6t)
>
> — National Cancer Inst (@theNCI) March 29, 2018 (https://twitter.com/theNCI/status/979432894006427649?ref_src=twsrc%5Etfw)

RESULTS

Before we begin, lets watch this YouTube video to understand clinical trials. This animation explains what clinical trials are, how they are conducted, and why they are important for patients with diseases like pancreatic cancer. The animation also provides an overview of study design, eligibility criteria, informed consent, safeguards, different phases of clinical trials, and the potential benefits and potential risks of participation. You can find out more about clinical trials and pancreatic cancer at: http://www.AnimatedPancreasPatient.com (https://www.youtube.com/redirect?v=bctaWQTYHJc&redir_token=e_5YP4ZfoVsqomGTtbOoIeZzUJR8MTUyMjY5Njc3NEAxNTIyNjEwMzco&event=video_description&q=http%3A%2F%2Fww

Phase III IMpower150 study meets primary endpoint of OS improvement with Atezolizumab + Bevacizumab + Chemotherapy vs. Bevacizumab + Chemotherapy in advanced NSCLC patients (https://www.roche.com/media/store/releases/med-cor-2018-03-26.htm)

"We are pleased that the IMpower150 study demonstrated a clinically meaningful survival benefit for people receiving their initial treatment for this type of advanced lung cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "These results add to the growing body of evidence

supporting the role of combining TECENTRIQ with Avastin. We will submit these additional data to global health authorities and hope to bring this potential treatment option to patients as soon as possible."

> Roche's phase III IMpower150 trial of combo atezolizumab in ... https://t.co/cqn5cIYpcf (https://t.co/cqn5cIYpcf) #Roche (https://twitter.com/hashtag/Roche?src=hash&ref_src=twsrc%5Etfw) #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) #IMpower150 (https://twitter.com/hashtag/IMpower150?src=hash&ref_src=twsrc%5Etfw) #atezolizumab (https://twitter.com/hashtag/atezolizumab?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/c6LR8UVvol (https://t.co/c6LR8UVvol)
>
> — TRM Oncology (@TRMoncology) March 29, 2018 (https://twitter.com/TRMoncology/status/979431958756380675?ref_src=twsrc%5Etfw)

Recurrent Endometrial Cancer responds to everolimus + letrozole: Responses in half of patients with no prior chemotherapy (https://sgo.confex.com/sgo/2018/meetingapp.cgi/Paper/10706)

EL is an active regimen in 24% of patients with recurrent EC. Responses in the NPC stratum suggest that EL is active in patients with chemo-naive recurrent EC. Further study of its activity in chemo-naive patients is warranted. While not statistically significant, more patients with PT had thromboembolic events.

> GOG3007 everolimus/letrozole combined therapy is an active regimen in recurrent endometrial cancer! pic.twitter.com/UF5ukUWag2 (https://t.co/UF5ukUWag2)
>
> — Gina Mantia-Smaldone (@GMantiaSmaldone) March 24, 2018 (https://twitter.com/GMantiaSmaldone/status/977536994522947584?ref_src=twsrc%5Etfw)

SGO 2018: 63% ORR observed with Mirvetuximab – Pembrolizumab combo in Ovarian Cancer patients with medium or high FRα expression levels (http://investor.immunogen.com/news-releases/news-release-details/immunogen-presents-data-forward-ii-assessment-mirvetuximab)

"We are encouraged by the early evidence of anti-tumor activity with durable responses and the tolerability profile of mirvetuximab in combination with pembrolizumab, particularly among the subset of patients with medium or high folate receptor alpha expression where we saw the greatest benefit," said Anna Berkenblit, M.D., Vice President and Chief Medical Officer of ImmunoGen. "Across multiple combinations, we've demonstrated that our Phase 3 single agent dose level for mirvetuximab combines readily with other therapies. The consistency of these findings further underscore the potential of mirvetuximab for ovarian cancer – both as monotherapy, and in combination with other therapies in earlier lines of treatment."

> What are your thoughts on the data for combo pembrolizumab and mirvetuximab soravtansine in ovarian cancer? @DrMatulonis (https://twitter.com/DrMatulonis?ref_src=twsrc%5Etfw) is excited after seeing the results from a recent trial presented at @SGO_org (https://twitter.com/SGO_org?ref_src=twsrc%5Etfw) 's Annual Meeting. #SGOMtg (https://twitter.com/hashtag/SGOMtg?src=hash&ref_src=twsrc%5Etfw) #OvarianCancer (https://twitter.com/hashtag/OvarianCancer?src=hash&ref_src=twsrc%5Etfw)
> Source: https://t.co/N7nJkeFYmK (https://t.co/N7nJkeFYmK) pic.twitter.com/j2NoVZxX2d (https://t.co/j2NoVZxX2d)
>
> — Targeted Oncology (@TargetedOnc) March 31, 2018 (https://twitter.com/TargetedOnc/status/980157928673107968?ref_src=twsrc%5Etfw)

SGO 2018: Encouraging trends observed with Niraparib + Pembrolizumab in platinum resistant/refractory Ovarian Cancer patients (http://ir.tesarobio.com/news-releases/news-release-details/data-topacio-trial-reported-sgo-demonstrates-compelling-clinical)

"Patients with platinum-resistant or platinum-refractory ovarian cancer have limited treatment options available to them. Approximately 10,000 women in each of the US and EU begin treatment for platinum-resistant or refractory ovarian cancer each year," said Mary Lynne Hedley, Ph.D., President and COO of TESARO. "Preliminary results from TOPACIO suggest the combination of niraparib and an anti-PD-1 antibody could provide meaningful clinical benefit to these patients, regardless of biomarker status. Planning of a registration study is underway to support approval of ZEJULA and TSR-042 combination therapy for these patients. TSR-042 is TESARO's anti-PD-1 antibody, which is currently in a registration study for MSI-H tumors."

"These data provide a compelling initial step in our ovarian cancer development strategy which is progressing from monotherapy ZEJULA utilized in PRIMA, NOVA and QUADRA to doublet and triplet combination approaches with anti-PD-1 antibodies and bevacizumab," said Marty Huber, M.D., Senior Vice President and Chief Medical Officer of TESARO. "Our ultimate goal is to maximize the benefit to women across the full spectrum of ovarian cancer"

> This trial indicated some durable responses with the combination of pembrolizumab and niraparib in ovarian cancer. This was presented at @SGO_org (https://twitter.com/SGO_org?ref_src=twsrc%5Etfw)'s Annual Meeting, but you can review these results here: https://t.co/YpjfF9bImJ (https://t.co/YpjfF9bImJ) #SGOMtg (https://twitter.com/hashtag/SGOMtg?src=hash&ref_src=twsrc%5Etfw) #OvarianCancer (https://twitter.com/hashtag/OvarianCancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/I7WACYtTdI (https://t.co/I7WACYtTdI)
>
> — Targeted Oncology (@TargetedOnc) April 1, 2018 (https://twitter.com/TargetedOnc/status/980248471721664512?ref_src=twsrc%5Etfw)

SGO 2018: Phase III SOLO2 trial shows significant PFS improvement with Olaparib in platinum-sensitive relapsed ovarian cancer (PSROC) patients in 3L maintenance settings (https://sgo.confex.com/sgo/2017/meetingapp.cgi/Paper/8718)

Olaparib tablet maintenance treatment in SOLO2 led to a clinically meaningful, statistically significant PFS benefit in pts with PSROC and a *BRCA*m. Key endpoints of PFS by BICR and PFS2 substantiated the efficacy benefit. Maintenance treatment with the tablet formulation of olaparib was well tolerated, with a low incidence of discontinuation due to toxicity.

SGO 2018: Phase II MEDIOLA study shows 70% ORR in relapsed Ovarian Cancer patients with Olaparib/

Durvalumab combination (http://www.onclive.com/conference-coverage/sgo-2018/olaparibdurvalumab-combo-active-in-relapsed-ovarian-cancer)

"The combination of olaparib and durvalumab was well tolerated, with a low incidence of grade 3 or higher adverse events or all-grade immune-related adverse events," Yvette Drew, MD, of Newcastle University in Newcastle-Upon-Tyne, England, reported at the 2018 Society of Gynecologic Oncology Annual Meeting.

"Preliminary efficacy results suggest strong activity in relapsed platinum-sensitive ovarian cancer, particularly in early-line patients...Baseline PD-L1 expression and tumor-infiltrating lymphocytes (TILs) did not appear to correlate with clinical outcomes," added Drew.

> Late Breaking Abstract session: Dr. Drew presents results of MEDIOLA basket trial of olaparib and durvalumab combo in relapsed BRCA+ platinum sensitive ovarian cancer #SGOmtg (https://twitter.com/hashtag/SGOmtg?src=hash&ref_src=twsrc%5Etfw) #gyncsm (https://twitter.com/hashtag/gyncsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/lycZZlxYYR (https://t.co/lycZZlxYYR)
>
> — Annie Ellis (@Stigetta) March 26, 2018 (https://twitter.com/Stigetta/status/978366705050243073?ref_src=twsrc%5Etfw)

PFS improvement observed in Phase III trial of Sorafenib in rare sarcomas (https://www.cancer.gov/news-events/press-releases/2018/sorafenib-desmoid-trial?cid=eb_govdel)

"Sorafenib is a novel way of treating this rare cancer," said lead investigator and study chair Mrinal M. Gounder, M.D., sarcoma medical oncologist at Memorial Sloan Kettering Cancer Center in New York City. "The promising results of this phase 3 trial represent a paradigm shift in the approach to treatment of patients with desmoid tumors."

> Article by Mathew Shanley @RareDR (https://twitter.com/RareDR?ref_src=twsrc%5Etfw) on promising interim results of clinical trial sponsored by @NIH (https://twitter.com/NIH?ref_src=twsrc%5Etfw) @theNCI (https://twitter.com/theNCI?ref_src=twsrc%5Etfw) treating patients with rare cancer – desmoid tumors or aggressive fibromatosis – with sorafenib https://t.co/1nq8bjqXic (https://t.co/1nq8bjqXic) @NCItreatment (https://twitter.com/NCItreatment?ref_src=twsrc%5Etfw)
>
> — NCI Media Relations (@NCIMedia) March 30, 2018 (https://twitter.com/NCIMedia/status/979716249184882688?ref_src=twsrc%5Etfw)

IKS 2018: Stable disease with tumor shrinkage reported with NK100 in Ovarian Cancer patients (http://ir.fatetherapeutics.com/news-releases/news-release-details/fate-therapeutics-announces-initial-clinical-data-fate-nk100)

"We are very encouraged by our initial clinical observations of FATE-NK100 in heavily pre-treated patients with recurrent ovarian cancer," said Melissa Geller M.D., Associate Professor of Gynecologic Oncology, Department of Obstetrics, Gynecology and Women's Health at the University of Minnesota and Principal Investigator of the APOLLO clinical trial at the Masonic Cancer Center. "Currently approved single-agent therapies for platinum-resistant ovarian cancer typically have low response rates and short median progression-free survival. The administration of NK100 directly within the peritoneal cavity is a novel therapeutic strategy to potentially improve these dismal outcomes."

> #UMNCancer (https://twitter.com/hashtag/UMNCancer?src=hash&ref_src=twsrc%5Etfw) in the news: "Fate Therapeutics Announces Initial Clinical Data of FATE-NK100 for Recurrent Ovarian Cancer at the Innate Killer Summit 2018" – Featuring the work of Melissa Geller, MD. @UMNHealth (https://twitter.com/UMNHealth?ref_src=twsrc%5Etfw) @umnmedschool (https://twitter.com/umnmedschool?ref_src=twsrc%5Etfw) https://t.co/W2pG6vZUeZ (https://t.co/W2pG6vZUeZ) pic.twitter.com/xprkWNoRWf (https://t.co/xprkWNoRWf)
>
> — MasonicCancerCenter (@UMN_Cancer) March 29, 2018 (https://twitter.com/UMN_Cancer/status/979370134832902144?ref_src=twsrc%5Etfw)

SPECIAL STATUSES

via GIPHY (https://giphy.com/gifs/ethanbarnowsky-AxVvk1fnzqHp3GGUuI)

Astellas and Seattle Genetics Receive FDA Breakthrough Therapy Designation for Enfortumab Vedotin in Locally Advanced or Metastatic Urothelial Cancer (https://newsroom.astellas.us/2018-03-26-Astellas-and-Seattle-Genetics-Receive-FDA-Breakthrough-Therapy-Designation-for-Enfortumab-Vedotin-in-Locally-Advanced-or-Metastatic-Urothelial-Cancer,1)

"The FDA Breakthrough Therapy Designation underscores the potential of enfortumab vedotin as a meaningful treatment for patients with locally advanced or metastatic urothelial cancer. Further, it supports our rapid development plans for this ADC, including the ongoing pivotal study in this patient population," said Robert Lechleider, M.D., Vice President, Clinical Development at Seattle Genetics. "Seattle Genetics is an emerging multi-product oncology company, advancing a robust pipeline with the goal of improving outcomes for cancer patients. Enfortumab vedotin is at the forefront of our late-stage clinical pipeline, and we are working closely with our partner and the FDA to bring this potential new treatment to patients as quickly as possible."

"Achieving Breakthrough Therapy Designation for enfortumab vedotin is another step forward in our goal to bring an additional treatment option to patients who need it most," said Steven Benner, M.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development at Astellas. "With the enfortumab vedotin registrational phase 2 trial and CPI-combination trial actively underway, Astellas looks forward to expanding development of enfortumab vedotin and its oncology pipeline, including treatments that would target some of the hardest-to-treat cancers."

#FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) grants breakthrough therapy designation to #enfortumab (https://twitter.com/hashtag/enfortumab?src=hash&ref_src=twsrc%5Etfw) vedotin https://t.co/m51ZjE6PLh (https://t.co/m51ZjE6PLh) via @OncologyCentral (https://twitter.com/OncologyCentral?ref_src=twsrc%5Etfw)

— Future Science OA (@fsgfso) March 28, 2018 (https://twitter.com/fsgfso/status/978904147163516928?ref_src=twsrc%5Etfw)

Priority review and Breakthrough Therapy designation to Nivolumab + Ipilimumab in MSI-H or dMMR mCRC patients; FDA action date: Jul 2018 (https://news.bms.com/press-release/bmy/us-food-and-drug-administration-fda-accepts-bristol-myers-squibbs-application-opdi)

"The FDA acceptance of this application with priority review reinforces our belief in the potential of the *Opdivo* plus *Yervoy* combination to treat patients with previously treated metastatic colorectal cancer defined by MSI-H or dMMR biomarkers, and is a result of our longstanding commitment to the exploration of I-O/I-O combinations for patient populations with high unmet need," said Ian M. Waxman, M.D., development lead, Gastrointestinal Cancers, Bristol-Myers Squibb. "We look forward to working with the FDA with the goal of bringing this combination to these colorectal cancer patients."

FDA granted priority reviewe for the combination of nivolumab plus ipilimumab for MSI-H/dMMR CRC. Read more: https://t.co/hV4KC75E2o (https://t.co/hV4KC75E2o) #ColorectalCancer (https://twitter.com/hashtag/ColorectalCancer?src=hash&ref_src=twsrc%5Etfw) #CancerResearch (https://twitter.com/hashtag/CancerResearch?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/k8i8aLtYC8 (https://t.co/k8i8aLtYC8)

— Targeted Oncology (@TargetedOnc) March 28, 2018 (https://twitter.com/TargetedOnc/status/979055628353142784?ref_src=twsrc%5Etfw)

DS-8201 receives SAKIGAKE designation for advanced HER2+ve gastric or GEJ cancer (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006829.html)

"There are no HER2-targeting treatment options currently available for patients with HER2-positive gastric cancer whose tumors are no longer controlled by trastuzumab," said Koichi Akahane, PhD, MBA, Executive Officer, Head of Oncology Function, R&D Division, Daiichi Sankyo. "We look forward to working closely with the Japan Ministry of Health, Labour and Welfare under the terms of the SAKIGAKE program to accelerate the development of DS-8201 particularly since Japan has one of the highest incidence rates of gastric cancer worldwide."

SAKIGAKE Designation for Daiichi Sankyo's DS-8201 HER2-targeting antibody drug conjugate (ADC) https://t.co/t7VMKv6WGS (https://t.co/t7VMKv6WGS) pic.twitter.com/8i4c5ngp76 (https://t.co/8i4c5ngp76)

— Pharma Business Int (@PBIForum) March 29, 2018 (https://twitter.com/PBIForum/status/979327944584716288?ref_src=twsrc%5Etfw)

REGULATORY NEWS

via GIPHY (https://giphy.com/gifs/street-KUW9EwVKezia4)

PDUFA extension for radiotherapeutic norepinephrine reuptake transporter substrate, iobenguane I 131, in rare NETs (http://ir.progenics.com/news-releases/news-release-details/progenics-pharmaceuticals-announces-three-month-extension-pdufa)

"We remain confident in our NDA submission and are committed to bringing AZEDRA forward as an option for patients with malignant pheo and para," said Mark Baker, Chief Executive Officer of Progenics. "We look forward to continuing our dialogue with the Agency as we prepare for a potential approval of AZEDRA."

$PGNX (https://twitter.com/search?q=%24PGNX&src=ctag&ref_src=twsrc%5Etfw) – Progenics Pharmaceuticals Announces Three-Month Extension of PDUFA Date for AZEDRA® (iobenguane I 131) https://t.co/nhOIlDyGco (https://t.co/nhOIlDyGco)

— TT300z (@tt300z) March 22, 2018 (https://twitter.com/tt300z/status/976916206333677571?ref_src=twsrc%5Etfw)

Loxo completes rolling NDA submission for Larotectinib in NTRK+ve solid tumors (https://ir.loxooncology.com/press-releases/loxo-oncology-completes-rolling-submission-of-new-drug-application-to-u.s.-food-and-drug-administration-for-larotrectinib-for-the-treatment-of-trk-fusion-cancer)

"We are grateful to the many patients who participated in our clinical trials in the spirit of helping others with advanced cancer," said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. "We hope that the larotrectinib development program inspires others to develop drugs for both adult and pediatric patients on the basis of tumor genetics rather than tumor site of origin."

Loxo Oncology completes rolling submission of new drug application for larotrectinib – Westfair Online: Westfair Online Loxo Oncology completes rolling submission of new drug application for larotrectinib Westfair Online Stamford-based Loxo Oncology Inc.... https://t.co/Hr5zGpQoXW (https://t.co/Hr5zGpQoXW) pic.twitter.com/9tWDwnpMLV (https://t.co/9tWDwnpMLV)

— Oncology Board (@mb_Oncology) March 26, 2018 (https://twitter.com/mb_Oncology/status/978410910115966976?ref_src=twsrc%5Etfw)

Phase III SEQUOIA study to continue as per DMC recommendation without modification (http://ir.armobio.com/news-releases/news-release-details/armo-biosciences-announces-positive-outcome-first-interim)

"Clearing the first interim analysis with feedback from the DMC to continue the SEQUOIA study without modifications is a key corporate milestone for ARMO in 2018," said Joseph Leveque, MD, Chief Medical Officer of

ARMO Biosciences. "The DMC's recommendation supports the safety profile we have seen with pegilodecakin when combined with 5-fluorouracyl and platinum based chemotherapy which is the basis for a number of difficult to treat cancers. As such, we believe that pegilodecakin in combination with FOLFOX could provide a safe and efficacious therapeutic option for second-line PDAC patients. The SEQUOIA study continues to enroll well and had 178 patients randomized as of March 15th of this year, which keeps us on track to deliver both the second interim analysis and the final data analysis on this pivotal study in 2020."

> ARMO long acting IL10 AM0010 (pegilodecakin) prolongs survival in pancreatic cancer Phase I. ASCO | @scoopit (https://twitter.com/scoopit?ref_src=twsrc%5Etfw) https://t.co/gyS2Ozcddy (https://t.co/gyS2Ozcddy)
>
> — Krishan Maggon (@kkmaggon) June 12, 2017 (https://twitter.com/kkmaggon/status/874151815251726336?ref_src=twsrc%5Etfw)

Nivolumab receives positive CHMP opinion for Q4W Dosing in advanced Melanoma and previously treated RCC patients (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-receives-positive-chmp-opinion-recommen-0)

"BMS is committed to improving cancer care by, among other things, addressing scheduling and convenience concerns of patients with a range of dosing options for an Immuno-Oncology agent that allows for enhanced flexibility," said Fouad Namouni, M.D., head of development, Oncology, Bristol-Myers Squibb. "This positive CHMP opinion reinforces our commitment and we look forward to hearing from the European Commission. Once approved, the Opdivo four-week dosing infused over 60 minutes would enable BMS to deliver on our promise to explore potentially more flexible and convenient dosing options for patients, caregivers and healthcare providers alike."

> Nivolumab plus ipilimumab treatment associated with better overall survival compared to sunitinib treatment in patients with previously untreated advanced renal-cell carcinoma.https://t.co/RQrgui8H53 (https://t.co/RQrgui8H53) #Cancer (https://twitter.com/hashtag/Cancer?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) #Sunitinib (https://twitter.com/hashtag/Sunitinib?src=hash&ref_src=twsrc%5Etfw)
>
> — CellworksLife (@CellworksLife) March 30, 2018 (https://twitter.com/CellworksLife/status/979734996905857024?ref_src=twsrc%5Etfw)

CHMP OPINION: Positive vote to Rucaparib's application in Ovarian Cancer (http://phx.corporate-ir.net/phoenix.zhtml?c=247187&p=irol-newsArticle_Print&ID=2339488)

"The recommendation to approve Rubraca as monotherapy is welcome news, as once approved it will offer a new treatment option for women with advanced, recurrent ovarian cancer who have BRCA mutant platinum sensitive disease and are unsuitable for platinum based chemotherapy. In this analysis, we observed many women benefiting from extended progression-free survival with acceptable tolerability," said Dr. Rebecca Kristeleit, Clinical Senior Lecturer and Consultant Medical Oncologist, University College London/University College London Hospitals UK. "These are really important data demonstrating meaningful efficacy and a new non-chemotherapy treatment option for this group of patients who have already been exposed to a number of chemotherapy regimens."

> EU's CHMP Supports Rubraca's Approval for Advanced, Recurrent Ovarian Cancer https://t.co/SBdK9zXt6V (https://t.co/SBdK9zXt6V) pic.twitter.com/94l4AJCJac (https://t.co/94l4AJCJac)
>
> — BioNews Services (@bionewsservices) March 28, 2018 (https://twitter.com/bionewsservices/status/979064432662929408?ref_src=twsrc%5Etfw)

NICE OPINION: Cabozantinib gets a green light in medullary thyroid cancer (http://www.pharmatimes.com/news/final_nice_green_light_for_ipsens_cometriq_1229604)

Ipsen's Cometriq can now be routinely funded by the NHS to treat patients with medullary thyroid cancer (MTC) in England and Wales.

The National Institute for Health and Care Excellence has issued guidelines recommending the drug as an option for treating progressive MTC in adults with unresectable, locally advanced or metastatic disease.

This is a rare cancer, accounting for 3-12 percent of all thyroid cancers, and can spread to the lungs or bone. Approximately 25 percent of MTCs are the result of an inherited faulty gene that runs in the family.

> What advancements have been made in treatment options for medullary thyroid cancer?https://t.co/zmTnbfNV88 (https://t.co/zmTnbfNV88) pic.twitter.com/vV2Zj7r6Oe (https://t.co/vV2Zj7r6Oe)
>
> — Oncology Central (@OncologyCentral) March 22, 2018 (https://twitter.com/OncologyCentral/status/976840675449647104?ref_src=twsrc%5Etfw)

TRIAL STATUSES

via GIPHY (https://giphy.com/gifs/test-gw3IWyGkCorsazTi)

Phase II trial of PI3K / AKT / mTOR pathway inhibitor, GDC-0084, commences in GBM patients (https://kza.irmau.com/irm/PDF/1847_1/KaziacommencesPhaseIIclinicalstudyofGDC0084)

Kazia CEO, Dr James Garner, commented, "the entire team has been working hard to design and implement the GDC-0084 clinical study. We are very pleased to now have the trial underway, and look forward to working with the participating clinicians. The need for new therapies in this disease remains immense, and we believe that GDC-0084 may have a valuable role to play in improving outcomes for patients with glioblastoma."

> Novel Australian Drug GDC-0084 Included in Phase II Adaptive Trial for GBM.#Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) #cancersurvivor (https://twitter.com/hashtag/cancersurvivor?src=hash&ref_src=twsrc%5Etfw) @AACR (https://twitter.com/AACR?ref_src=twsrc%5Etfw) @ASCO (https://twitter.com/ASCO?ref_src=twsrc%5Etfw) @CPhIWW (https://twitter.com/CPhIWW?ref_src=twsrc%5Etfw) #braincancer (https://twitter.com/hashtag/braincancer?src=hash&ref_src=twsrc%5Etfw)https://t.co/JVP4AyV9UK (https://t.co/JVP4AyV9UK)
>
> — Onco'Zine – Network (@OncoZine) March 31, 2018 (https://twitter.com/OncoZine/status/980126803594436608?ref_src=twsrc%5Etfw)

First patient enrolled in the Phase IIb CYPRESS 2 trial evaluating AM0010 + Nivolumab in 2L, PD-L1 low/neg NSCLC patients (http://ir.armobio.com/news-releases/news-release-details/armo-biosciences-enrolls-first-patient-cypress-2-trial)

"We are pleased to have dosed the first patient in our CYPRESS development program, which will guide our registrational strategy for pegilodecakin in NSCLC," said Joseph Leveque, MD, Chief Medical Officer of ARMO Biosciences. "In our Phase 1 b trial, pegilodecakin showed very encouraging disease control (DCR), overall response (ORR), progression-free survival (PFS) and overall survival (OS) when combined with pembrolizumab or nivolumab, regardless of the PD-L1 expression, tumor mutational burden (TMB) or disseminated disease in NSCLC patients. We expect that the CYPRESS studies could provide confirmatory translational data to our Phase 1b experience and will allow us to define targeted registrational studies with pegilodecakin in these tough to treat patient populations, which could potentially commence as early as 2019."

> PEGylated Human IL-10 AM0010 in Combination with Nivolumab in Renal Cell Cancer https://t.co/JkQIJ8sgKL (https://t.co/JkQIJ8sgKL) pic.twitter.com/Ly1r5KBqqP (https://t.co/Ly1r5KBqqP)
>
> — Oncology Tube (@oncologytube) March 2, 2018 (https://twitter.com/oncologytube/status/969680350803763201?ref_src=twsrc%5Etfw)

COLLABORATIONS

via GIPHY (https://giphy.com/gifs/collaboration-UBWXc146FZHRm)

Bluebird bio and Celgene to co-develop and co-rromote Anti-BCMA CAR T Cell Therapy bb2121 in the United States (http://investor.bluebirdbio.com/news-releases/news-release-details/bluebird-bio-and-celgene-corporation-enter-agreement-co-develop)

"Entering into this co-development and co-promotion partnership with Celgene is a significant step forward in building a fully integrated oncology franchise for bluebird and together, we are committed to rapidly advancing development of bb2121 for patients," said Joanne Smith-Farrell, Ph.D., oncology franchise leader and senior vice president, corporate development and strategy, bluebird bio. "The collaboration builds upon our extensive research and development capabilities in oncology and is a testament to the strong partnership that exists between our two companies."

> Bluebird Bio and Celgene Corporation Enter into Agreement to Co-Develop and Co-Promote Anti-BCMA CAR T Cell Therapy bb2121 in the United States. #partnership (https://twitter.com/hashtag/partnership?src=hash&ref_src=twsrc%5Etfw) #Pharmaceutical (https://twitter.com/hashtag/Pharmaceutical?src=hash&ref_src=twsrc%5Etfw) #tcellrx (https://twitter.com/hashtag/tcellrx?src=hash&ref_src=twsrc%5Etfw) #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/fpnpfLanl6 (https://t.co/fpnpfLanl6) pic.twitter.com/LeWYRuQEcR (https://t.co/LeWYRuQEcR)
>
> — Drugdu.com (@Drugdu) April 1, 2018 (https://twitter.com/Drugdu/status/980267176308420608?ref_src=twsrc%5Etfw)

NCCN GUIDELINES

via GIPHY (https://giphy.com/gifs/quark-4IPUYGDCujDxu)

Management of immune-related adverse events in patients treated with Immune Checkpoint Inhibitor (ICPi) therapy (http://ascopubs.org/doi/abs/10.1200/JCO.2017.77.6385)

The systematic review identified 204 eligible publications. Much of the evidence consisted of systematic reviews of observational data, consensus guidelines, case series, and case reports. Due to the paucity of high-quality evidence on management of immune-related adverse events, recommendations are based on expert consensus.

> Just returned from #KScancerimm (https://twitter.com/hashtag/KScancerimm?src=hash&ref_src=twsrc%5Etfw) @KeystoneSymp (https://twitter.com/KeystoneSymp?ref_src=twsrc%5Etfw) to find a new review by one of the speakers (@andyjminn (https://twitter.com/andyjminn?ref_src=twsrc%5Etfw)) about MoA-driven combination approaches to overcome resistance to and broaden utility of immune checkpoint inhibitors: https://t.co/q8DX62swGb (https://t.co/q8DX62swGb) @CellPressNews (https://twitter.com/CellPressNews?ref_src=twsrc%5Etfw) @ImmunityCP (https://twitter.com/ImmunityCP?ref_src=twsrc%5Etfw) pic.twitter.com/QHGphdgavQ (https://t.co/QHGphdgavQ)
>
> — Ingo Hartung (@HartungIngo) March 30, 2018 (https://twitter.com/HartungIngo/status/979710260012298240?ref_src=twsrc%5Etfw)

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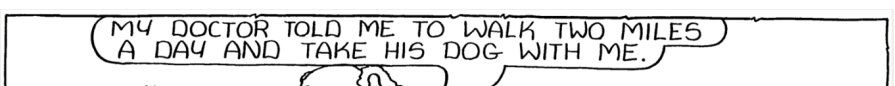
And now, time for some humor before we sign-off....



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Source: Mooselakecartoons.com (https://mooselakecartoons.com/health/wtv6a3kqontdjlvscm9kv39870nh08)

About the Author:


(https://io.wp.com/www.sciwri.club/wp-content/uploads/2018/03/RT.jpg)

Richa (https://www.linkedin.com/in/richatewari/) earned her PhD at the National Brain Research Centre, India. For her thesis, she worked on the dreaded Glioblastoma multiforme. That was her first in-depth exposure to academic research in cancer biology. After her PhD, she expanded her research experience by working in the field of immunology at UCLA, USA. After her return to India, Richa switched to a corporate setting but continued her engagement with the cancer field. She is currently loving her work, which affords her the opportunity to continue developing her knowledge in the biomedical field of cancer. Outside of work, she enjoys watching, identifying and photographing birds.

Editor and Blog Design:


(https://i1.wp.com/www.sciwri.club/wp-content/uploads/2016/06/Self2015.jpg)

Abhi Dey (https://www.linkedin.com/in/abhinavdey/)

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

Image Sources: Pixabay, Giphy, Wikipedia and Twitter

Cover image:Artist's rendering of small chemical ornaments (cones) slow the release of anti-cancer antibodies (blue) from this functionalized mesoporous silica (orange) By ENERGY.GOV (https://flic.kr/p/fuajMn) [Public domain], via Wikimedia Commons

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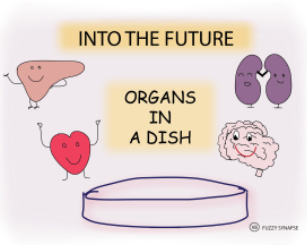

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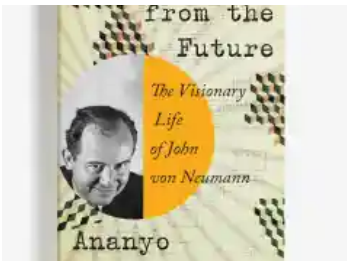

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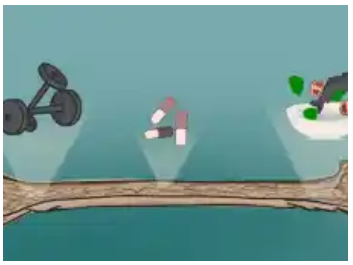

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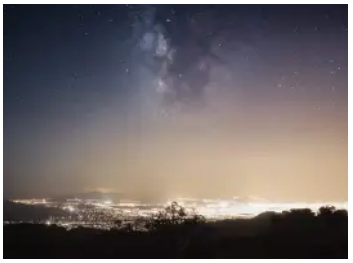

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