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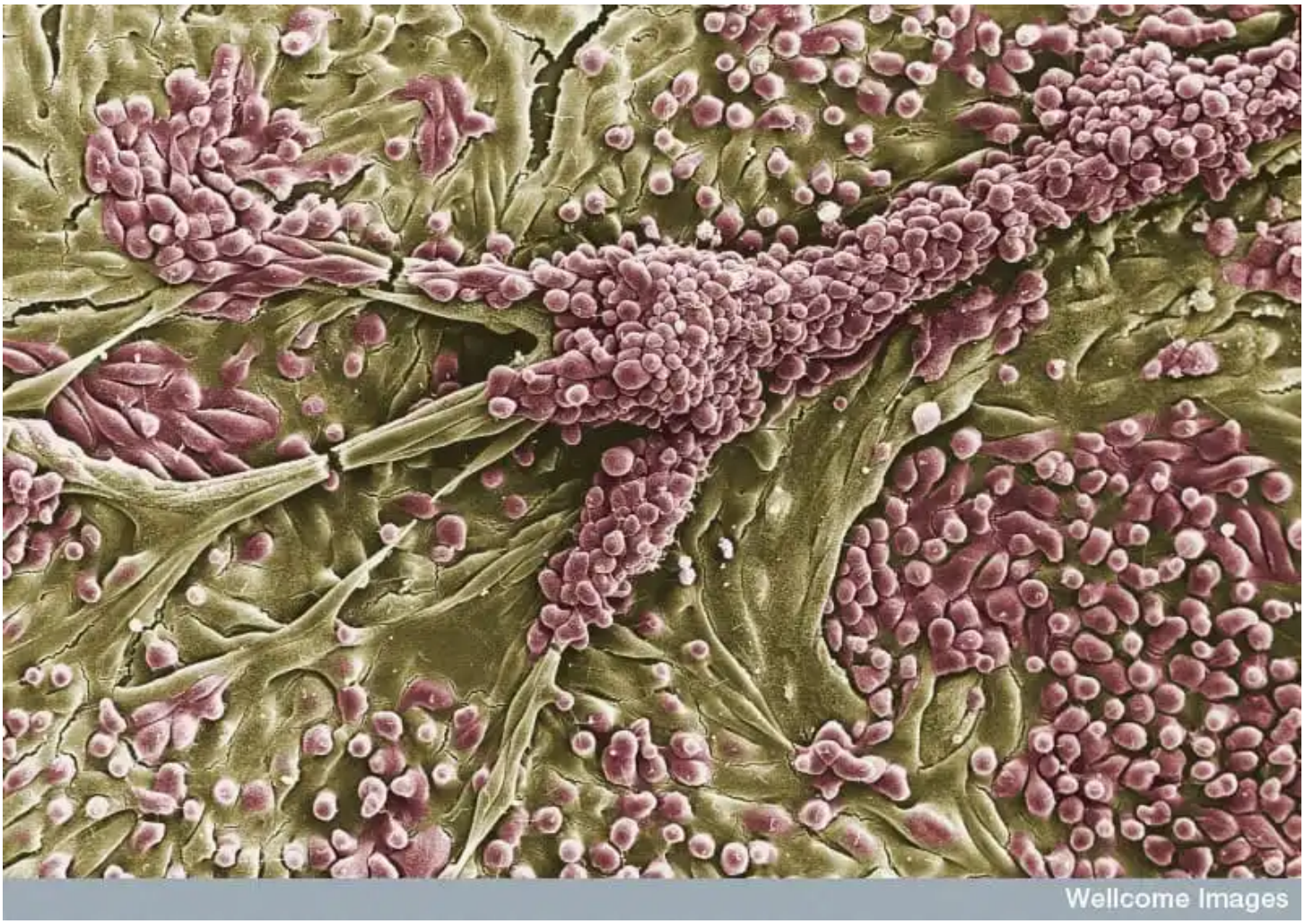
Onco-This-Week

September 22, 2018(https://sciwri.club/archives/date/2018/09/22)



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Editor's Note: *In the latest edition of Onco-this-Week, Richa Tewari updates us about #HealthCanada (https://twitter.com/hashtag/HealthCanada?src=hash)'s Approval of CABOMETYX® (#cabozantinib (https://twitter.com/hashtag/Cabozantinib?src=hash)) tablets for the Treatment of Adults with Previously Treated Advanced Renal Cell Carcinoma. Also making news is half of patients of relapsed/refractory chronic lymphocytic leukemia achieving complete remission in data combining #Venetoclax (https://twitter.com/hashtag/Venetoclax?src=hash) with #Rituximab (https://twitter.com/hashtag/Rituximab?src=hash). #Johnson&Johnson (https://twitter.com/hashtag/*

JNJ?src=hash)'s subsidiary #Janssen (https://twitter.com/hashtag/Janssen?src=hash) files NDA for #Erdafitinib (https://twitter.com/hashtag/Erdafitinib?src=hash) in Urothelial Cancer Indication and #Azedra (https://twitter.com/hashtag/Azedra?src=hash) added to NCCN Guidelines for the treatment of pheochromocytoma and paraganglioma. There is even more news on clinical trials, trials' updates, regulatory issues, collaborations and an analysis of the highlights in the OTW In-a-Capsule along with our regular trivia section that talks about NICE. Wondering why NICE is so nice? Scroll on. –Abhi Dey (https://www.linkedin.com/in/abhinavdey/)

OTW In a Capsule

1. NICE's negative opinion to Kymriah (tisagenlecleucel-T) in adults with relapsed/refractory B-cell lymphoma. Though NICE recognised the significant clinical benefits of Kymriah, it is still apprehensive about the cost-effectiveness of the therapy which was declared ineligible for routine funding or use within the Cancer Drugs Fund (CDF), even when Novartis offered a confidential discount on the list price of £282,000. It is noteworthy that Kymriah was backed for CDF funding by NICE in case of younger patients up to 25 years old with refractory B-cell ALL in relapse post-transplant or in second or later relapse. Next NICE meeting is scheduled for 23 October 2018 and Novartis will be eager to see if they can secure positive NICE recommendation then.

2. Positive CHMP opinion for chemo-free combination of Venetoclax + Rituximab in 2L+ CLL patients. Venetoclax + Rituximab's combo inches closer to EU approval based on Ph III MURANO trial data. The combination was granted accelerated approval by FDA in patients with 17p deletion based on overall response rate in 2016, later changed to regular approval in Jun 2018 based on PFS improvement; however, the cherry on the cake was rate of MRD-negativity since the benefit is seen regardless of the risk features.

3. Testing Pelareorep + Nivolumab combination for efficacy in R/R multiple myeloma patients. The immuno-oncolytic virus Pelareorep is presumed to turn cold tumors hot by inducing selective tumor lysis. On the other hand, though PD-1/PD-L1 blockade is associated with tumor regression in several malignancies, checkpoint inhibitors have shown limited activity in myeloma patients (remember PD-1 inhibitor JNJ 63723283 + daratumumab trial; durvalumab + daratumumab trial; and pembrolizumab trials put on hold due to safety concerns?). It will be interesting to see if a pro-inflammatory phenotype can be developed in the tumor microenvironment by combining pelareorep with checkpoint inhibitors.

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DRUG APPROVALS

Cabozantinib approved in Canada for the Treatment of Previously Treated Advanced RCC based on ph 3 pivotal METEOR trial (http://ir.exelixis.com/phoenix.zhtml?c=120923&p=irol-newsArticle&ID=2368033)

"The approval of CABOMETYX in Canada helps address a significant unmet need for patients with advanced kidney cancer whose disease has progressed on first-line therapy and who have limited treatments available," said Michael M. Morrissey, Ph.D., President and Chief Executive Officer of Exelixis. "We are glad to be partnering with Ipsen to bring this much needed treatment option to these patients and look forward to our continued collaboration."

> Exelixis' Partner Ipsen Announces Health Canada's Approval of CABOMETYX® (cabozantinib) Tablets for the Treatment of Adults with Previously Treated Advanced Renal Cell Carcinoma https://t.co/oQtoaJcl9e (https://t.co/oQtoaJcl9e) pic.twitter.com/GI5muNvU8M (https://t.co/GI5muNvU8M)
>
> — Latest News from Business Wire (@NewsFromBW) September 19, 2018 (https://twitter.com/NewsFromBW/status/1042377830468743169?ref_src=twsrc%5Etfw)

REGULATORY NEWS

Positive CHMP opinion for chemo-free combination of Venetoclax + Rituximab in 2L+ CLL patients based on Ph III MURANO trial data (https://news.abbvie.com/news/press-releases/abbvie-receives-positive-chmp-opinion-for-novel-chemotherapy-free-combination-venclyxto-venetoclax-tablets-with-rituximab-as-treatment-with-fixed-duration-for-patients-with-chronic-lymphocytic-leukemia-who-have-r)

“This positive CHMP opinion is one important step forward as AbbVie continues to further the research and development of novel medicines with the potential to transform the standard of care in blood cancers,” said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. “The combination of VENCLYXTO with rituximab has the potential to give patients with relapsed/refractory chronic lymphocytic leukemia a chance to live longer without their disease progressing, and to stop treatment after their two-year course.”

> Data Combining Venetoclax with Rituximab Half of patients achieved complete remission https://t.co/lc992PVuFg (https://t.co/lc992PVuFg) pic.twitter.com/kQcJ68j7y8 (https://t.co/kQcJ68j7y8)
>
> — Oncology Tube (@oncologytube) September 20, 2018 (https://twitter.com/oncologytube/status/1042610075854987264?ref_src=twsrc%5Etfw)

NDA submitted for FGFR inhibitor Erdafitinib in FGFR+ metastatic urothelial cancer based on data from Ph II BLC2001 (https://www.janssen.com/janssen-submits-new-drug-application-us-fda-seeking-approval-erdafitinib-treatment-metastatic)

“Erdafitinib has demonstrated promising results in the treatment of metastatic urothelial cancer, a disease where patients unfortunately have limited treatment options today,” said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. “We look forward to working with the FDA in the agency’s review of the application as we believe erdafitinib will provide patients with an important therapeutic option.”

> J&J Files NDA for Erdafitinib in Urothelial Cancer Indication – https://t.co/1uFGWS5BDV (https://t.co/1uFGWS5BDV) https://t.co/ugj9dVP7l4 (https://t.co/ugj9dVP7l4)
>
> — Fight Bladder Cancer (@BladderCancerUK) September 21, 2018 (https://twitter.com/BladderCancerUK/status/1043023944700157957?ref_src=twsrc%5Etfw)

EMA validates BMS’s application for Elotuzumab + Pomalidomide + Low-Dose Dexamethasone in Patients with Multiple Myeloma based on Ph II ELOQUENT-3 trial (https://news.bms.com/press-release/corporatefinancial-news/european-medicines-agency-validates-bristol-myers-squibbs-appl)

“Given the need for new treatment options for patients with multiple myeloma, we look forward to working closely with the EMA as they review this application,” said Fouad Namouni, M.D., head, oncology development, Bristol-Myers Squibb. “It is our hope that this new *Empliciti*-based combination will soon become available for patients in the European Union with multiple myeloma, whose disease progressed on lenalidomide and a PI.”

> #EMA (https://twitter.com/hashtag/EMA?src=hash&ref_src=twsrc%5Etfw) Validates Bristol-Myers’ Application for Empliciti (elotuzumab)+Pomalidomide https://t.co/rlNCmNWoYe (https://t.co/rlNCmNWoYe)
>
> — Research Analyst (@mastersrock222) September 19, 2018 (https://twitter.com/mastersrock222/status/1042276485158002688?ref_src=twsrc%5Etfw)

Azedra (iobenguane I 131) gets added to NCCN guidelines for Pheochromocytoma or Paraganglioma (https://

ir.progenics.com/news-releases/news-release-details/progenics-announces-addition-azedrar-iobenguane-i-131-national)

"NCCN is considered the arbiter of high-quality cancer care and we are extremely pleased that they have added AZEDRA to their Guidelines for the treatment of pheochromocytoma and paraganglioma," said Mark Baker, Chief Executive Officer of Progenics. "Inclusion in the NCCN Guidelines provides further validation of AZEDRA's value and will help raise awareness of this breakthrough in treatment for these rare, life-threatening tumors."

> Progenics has announced that Azedra has been added to the information presented in the NCCN Guidelines (link pinned at the top of our page):... https://t.co/043voFMfiN (https://t.co/043voFMfiN)
>
> — Pheo Para Project (@PheoParaProj) September 18, 2018 (https://twitter.com/PheoParaProj/status/1041888637766516741?ref_src=twsrc%5Etfw)

Clinical hold lifted from Ph I trial of HER2-targeting Dolaflexin ADC, XMT-1522 (http://ir.mersana.com/news-releases/news-release-details/mersana-announces-fda-lifts-partial-clinical-hold-xmt-1522)

"We are excited to resume enrollment on the XMT-1522 trial and to work with investigators to explore the full potential of both promising drug candidates in the solid tumor setting," said Anna Protopapas, Chief Executive Officer of Mersana.

> FDA lifts #clinicalhold (https://twitter.com/hashtag/clinicalhold?src=hash&ref_src=twsrc%5Etfw) from #Mersana (https://twitter.com/hashtag/Mersana?src=hash&ref_src=twsrc%5Etfw)'s #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) trial https://t.co/AaT6UGnqtO (https://t.co/AaT6UGnqtO) @FierceBiotech (https://twitter.com/FierceBiotech?ref_src=twsrc%5Etfw) @MersanaADC (https://twitter.com/MersanaADC?ref_src=twsrc%5Etfw) #ADC (https://twitter.com/hashtag/ADC?src=hash&ref_src=twsrc%5Etfw) #HER2 (https://twitter.com/hashtag/HER2?src=hash&ref_src=twsrc%5Etfw) #XMT1522 (https://twitter.com/hashtag/XMT1522?src=hash&ref_src=twsrc%5Etfw) #Dolaflexin (https://twitter.com/hashtag/Dolaflexin?src=hash&ref_src=twsrc%5Etfw) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw)
>
> — Plexus Ventures (@PlexusVentures) September 18, 2018 (https://twitter.com/PlexusVentures/status/1042081131196235777?ref_src=twsrc%5Etfw)

Positive NICE's recommendation to Dabrafenib plus trametinib in stage III BRAF V600 mutation-positive melanoma patients (https://www.nice.org.uk/news/article/patients-with-high-risk-skin-cancer-have-new-treatment-option)

Mirella Marlow, deputy director for the NICE Centre for Health Technology Evaluation, said: "There are currently no adjuvant treatments available for people with stage III BRAF V600 mutation-positive melanoma, a disease which can cause severe and debilitating symptoms.

NICE has approved dabrafenib (Tafinlar) with trametinib (Mekinist) as an option for the adjuvant treatment of resected stage III BRAF V600 mutation-positive melanoma in adults.

NICE approves dabrafenib with trametinib for adjuvant treatment of melanoma https://t.co/YZl9pCE2m8 (https://t.co/YZl9pCE2m8) pic.twitter.com/XQv7Tw5Hxe (https://t.co/XQv7Tw5Hxe)

— Univadis UK (@univadisUK) September 21, 2018 (https://twitter.com/univadisUK/status/1043092480583815168?ref_src=twsrc%5Etfw)

"We are therefore delighted that we were able to work with the company and NHS England to recommend dabrafenib plus trametinib as a new treatment option, marking an important development in the management of melanoma."

TRIAL RESULTS

CSCO 2018: Preliminary results with PD-1 inhibitor Tislelizumab in MSI-H or dMMR Solid Tumors patients presented (http://ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2368174)

"Tislelizumab is being developed in a broad clinical program as both a monotherapy and in combination with other treatments for a number of potential clinical indications. We are encouraged by the preliminary results presented today with tislelizumab for patients with MSI-H or dMMR solid tumors and are excited about starting a Phase 2 trial in China in patients with advanced forms of these tumors to test our belief that they are sensitive to immune checkpoint inhibition. We hope this further enables the availability of new treatments options, which are urgently needed, especially in China," commented Amy Peterson, M.D., Chief Medical Officer, Immuno-Oncology, at BeiGene.

BeiGene presents preliminary data on anti-PD1 tislelizumab in advanced solid #tumors (https://twitter.com/hashtag/tumors?src=hash&ref_src=twsrc%5Etfw) at #CSCO (https://twitter.com/hashtag/CSCO?src=hash&ref_src=twsrc%5Etfw)

Ph1/2 #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) is ongoing but 29% achieved ORR while AEs were typically grade 1 or 2https://t.co/05WWldnYC7 (https://t.co/05WWldnYC7)#biopharma (https://twitter.com/hashtag/biopharma?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #immunooncology (https://twitter.com/hashtag/immunooncology?src=hash&ref_src=twsrc%5Etfw) #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/O0SSouep9H (https://t.co/O0SSouep9H)

— DDNews Online (@DDNewsOnline) September 20, 2018 (https://twitter.com/DDNewsOnline/status/1042846249437716480?ref_src=twsrc%5Etfw)

Positive preliminary results announced from Ph Ib trial of GR-MD-02 and Pembrolizumab in Advanced Melanoma; expansion planned (http://investor.galectintherapeutics.com/news-releases/news-release-details/galectin-therapeutics-inc-announces-positive-preliminary-results)

"We are very encouraged by the objective response rate and the disease control rate observed in patients with advanced melanoma. These response rates were higher than expected with KEYTRUDA alone," said Dr. Curti, M.D., Director, Providence Melanoma Program. "An objective response rate of seven out of fourteen patients

(50%) and a disease control rate of nine out of fourteen patients (64%) with advanced melanoma is very encouraging. The published objective response rates in randomized studies using KEYTRUDA in patients with advanced melanoma range from 21% in patients who have had prior therapy to 39% in patients who had not received prior systemic therapy. Importantly, the combination was also very well tolerated, and treatment appears to be associated with fewer adverse events than expected with KEYTRUDA alone."

> Galectin Tx posts more positive data in Ph1b #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) of GR-MD-02 + pembrolizumab vs metastatic #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw)
>
> 50% ORR as well as drop in suppressive MDSCs in responding patients; progress on #biomarkers (https://twitter.com/hashtag/biomarkers?src=hash&ref_src=twsrc%5Etfw) of responsehttps://t.co/ziegkoiAye (https://t.co/ziegkoiAye)#galectins (https://twitter.com/hashtag/galectins?src=hash&ref_src=twsrc%5Etfw) #pharma (https://twitter.com/hashtag/pharma?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/nVT9mGLHvS (https://t.co/nVT9mGLHvS)
>
> — DDNews Online (@DDNewsOnline) September 20, 2018 (https://twitter.com/DDNewsOnline/status/1042792558684909569?ref_src=twsrc%5Etfw)

Ipilimumab + Nivolumab improve the proportion with tumor response and PFS HR rates for women with recurrent epithelial ovarian cancer as shown in NRG-GY003 data (https://www.nrgoncology.org/Portals/0/News/Press%20Releases/2018/FINAL_NRG-GY003_Press%20Release%209.19.2018.pdf?ver=2018-09-19-085238-407)

"From my perspective, this is the first evidence that the addition of CTLA4 targeted therapy to PD-1 targeted therapy in patients with ovarian cancer may be more beneficial than PD-1 targeted therapy alone. Future directions could include a trial combining nivolumab and ipilimumab in front line therapy as an adjunct to standard chemotherapy," stated Robert A. Burger, MD, the abstract Lead Author and Professor of Obstetrics and Gynecology at the Perelman School of Medicine at the University of Pennsylvania.

> NRG-GY003 suggests the addition of a CTLA-4 targeted therapy to a PD-1 targeted therapy could benefit women with #OvarianCancer (https://twitter.com/hashtag/OvarianCancer?src=hash&ref_src=twsrc%5Etfw) Read more: https://t.co/g7yA0R5UTu (https://t.co/g7yA0R5UTu) #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) #ipilimumab (https://twitter.com/hashtag/ipilimumab?src=hash&ref_src=twsrc%5Etfw) #nivolumab (https://twitter.com/hashtag/nivolumab?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/sVuBDr3SkE (https://t.co/sVuBDr3SkE)
>
> — NRG Oncology (@NRGonc) September 19, 2018 (https://twitter.com/NRGonc/status/1042416680209711109?ref_src=twsrc%5Etfw)

Complete tumour responses reported in Ph I saRNA MTL-CEBPA HCC patients off-study when subsequently administered SoC (https://www.minatx.com/wp-content/uploads/2018/09/20180919_MiNA_ILCA-meeting_Final.pdf)

"Although these instances are anecdotal, complete responses of tumours are a rarity in primary liver cancer," said Dr. Debashis Sarker, the Chief Investigator of the study and Principal Investigator at the National Institute for Health Research Clinical Research Facility at Guy's and St Thomas' and King's College London. "Observing two

patients responding in this manner to approved cancer therapies subsequent to treatment with MTL-CEBPA is very encouraging. I am pleased that MiNA is seeking to modify its ongoing trial to include investigations on the combination in additional patients and I look forward to the opportunity to further evaluate MTL-CEBPA."

> Honoured that our drug candidate MTL-CEBPA for liver cancer is featured in @newscientist (https://twitter.com/newscientist?ref_src=twsrc%5Etfw) https://t.co/VQcRUAeFvV (https://t.co/VQcRUAeFvV)
>
> — Robert Habib (@robertshabib) June 5, 2018 (https://twitter.com/robertshabib/status/1003936446363897856?ref_src=twsrc%5Etfw)

SPECIAL STATUSES

OBI-3424 granted FDA Orphan Drug Designation for OBI-3424 for the treatment of ALL (http://www.obipharma.com/2018/07/obi-pharma-granted-fda-orphan-drug-designation-for-obi-3424-for-the-treatment-of-hepatocellular-carcinoma-hcc/)

Amy Huang, General Manager of OBI Pharma, noted, "This additional orphan drug designation for OBI-3424 by the FDA is a significant step in the development of this drug candidate in ALL, including T-ALL, an unmet medical need disease with limited treatment options. We are excited that the FDA has recognized the need to develop novel targeted therapeutic agents such as OBI-3424 in the fight against ALL".

> .@OBIPharma (https://twitter.com/OBIPharma?ref_src=twsrc%5Etfw)'s OBI-3424 has been granted an orphan drug designation by @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) for the treatment of acute lymphoblastic #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw), a rare #BloodCancer (https://twitter.com/hashtag/BloodCancer?src=hash&ref_src=twsrc%5Etfw). https://t.co/tYzGMtVACG (https://t.co/tYzGMtVACG) pic.twitter.com/oiy6KWOe18 (https://t.co/oiy6KWOe18)
>
> — Rare Disease Report (@RareDR) September 21, 2018 (https://twitter.com/RareDR/status/1043186847541813248?ref_src=twsrc%5Etfw)

Albumin-stabilized pegylated liposomal docetaxel, ATI-1123, receives orphan drug designation in SCLC (http://ir.cytori.com/investor-relations/news/news-details/2018/Phase-2-Ready-Oncology-Drug-Receives-FDA-Orphan-Drug-Designation/default.aspx)

Cytori Therapeutics announced that it received FDA orphan drug designation for its ATI-1123 chemotherapy drug product candidate for the treatment of small cell lung cancer. ATI-1123 is an albumin-stabilized pegylated liposomal formulation of docetaxel. ATI-1123 is designed to have improved liposome stability attributed to pegylation, and is expected to have reduced toxicity and superior delivery. These characteristics of ATI-1123 are expected to provide a therapeutic for SCLC that offers comparable or better efficacy to currently-available standards while having a less intensive administration routine and improved side effect profile.

.@US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) has granted an orphan drug designation to @Cytori (https://twitter.com/Cytori?ref_src=twsrc%5Etfw)'s ATI-1123 #chemotherapy (https://twitter.com/hashtag/chemotherapy?src=hash&ref_src=twsrc%5Etfw) for the treatment of small cell lung #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) (#SCLC (https://twitter.com/hashtag/SCLC?src=hash&ref_src=twsrc%5Etfw)). https://t.co/HX5kDbsduM (https://t.co/HX5kDbsduM) pic.twitter.com/vasvpb8Uu5 (https://t.co/vasvpb8Uu5)

— Rare Disease Report (@RareDR) September 18, 2018 (https://twitter.com/RareDR/status/1042043002032730112?ref_src=twsrc%5Etfw)

CLR 131 receives FDA Rare Pediatric Disease Designation for treatment of Osteosarcoma (https://www.cellectar.com/news-media/press-releases/detail/189/fda-grants-rare-pediatric-disease-designation-to-cellectar)

"CLR 131 has demonstrated promise as an anticancer agent in preclinical and clinical settings, and we are working now to establish its impact on various rare and deadly pediatric cancers," said John Friend, M.D., chief medical officer of Cellectar. "Cellectar is pleased to have the opportunity to work closely with the FDA on our planned Phase 1 trial for these indications and we remain committed to advancing the pediatric programs as rapidly as possible."

Cellectar gets FDA rare pediatric disease designation for CLR 131 to treat osteosarcoma https://t.co/9YETxY1Ea1 (https://t.co/9YETxY1Ea1) via @Pharma (https://twitter.com/pharma?ref_src=twsrc%5Etfw) Business review

— Arun Kumar (@stemcology) September 19, 2018 (https://twitter.com/stemcology/status/1042431630365872129?ref_src=twsrc%5Etfw)

TRIAL STATUSES

First patient enrolled in Ph III TRYbeCA1 trial of Eryaspase in 2L Pancreatic cancer patients (http://investors.erytech.com/phoenix.zhtml?c=254271&p=irol-newsArticle&ID=2368155)

"The results from our landmark Phase 2b study are highly promising and underscore the importance of targeting tumor metabolism pathways in pancreatic cancer. We are hopeful to provide a novel treatment modality for this highly unmet medical need. We are very pleased that eryaspase has now moved into Phase 3 and patient enrollment has started as planned. Our first three enrolled patients mark the initiation of the trial in Europe. Early next year, we expect sites in the United States will begin enrolling as well," commented Iman El-Hariry, Chief Medical Officer.

@ERYTECH (https://twitter.com/erytech?ref_src=twsrc%5Etfw) enrolls first three patients in TRYbeCA1 trial evaluating eryaspase for the treatment of – https://t.co/rVuAs8Tbhw (https://t.co/rVuAs8Tbhw) #GoogleAlerts (https://twitter.com/hashtag/GoogleAlerts?src=hash&ref_src=twsrc%5Etfw)

— CapDecisif Management (@CapDecisif) September 20, 2018 (https://twitter.com/CapDecisif/status/1042899821915451392?ref_src=twsrc%5Etfw)

First neuroblastoma patient successfully dosed with innovative CAR therapy utilizing natural killer T cells (CAR-NKT) in Ph I GINAKIT2 trial (https://cellmedica.com/press-releases/first-neuroblastoma-patient-successfully-dosed-innovative-car-therapy-utilizing-natural-killer-t-cells-car-nkt/)

Dr. Andras Heczey, Principal Investigator, Assistant Professor, Pediatrics-Oncology at Baylor College of Medicine and Physician-Scientist, Texas Children's Cancer Center commented: "Dosing the first patient with this novel CAR-NKT therapy is an important milestone for all pediatric patients with neuroblastoma. CAR-NKTs may offer an exciting new therapeutic option for these patients and potentially for others with solid and hematological cancers. I am extremely grateful to the patients and families participating in this ground-breaking study."

> @ERYTECH (https://twitter.com/erytech?ref_src=twsrc%5Etfw) enrolls first three patients in TRYbeCA1 trial evaluating eryaspase for the treatment of – https://t.co/rVuAs8Tbhw (https://t.co/rVuAs8Tbhw) #GoogleAlerts (https://twitter.com/hashtag/GoogleAlerts?src=hash&ref_src=twsrc%5Etfw)
>
> — CapDecisif Management (@CapDecisif) September 20, 2018 (https://twitter.com/CapDecisif/status/1042899821915451392?ref_src=twsrc%5Etfw)

Chris Nowers, Cell Medica's CEO, said: "We believe that our CAR-NKT platform has a unique profile, with a potential to target solid and hematological tumors, as well as the possibility of a subsequent allogeneic "off the shelf" CAR-NKT therapy that could address some challenges of current autologous CAR-T therapies. This study marks an important step forward for Cell Medica and we are proud to be leading the development of this innovative class of next generation CAR therapies with our colleagues at BCM and Texas Children's."

Pelareorep + Nivolumab combination to be tested for efficacy in R/R multiple myeloma patients (https://www.oncolyticsbiotech.com/press-releases/detail/428/oncolytics-biotech-announces-investigator-sponsored)

"This study expands on our strategy of investigating the importance of systemic pelareorep administration followed by checkpoint blockade in selected indications. This investigation with nivolumab represents our third checkpoint inhibitor study entering the clinic after our recently announced window of opportunity study with Tecentriq® in breast cancer and our previously announced combinations with Keytruda® in multiple myeloma and pancreatic cancer," said Dr. Matt Coffey, President & CEO of Oncolytics Biotech.

> Oncolytics Biotech® Collaborates with SOLTI to Conduct a Window of Opportunity Study in #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) with Pelareorephttps://t.co/OgJlh69pdK (https://t.co/OgJlh69pdK) pic.twitter.com/PXbgDv7wCt (https://t.co/PXbgDv7wCt)
>
> — BestBreastNews (@BestBreastNews) September 12, 2018 (https://twitter.com/BestBreastNews/status/1039852375157006336?ref_src=twsrc%5Etfw)

"The data from this study will add to a growing critical mass of immunological and clinical data being developed by combining pelareorep with checkpoint inhibitors. Importantly, it will not only help us demonstrate the specific role of pelareorep in promoting an inflamed phenotype, it should also help us understand how the virus may promote responses to checkpoint blockade in cold tumors, thus potentially expanding the commercial potential of these immunotherapies."

Tocagen Announces Early Completion of Enrollment in Toca 5 Pivotal Phase 3 Brain Cancer Trial (http://ir.tocagen.com/phoenix.zhtml?c=254300&p=irol-newsArticle&ID=2368044)

“Achieving our enrollment goal ahead of schedule is a testament to the enthusiasm and dedication of our investigators and study coordinators as well as the participating patients, families and patient advocates,” said Asha Das, M.D., senior vice president and chief medical officer of Tocagen. “Achieving this enrollment goal takes us one step closer towards a potentially transformative new treatment option for patients with brain cancer.”

> Proud to announce we’ve completed enrollment in our Toca 5 Ph 3 trial. We applaud the investigators, sites, patients, families & advocates for their dedication to bringing us closer to a potentially transformative new treatment for #braincancer (https://twitter.com/hashtag/braincancer?src=hash&ref_src=twsrc%5Etfw). https://t.co/5U2fsiirF8 (https://t.co/5U2fsiirF8) $TOCA (https://twitter.com/search?q=%24TOCA&src=ctag&ref_src=twsrc%5Etfw) pic.twitter.com/260CxK5kb5 (https://t.co/260CxK5kb5)
>
> — Tocagen (@Tocagen) September 19, 2018 (https://twitter.com/Tocagen/status/1042445173358120960?ref_src=twsrc%5Etfw)

“Completing enrollment in Toca 5 is the latest example of our recent progress as we continue to execute against our goals,” said Marty Duvall, chief executive officer of Tocagen. “This important milestone also triggers the next milestone payment of $2 million from ApolloBio, our licensor of Toca 511 & Toca FC within the greater China region.”

APOLLO Oncology clinical trials program initiated to assess efficacy of CBT’s assets in combination with immunotherapies (https://www.cbtpharma.com/updates/cbt-pharmaceuticals-initiates-the-apollo-oncology-clinical-trials-program/)

“Initiating our APOLLO Oncology Clinical Trials Program and dosing the first patient is a major milestone for CBT as we advance our mission to improve the lives of cancer patients through combination treatment regimens,” stated Sanjeev Redkar, PhD, Co-Founder and President. “The APOLLO program is designed to investigate our proprietary assets alongside each other and is focused on understanding the science and genetics to identify the appropriate patients likely to benefit from the regimen. We are grateful for the support of our investigators in running our series of trials.”

> CBT Pharmaceuticals Initiates the APOLLO Oncology Clinical Trials Program – GlobeNewswire (press release): GlobeNewswire (press release) CBT Pharmaceuticals Initiates the APOLLO Oncology Clinical Trials Program GlobeNewswire (press release) “Initiating... https://t.co/Kp7HLSMwYN (https://t.co/Kp7HLSMwYN)
>
> — Oncology Board (@mb_Oncology) September 18, 2018 (https://twitter.com/mb_Oncology/status/1042132914303987712?ref_src=twsrc%5Etfw)

COLLABORATIONS

Daiichi Sankyo to evaluate efficacy of DS-8201 + Pembrolizumab in HER2 Expressing Breast and HER2 Expressing or HER2 Mutant Lung Cancers (https://www.prnewswire.com/news-releases/daiichi-sankyo-announces-clinical-research-collaboration-to-evaluate-ds-8201-in-combination-with-keytruda-pembrolizumab-in-her2-expressing-breast-and-her2-expressing-or-her2-mutant-lung-cancers-300715756.html)

“We are excited to pursue this opportunity to evaluate the safety, tolerability and activity of DS-8201 in combination with KEYTRUDA and whether this combination may provide a potential new treatment approach

for patients with HER2 expressing advanced breast and non-small cell lung cancer," said Tom Held, Vice President, Head, Antibody Drug Conjugate Task Force, Oncology Research and Development, Daiichi Sankyo. "Strategic collaborations like this support our goal to pursue, investigate and maximize the application of DS-8201 in combination with other compounds that target different pathways to address unmet needs of patients with cancer."

> #DaiichiSankyo (https://twitter.com/hashtag/DaiichiSankyo?src=hash&ref_src=twsrc%5Etfw) to test #DS8201 (https://twitter.com/hashtag/DS8201?src=hash&ref_src=twsrc%5Etfw) in combo with #Keytruda (https://twitter.com/hashtag/Keytruda?src=hash&ref_src=twsrc%5Etfw) for #HER2 (https://twitter.com/hashtag/HER2?src=hash&ref_src=twsrc%5Etfw)+ #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) & #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw). Interesting strategy pairing an antibody drug conjugate with a checkpoint inhibitor! Look out for our upcoming #ebook (https://twitter.com/hashtag/ebook?src=hash&ref_src=twsrc%5Etfw) on ADCs from #DRGOncology (https://twitter.com/hashtag/DRGOncology?src=hash&ref_src=twsrc%5Etfw) experts at https://t.co/jTvRgVZlqP (https://t.co/jTvRgVZlqP)
>
> — Andrew Merron (@Amerron_DRG) September 20, 2018 (https://twitter.com/Amerron_DRG/status/1042779754460528640?ref_src=twsrc%5Etfw)

What is NICE?

The National Institute for Health and Care Excellence (NICE) is an executive non-departmental public body of the Department of Health in the United Kingdom.

What does NICE do?

NICE improves outcomes for people using the NHS and other public health and social care services by providing national guidance and advice by:

• Producing evidence-based guidance and advice for health, public health and social care practitioners.
• Developing quality standards and performance metrics for those providing and commissioning health, public health and social care services.
• Providing a range of information services for commissioners, practitioners and managers across the spectrum of health and social care.

Which countries are covered under NICE's guidance?

NICE's guidance is officially England-only. However, it has agreements to provide certain NICE products and services to Wales, Scotland and Northern Ireland.

What are the different categories of NICE guidance?

These are the following categories NICE provides guidance for:

• Conditions and diseases (including cancer) • Health protection • Lifestyle and wellbeing • Population groups • Service delivery, organisation and staffing • Settings

What is a recent example of NICE's recommendation in oncology?

On September 19th (2018), NICE declared Kymriah (tisagenlecleucel-T) CAR-T too expensive to recommend as a treatment for adults with relapsed/refractory B-cell lymphoma, two weeks after endorsing its use in children and young people.

Source: https://www.nice.org.uk/about

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: (Cell Image Library) A colorized SEM image of a human proximal tubule, showing the tubular structure and projections extending over the tissue surface.Technical Details :B0007346 Human kidney proximal tubule. Wellcome Images available under the following creative commons usage http://creativecommons.org/licenses/by-nc-nd/2.0/uk/– Source (http://cellimagelibrary.org/images/39090)

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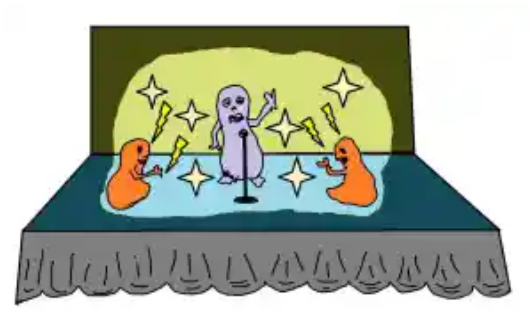

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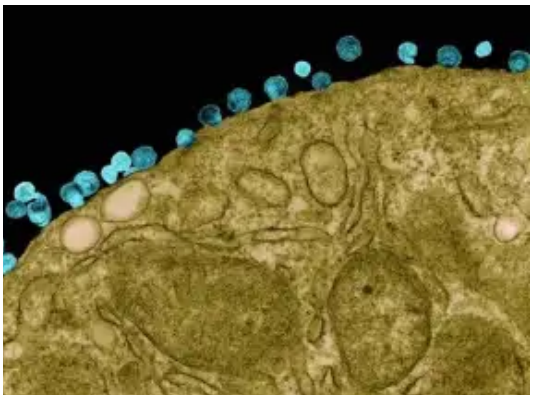

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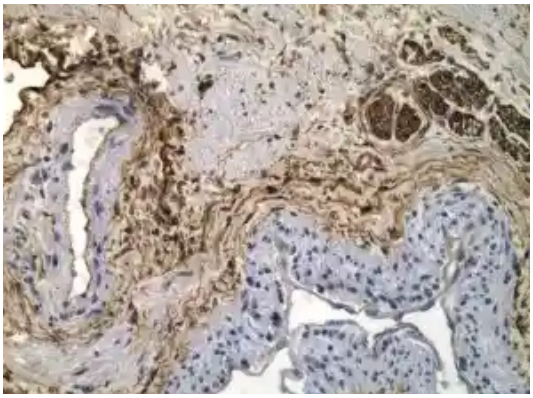

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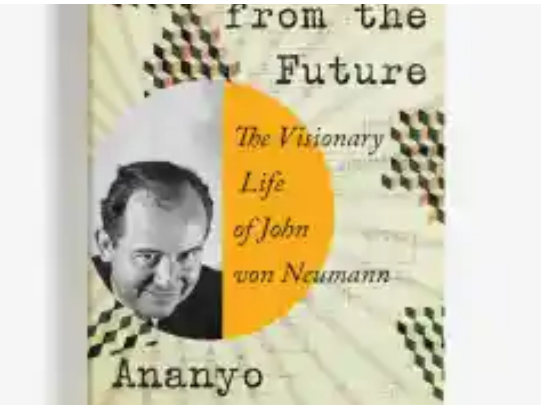

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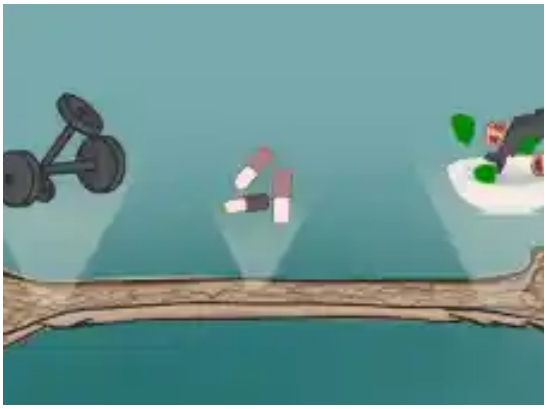

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