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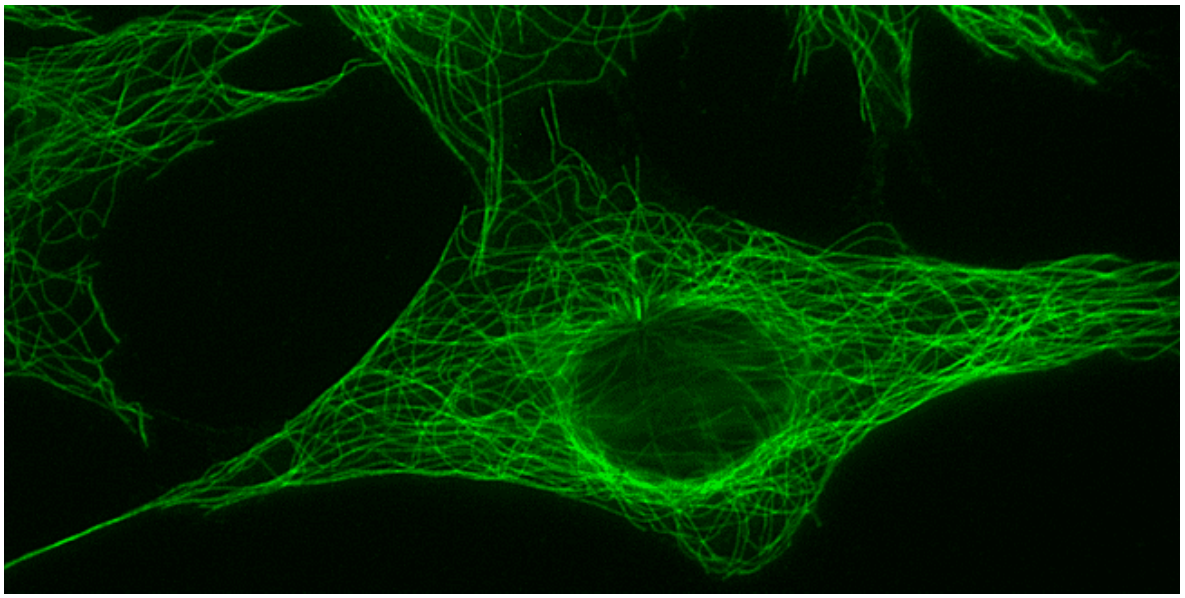
Onco-this-Week

May 5, 2018(https://sciwri.club/archives/date/2018/05/05)



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Editor's Note: In this edition of Onco-this-Week, Richa Tewari highlights the FDA's approvals of Kymriah in subcategory of Lymphoma patients and Dabrafenib + Trametinib combination for Adjuvant treatment of BRAF V600-mut Melanoma along with the priority review to sBLA for Pembrolizumab + Pemetrexed + Chemotherapy as first line treatment in metastatic non-squamous NSCLC. In addition, our educational video section shares the personal perspective of a clinical researcher, Jamie Roberts, on why you should support precision medicine and check out the infographic on the facts about childhood cancer.- Abhi Dey (https://www.linkedin.com/in/abhinavdey/)

This edition of Onco-this-Week is Sponsored by Nano-Tag Biotechnologies (https://goo.gl/XM63s6)

(https://goo.gl/XM63s6)

Note from our Sponsor: *"NanoTag Biotechnologies is a German company founded in July 2015 by scientists with a strong background in biochemistry as well as quantitative super-resolution imaging. Situated in Göttingen, we are in constant exchange with scientists developing and applying tools for innovative cutting-edge research. The inspiring atmosphere created by leading scientists and an excellent network of entrepreneurship is an ideal breeding ground for our vision to produce thoroughly validated high-quality tools for life-sciences, biotechnology and bio-medical research. Currently, our portfolio mainly focuses on single-domain antibody-based affinity reagents ("Tags") for biochemical and fluorescence-based applications. In the near future, we are going to expand our portfolio to enzymes, affinity resins and secondary reagents for various immunoassays (IP, IF, IHC, IHC-P, WB...). Feel free to contact us (http://nano-tag.com/about-us) anytime to discuss custom projects."*

Cover image*: [Courtesy: Felipe Opazo (https://www.linkedin.com/in/felipe-opazo-47248a4/) (CEO) Nano-Tag Biotechnologies (https://goo.gl/XM63s6)] PFA fixed 3T3 cells decorated with a primary mouse monoclonal anti-α-tubulin antibody (SYSY cat. no. 302 211) and stained with FluoTag-X2 anti-mouse AbberiorSTAR488. (For more info click here (http://nano-tag.com/products/fluotag-x2-anti-mouse-igg))*

Educational Video: Faces of the Precision Medicine Initiative — Jamie Roberts (Clinical Trials Transformation Initiative) shares her personal story, from the perspective of a patient and healthcare professional, about why she supports precision medicine. (Source: NIH (https://www.nih.gov/research-training/precision-medicine-initiative/faces-precision-medicine-initiative-jamie-roberts))

DRUG APPROVALS

FDA APPROVAL: Kymriah® (tisagenlecleucel) receives second FDA approval; for treatment of R/R DLBCL patients (https://www.novartis.com/news/media-releases/kymriahr-tisagenlecleucel-first-class-car-t-therapy-from-novartis-receives-second-fda-approval-treat-appropriate-rr-patients-large-b-cell-lymphoma)

"Today's FDA approval of Kymriah provides another opportunity for Novartis to build on its leadership in CAR-T development, delivering a potentially transformative therapy with durable and sustained response rates and a well-characterized safety profile to help patients in dire need of new treatment options," said Liz Barrett, CEO, Novartis Oncology. "We look forward to leveraging all of our learnings and new capabilities from the initial launch of Kymriah in pediatric and young adult B-cell ALL for this larger group of patients."

"The goal of Kymriah is to provide physicians with a therapy that has demonstrated durable response rates in relapsed or refractory DLBCL patients, a patient population that has endured multiple rounds of chemotherapy with many having experienced unsuccessful stem cell transplants," said Stephen J. Schuster, MD, the Robert and Margarita Louis-Dreyfus Professor in Chronic Lymphocytic Leukemia and Lymphoma Clinical Care and Research in Penn's Perelman School of Medicine and director of the Lymphoma Program at the Abramson Cancer Center. "With this approval, physicians now have a meaningful therapeutic option that can achieve and maintain a sustained response without stem cell transplant along with a consistent safety profile."

> The U.S. Food and Drug Administration has approved the CAR T-cell therapy called tisagenlecleucel (Kymriah™) for certain lymphoma patients. https://t.co/OhRo9tyKoR (https://t.co/OhRo9tyKoR) pic.twitter.com/9AZEopFkBg (https://t.co/9AZEopFkBg)
>
> — Dana-Farber (@DanaFarber) May 2, 2018 (https://twitter.com/DanaFarber/status/991779241053380615?ref_src=twsrc%5Etfw)

Based on Ph III COMBI-AD trial data, Novartis receives approval of Dabrafenib + Trametinib combo for Adjuvant treatment of BRAF V600-mut Melanoma (https://www.novartis.com/news/media-releases/novartis-receives-fda-approval-tafinlarr-mekinistr-adjuvant-treatment-braf-v600-mutant-melanoma)

"Since the initial approval of Tafinlar and Mekinist in metastatic melanoma in 2013, the combination has become an important therapy for many patients carrying a BRAF mutation in both melanoma and lung cancers," said Liz

Barrett, CEO, Novartis Oncology. “Today’s FDA approval is an important milestone for patients who previously had limited treatment options in the adjuvant setting, and reflects our commitment to the ongoing development of this breakthrough treatment.”

> FDA: Tafinlar and Mekinist combo is now approved for treatment of unresectable or metastatic anaplastic thyroid cancer with the BRAF V600E mutation https://t.co/DxIya7mz22 (https://t.co/DxIya7mz22) pic.twitter.com/IrupNucPBk (https://t.co/IrupNucPBk)
>
> — MedPage Today (@medpagetoday) May 4, 2018 (https://twitter.com/medpagetoday/status/992494246610468875?ref_src=twsrc%5Etfw)

REGULATORY NEWS

EMA validates BMY application for potential treatment of 1L NSCLC patients who have TMB >10 mutations/megabase (https://news.bms.com/press-release/corporatefinancial-news/european-medicines-agency-validates-bristol-myers-squibbs-ty-0)

Sabine Maier, M.D., development lead, thoracic cancers, Bristol-Myers Squibb, commented, “Europe has one of the highest incidence rates of advanced lung cancer, currently accounting for 20% of all cancer deaths. The *Opdivo* plus low-dose *Yervoy* combination has the potential to offer first-line NSCLC patients with TMB ≥10 mut/Mb a chemotherapy-sparing I-O/I-O regimen. The validation of our application by the EMA is a step forward in the regulatory review process, and we will continue to work with urgency to bring precision immunotherapy to patients with lung cancer in the European Union.”

> Opdivo Plus Low-Dose Yervoy Combination Reduces the Risk of Progression or Death... https://t.co/MQd60UbrUl (https://t.co/MQd60UbrUl) pic.twitter.com/deRXUXz1aB (https://t.co/deRXUXz1aB)
>
> — Precision Medicine (@JournPrecMed) April 18, 2018 (https://twitter.com/JournPrecMed/status/986591621901844480?ref_src=twsrc%5Etfw)

Additional CMC info requested by FDA in support of IND application for PVRIG-targeting IO antibody COM701 (https://www.cgen.com/wp-content/uploads/COM701-IND-Update-Final-04-27-2018.pdf)

“We are working closely with the FDA to provide the additional information requested as quickly as possible. In anticipation for FDA clearance, site selection activities in multiple centers in the United States are currently ongoing to allow future patient enrollment, and we look forward to evaluating COM701 in a clinical setting,” stated Anat Cohen-Dayag, PhD, President and CEO of Compugen. “We continue to be encouraged by the preclinical data for COM701, which suggest that targeting PVRIG may be a primary means of stimulating an anti-tumor immune response in certain cancers that may be unresponsive to available treatments.”

> Compugen not quite there with COM701 IND; shares down 7% https://t.co/IlsORYTFd6 (https://t.co/IlsORYTFd6) $CGEN (https://twitter.com/search?q=%24CGEN&src=ctag&ref_src=twsrc%5Etfw)
>
> — Breaking News (@MarketCurrents) April 27, 2018 (https://twitter.com/MarketCurrents/status/989895512382881792?ref_src=twsrc%5Etfw)

Priority review to sBLA for Pembrolizumab + Pemetrexed + Chemotherapy based on Ph III KEYNOTE-189 trial as 1L treatment of metastatic non-squamous NSCLC; PDUFA: Sep 23, 2018 (http://www.mrknewsroom.com/news-release/oncology/fda-grants-priority-review-mercks-sbla-keytruda-pembrolizumab-combination-peme)

“KEYTRUDA is the first immunotherapy to significantly extend survival of patients with nonsquamous non-small cell lung cancer in combination with chemotherapy as a first-line treatment, including in patients whose tumors are either PD-L1 negative or are untested,” said Dr. Roger M. Perlmutter, president, Merck Research Laboratories.

"With this sBLA acceptance by the FDA, we are pleased that data from KEYNOTE-189 is now under review by regulatory authorities in the United States, Europe, and Japan."

> In wake of practice-changing KEYNOTE-189 results, here are my thoughts on management options for pts w/<1% PD-L1, who were included on trial, but had more modest difference in activity from adding pembro to chemo. I welcome thoughts from others. https://t.co/U1F7RSyFrW (https://t.co/U1F7RSyFrW)#LCSM (https://twitter.com/hashtag/LCSM?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/zxVroEbh9z (https://t.co/zxVroEbh9z)
>
> — H. Jack West, MD (@JackWestMD) May 4, 2018 (https://twitter.com/JackWestMD/status/992451279979925504?ref_src=twsrc%5Etfw)

Priority review granted to PD-1 inhibitor Cemiplimab's BLA for cutaneous squamous cell carcinoma (CSCC); PDUFA: Oct 28, 2018 (http://mediaroom.sanofi.com/fda-to-conduct-priority-review-of-cemiplimab-as-a-potential-treatment-for-advanced-cutaneous-squamous-cell-carcinoma/)

The FDA accepted priority review BLA for cemiplimab for the treatment of patients with metastatic CSCC or patients with locally advanced CSCC who are not candidates for surgery. Cemiplimab is an investigational human monoclonal antibody targeting PD-1 and was granted Breakthrough Therapy designation status by the FDA in September 2017 with a target action date of October 28, 2018. In the EU, the EMA accepted for review in April 2018 the MAA for cemiplimab in patients with metastatic CSCC or patients with locally advanced CSCC who are not candidates for surgery.

The BLA submission is based on a Ph II pivotal, single-arm, open-label clinical trial of cemiplimab for advanced CSCC (EMPOWER-CSCC 1) in addition to Ph I data from two advanced CSCC expansion cohorts.

> A priority review was granted by the FDA for cemiplimab in treatment of metastatic cutaneous squamous cell carcinoma (CSCC) or those with locally advanced CSCC not eligible for surgery. Read on: https://t.co/cJXxgDeeoD (https://t.co/cJXxgDeeoD) #Carcinokma (https://twitter.com/hashtag/Carcinokma?src=hash&ref_src=twsrc%5Etfw) #CancerResearch (https://twitter.com/hashtag/CancerResearch?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/up30UGbgmE (https://t.co/up30UGbgmE)
>
> — Targeted Oncology (@TargetedOnc) May 1, 2018 (https://twitter.com/TargetedOnc/status/991406959416041473?ref_src=twsrc%5Etfw)

RESULTS

Ph III KEYNOTE-407 met secondary endpoint of ORR in an interim analysis (http://www.mrknewsroom.com/news-release/oncology/merck-provides-update-keynote-407-trial)

Merck (NYSE:MRK), known as MSD outside the United States and Canada, announced that the pivotal Phase 3 KEYNOTE-407 trial investigating KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in combination with carboplatin-paclitaxel or nab-paclitaxel as first line treatment for metastatic squamous non-small cell lung cancer (sNSCLC) met a pre-specified secondary endpoint of overall response rate (ORR) in an early cohort of participants at an interim analysis. Based on these data, Merck has recently submitted a sBLA to FDA.

> Merck Provides Update on KEYNOTE-407 Trial | Business Wire https://t.co/s9cHGCLoX8 (https://t.co/s9cHGCLoX8)
>
> — gatienne maingonnat (@GatienneM) May 3, 2018 (https://twitter.com/GatienneM/status/992129082929315840?ref_src=twsrc%5Etfw)

New approach to treating patients with stage IV Wilms tumor will transform clinical practice, study shows

(https://childrensnational.org/news-and-events/childrens-newsroom/2018/new-approach-to-treating-patients-with-stage-iv-wilms-tumor-will-transform-clinical-practice)

"These findings will change clinical practice and improve survival for patients with Wilms tumor whose cancer has spread to the lungs" said Dr. Dome. "The risk-adapted approach to treatment based on tumor biology and tumor response provides a framework for future studies as we come one step closer to achieving 100 percent survival without treatment-associated side effects."

> Treatment of stage IV favorable histology Wilms tumor with lung metastases https://t.co/WdxYYBNmon (https://t.co/WdxYYBNmon) #pedonc (https://twitter.com/hashtag/pedonc?src=hash&ref_src=twsrc%5Etfw) #pedcsm (https://twitter.com/hashtag/pedcsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/36uZVKyeX4 (https://t.co/36uZVKyeX4)
>
> — J Clinical Oncology (@JCO_ASCO) April 23, 2018 (https://twitter.com/JCO_ASCO/status/988487700197117952?ref_src=twsrc%5Etfw)

Positive top-line data announced from Ph IIb STORM study of XPO1 inh Selinexor in penta-refractory MM patients (http://investors.karyopharm.com/news-releases/news-release-details/karyopharm-announces-positive-top-line-data-phase-2b-storm-study)

Paul G. Richardson, MD, Director of Clinical Research, Jerome Lipper Multiple Myeloma Center at the Dana-Farber Cancer Institute, said, "Despite numerous advances in myeloma treatment, currently available therapies are insufficient to address the increasing number of patients with highly resistant, penta-refractory myeloma, where the disease has ultimately become non-responsive to approved therapy. There is, therefore, a real urgency for new therapies with novel mechanisms of action for these patients, who have a critical unmet medical need. Selinexor's targeted inhibition of nuclear export could potentially expand the armamentarium of treatment options significantly in this important population for which no other established treatment is readily available."

"The 25.4% response rate and 4.4 month duration of response observed in the STORM study are highly compelling," stated Sundar Jagannath, MD, Director of the Multiple Myeloma Program and Professor of Medicine (Hematology and Medical Oncology) at Tisch Cancer Institute at Mount Sinai School of Medicine. "For an orally administered therapy, these new data underscore selinexor's potential to be an exciting new treatment option for these difficult-to-treat patients who have exhausted approved therapies."

> Karyopharm stock soars on selinexor's positive PhIIb update, plans for an NDA$KPTI (https://twitter.com/search?q=%24KPTI&src=ctag&ref_src=twsrc%5Etfw) +26%@BrittanyMeiling (https://twitter.com/BrittanyMeiling?ref_src=twsrc%5Etfw) https://t.co/W4HrzWEXlY (https://t.co/W4HrzWEXlY)
>
> — John Carroll (@JohnCendpts) April 30, 2018 (https://twitter.com/JohnCendpts/status/991058649140420608?ref_src=twsrc%5Etfw)

Novel Theranostic Approach for Treating Pancreatic Cancer Patients Shows Promise (http://www.snmmi.org/NewsPublications/NewsDetail.aspx?ItemNumber=28682)

"The research presented warrants further development of 177Lu-3BP-227, in order to provide patients with more effective treatment and less side effects than cytotoxic chemotherapy," explains Christiane Smerling, PhD, head of Nuclear Medicine and Imaging at 3B Pharmaceuticals GmbH in Berlin, Germany.

She points out, "Exploiting a hitherto underexplored receptor, these findings broaden the scope of nuclear medicine treatment for pancreatic adenocarcinoma and potentially other indications expressing neurotensin receptors, such as Ewing sarcoma. A theranostic approach using molecular imaging to identify potential responders will allow more effective treatment of a highly underserved patient population."

Novel Theranostic Approach for Treating Pancreatic Cancer Patients Shows Promise #PancreaticCancer (https://twitter.com/hashtag/PancreaticCancer?src=hash&ref_src=twsrc%5Etfw) #NuclearMedicine (https://twitter.com/hashtag/NuclearMedicine?src=hash&ref_src=twsrc%5Etfw) https://t.co/oCIJitgPkW (https://t.co/oCIJitgPkW) pic.twitter.com/Lf5KZzG8BW (https://t.co/Lf5KZzG8BW)

— SNMMI (@SNM_MI) May 1, 2018 (https://twitter.com/SNM_MI/status/991401695757373443?ref_src=twsrc%5Etfw)

PROGRAM UPDATES

ACQUISITION: Janssen to acquire BeneVir Biopharm to advance oncolytic immunotherapy regimens (http://www.janssen.com/janssen-acquire-benevir-biopharm-advance-immunotherapy-regimens)

"Oncolytic viral immunotherapy holds exciting potential in the treatment of solid tumors through the priming and augmenting of an anti-tumor immune response," said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "BeneVir's unique technology platform complements our immuno-oncology research, which is focused on bringing forward an array of novel immunotherapies and combinations that may improve treatment outcomes for patients."

Janssen advances immunotherapy regimens with BeneVir Biopharm acquisition https://t.co/dxvI5HPlZV (https://t.co/dxvI5HPlZV) pic.twitter.com/vHDsr2zDuB (https://t.co/vHDsr2zDuB)

— Pharma Business Int (@PBIForum) May 3, 2018 (https://twitter.com/PBIForum/status/992059655235948544?ref_src=twsrc%5Etfw)

COLLABORATION: NeoImmuneTech and Roche to evaluate HyLeukin-7 +Atezolizumab in Advanced High-Risk Skin Cancers (http://neoimmunetech.com/pressrelease/1889)

"We are very excited to collaborate with Roche, a global leader in immuno-oncology, and with key opinion leaders from the ION, to advance the development of HyLeukin-7 and analyze its synergy with immune-checkpoint inhibitors," said NeoImmuneTech Chief Executive Officer Se Hwan Yang, Ph.D. "We believe that this combination regimen will deliver a strong dual effect over cancer by both increasing the numbers of T cells and eliminating cancer cells' escape route."

"HyLeukin-7 has shown in multiple studies to substantially increase the total body complement of T cells with little toxicity. HyLeukin-7 is designed to be effective when used in concert with a variety of different immunotherapy regimens, including the combination with anti-PD-(L)1 that is being tested in this trial," said Martin A. "Mac" Cheever, MD, Director of the Immune Oncology Network, which is based at Fred Hutchinson Cancer Research Center. He is also director of the National Cancer Institute's Cancer Immunotherapy Trials Network.

NeoImmuneTech and its parent company Genexine have entered into an agreement with Roche to enable studies of a combination treatment in three advanced high-risk skin cancer types. https://t.co/JuyeM8EH6C (https://t.co/JuyeM8EH6C) #mdBioHealth (https://twitter.com/hashtag/mdBioHealth?src=hash&ref_src=twsrc%5Etfw)

— Maryland Commerce (@MDBiz) May 4, 2018 (https://twitter.com/MDBiz/status/992464041980329984?ref_src=twsrc%5Etfw)

COLLABORATION: Exelixis and Invenra Enter Into Collaboration to Discover and Develop Novel Biologics to Treat Cancer (http://ir.exelixis.com/phoenix.zhtml?c=120923&p=irol-newsArticle&ID=2346478)

"Partnering with Invenra to leverage its deep expertise in protein engineering and the discovery of multispecific

antibodies is an important step toward adding proprietary biologics to the Exelixis pipeline," said Peter Lamb, Ph.D., Executive Vice President, Discovery Research and Chief Scientific Officer of Exelixis." We are excited to work with the Invenra team and have structured our collaboration to provide relatively small financial support upfront and pay for success down the road. As we rebuild our internal small molecule discovery capability, this partnership provides a complementary approach that enables us to target pathways not accessible to small molecules, increasing our ability to advance novel therapies into the clinic."

"We're very excited to partner with Exelixis on this multi-asset collaboration as the company moves beyond its small molecule expertise to build a biologics pipeline," said Roland Green, Ph.D., Chief Executive Officer and Co-Founder of Invenra. "Invenra's B-Body™ platform has been validated internally. Our innovative technologies to discover, characterize, and generate multispecific antibodies pair well with Exelixis' demonstrated success in oncology clinical development and commercialization. We look forward to working together with the Exelixis team to bring forward potential new anti-cancer therapies."

> We have entered into a collaboration with @invenra (https://twitter.com/invenra?ref_src=twsrc%5Etfw) to discover and develop novel #biologics (https://twitter.com/hashtag/biologics?src=hash&ref_src=twsrc%5Etfw) for the treatment of cancer. $EXEL (https://twitter.com/search?q=%24EXEL&src=ctag&ref_src=twsrc%5Etfw) Learn more: https://t.co/9A4tERvSie (https://t.co/9A4tERvSie) pic.twitter.com/MOcdhhRIhU (https://t.co/MOcdhhRIhU)
>
> — Exelixis (@ExelixisInc) May 2, 2018 (https://twitter.com/ExelixisInc/status/991772678699737088?ref_src=twsrc%5Etfw)

COLLABORATION: Moderna and Merck Expand mRNA Cancer Vaccines Collaboration (https://www.modernatx.com/newsroom/press-releases/moderna-and-merck-expand-mrna-cancer-vaccines-collaboration)

"Augmentation of immune responses offers great promise in cancer therapy, as our work with the PD-1-specific antibody KEYTRUDA has shown," said Dr. Roger M. Perlmutter, President, Merck Research Laboratories. "We now look forward to expanding our exploration of mRNA cancer vaccines, working in concert with our colleagues at Moderna."

"We are excited to build upon our productive relationship with Merck and to rapidly advance our novel mRNA-based KRAS cancer vaccine into the clinic," said Stéphane Bancel, Moderna's Chief Executive Officer. "While KRAS has long been a challenging target, we believe our mRNA platform offers a novel approach designed to generate and specifically present KRAS mutations to the immune system, potentially allowing the patient's own immune system to attack and eradicate cancers that harbor these mutations."

> Merck and Moderna Expand Cancer Vaccine Partnership with Another $125 Million https://t.co/W8pRsrnMVy (https://t.co/W8pRsrnMVy) pic.twitter.com/Uzvaq5Fpxp (https://t.co/Uzvaq5Fpxp)
>
> — BioSpace (@biospace) May 4, 2018 (https://twitter.com/biospace/status/992513942902669313?ref_src=twsrc%5Etfw)

Ferring to commercialise novel gene therapy, rAd-IFN/Syn3, for bladder cancer patients (https://www.ferring.com/en/media/press-releases/ferring-signs-global-agreement-to-commercialise-novel-gene-therapy-for-bladder-cancer-patients/)

"We are excited about the potential to commercialise rAd-IFN/Syn3, a novel gene therapy for bladder cancer patients," said Michel Pettigrew, President of the Executive Board and Chief Operating Officer, Ferring Pharmaceuticals. "The gene therapy sector is growing rapidly and building a presence in this specialised area is a very positive opportunity for Ferring."

"Today, bladder cancer patients have very limited medical options and new treatments that delay or prevent total

removal of the bladder and improve clinical outcomes are urgently needed for patients," said Professor Klaus Dugi, Chief Medical Officer, Ferring Pharmaceuticals. "Phase 2 clinical results for rAd-IFN/Syn3 were very encouraging and we look forward to the Phase 3 data."

> BREAKING NEWS: Ferring announces global agreement with FKD Therapies to commercialise novel #genetherapy (https://twitter.com/hashtag/genetherapy?src=hash&ref_src=twsrc%5Etfw) for bladder #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) patients. https://t.co/v53trK4DGi (https://t.co/v53trK4DGi) #bladder (https://twitter.com/hashtag/bladder?src=hash&ref_src=twsrc%5Etfw) #bladdercancer (https://twitter.com/hashtag/bladdercancer?src=hash&ref_src=twsrc%5Etfw) #urology (https://twitter.com/hashtag/urology?src=hash&ref_src=twsrc%5Etfw) #uroonc (https://twitter.com/hashtag/uroonc?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #pharma (https://twitter.com/hashtag/pharma?src=hash&ref_src=twsrc%5Etfw) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/ljrAJ8im9I (https://t.co/ljrAJ8im9I)
>
> — Ferring Pharmaceuticals (@ferring) May 3, 2018 (https://twitter.com/ferring/status/992011974870528000?ref_src=twsrc%5Etfw)

TRIAL STATUSES

Medicenna Amends Protocol of Ph IIb Recurrent GBM Study of MDNA55 in Response to Strong Safety Data and Early Efficacy Read-outs (http://www.medicenna.com/Investors/press-releases/press-release-details/2018/Medicenna-Amends-Protocol-of-Phase-2b-Recurrent-Glioblastoma-Study-of-MDNA55-in-Response-to-Strong-Safety-Data-and-Early-Efficacy-Read-outs/default.aspx)

"We are pleased with the safety profile to date and early efficacy signals of MDNA55. We are amending the protocol at the recommendation of our clinical advisors to further improve the chances for demonstrating increased therapeutic benefit for patients living with this life-threatening disease," said Fahar Merchant, PhD, President and Chief Executive Officer of Medicenna.

Principal Investigator, John H. Sampson MD, PhD, of Duke University Medical Center Department of Neurosurgery, commented, "The study has contributed substantially to the improvement of Convection Enhanced Delivery of drugs directly into brain tumors. More importantly, we are seeing definite biological effects of MDNA55 in some patients as we await final study results to see whether these translate into robust longer term benefits."

"We have used the occasion of this recruitment milestone to implement optimal methodologies in the amended protocol," commented Martin Bexon MD, Head of Clinical Development. "With the experience gleaned from the ongoing Phase 2b clinical trial of MDNA55 in rGBM, we are able, for instance, to allow for more personalized dosing based on the tumor load and incorporate advanced imaging modalities to measure treatment responses more reliably, despite significant changes due to necrosis and inflammation." Additionally, the amendment will allow investigators to administer a second dose of MDNA55 where appropriate.

> Using $MRIC (https://twitter.com/search?q=%24MRIC&src=ctag&ref_src=twsrc%5Etfw) Clearpoint System BRIEF-Medicenna Amends Protocol Of Phase 2B Recurrent Glioblastoma Study Of MDNA55 https://t.co/x99NhtBDGk (https://t.co/x99NhtBDGk) $MDNA (https://twitter.com/search?q=%24MDNA&src=ctag&ref_src=twsrc%5Etfw) $MDNA.TO (https://twitter.com/search?q=%24MDNA.TO&src=ctag&ref_src=twsrc%5Etfw)
>
> — Michael Bigger (@biggercapital) May 2, 2018 (https://twitter.com/biggercapital/status/991640198747447296?ref_src=twsrc%5Etfw)

NICE RECOMMENDATION

Pembrolizumab to be funded by NHS based on KEYNOTE-045 trial data (http://www.pharmatimes.com/news/final_nice_nod_for_keytruda_in_bladder_cancer_1233732)

“A cisplatin-containing chemotherapy is usually the first line of treatment for people with late stage bladder cancer, but many patients may not be suitable due to underlying clinical parameters. If people can’t tolerate it, there aren’t many options left. It is very exciting to see breakthroughs like this, where new treatments are likely to offer meaningful objective response for a number of patients receiving treatment and it is generally well tolerated – a major change in clinical practice.”

Infographically Speaking…

Facts About Childhood Cancer (https://visual.ly/community/infographic/health/facts-about-childhood-cancer/?utm_source=visually_embed)

From Visually (https://visual.ly?utm_source=content-embed&utm_medium=embed).

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: Wikipedia and Twitter

Cover image: (Courtesy: Nano-Tag Biotechnologies (http://nano-tag.com/)) PFA fixed 3T3 cells decorated with a primary mouse monoclonal anti-α-tubulin antibody (SYSY cat. no. 302 211) and stained with FluoTag-X2 anti-mouse AbberiorSTAR488. (For more info click here (http://nano-tag.com/products/fluotag-x2-anti-mouse-igg))

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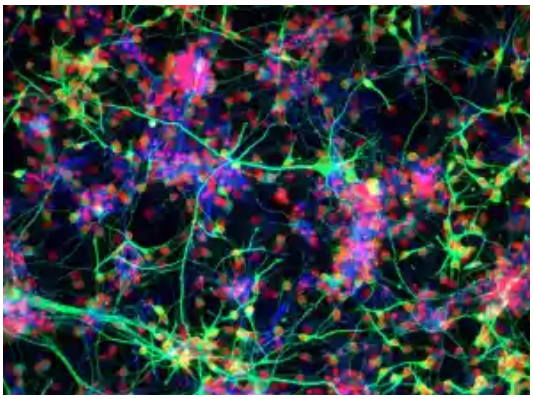

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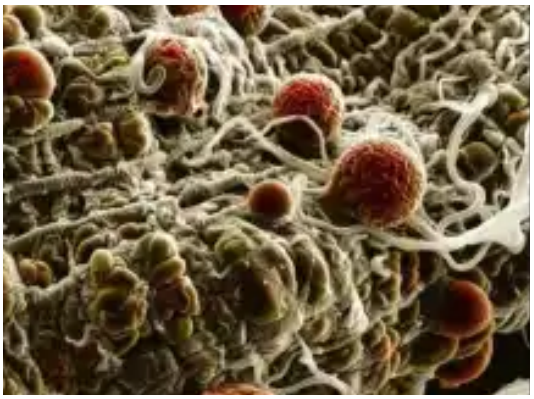

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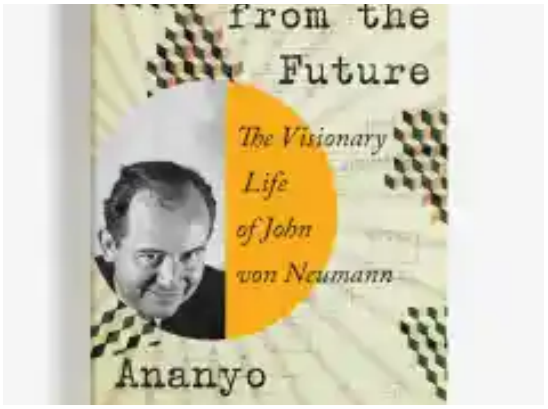

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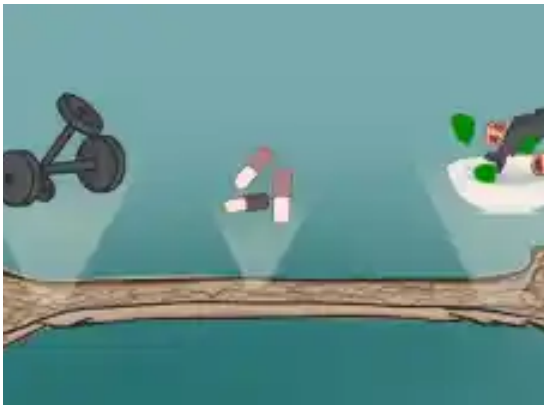

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