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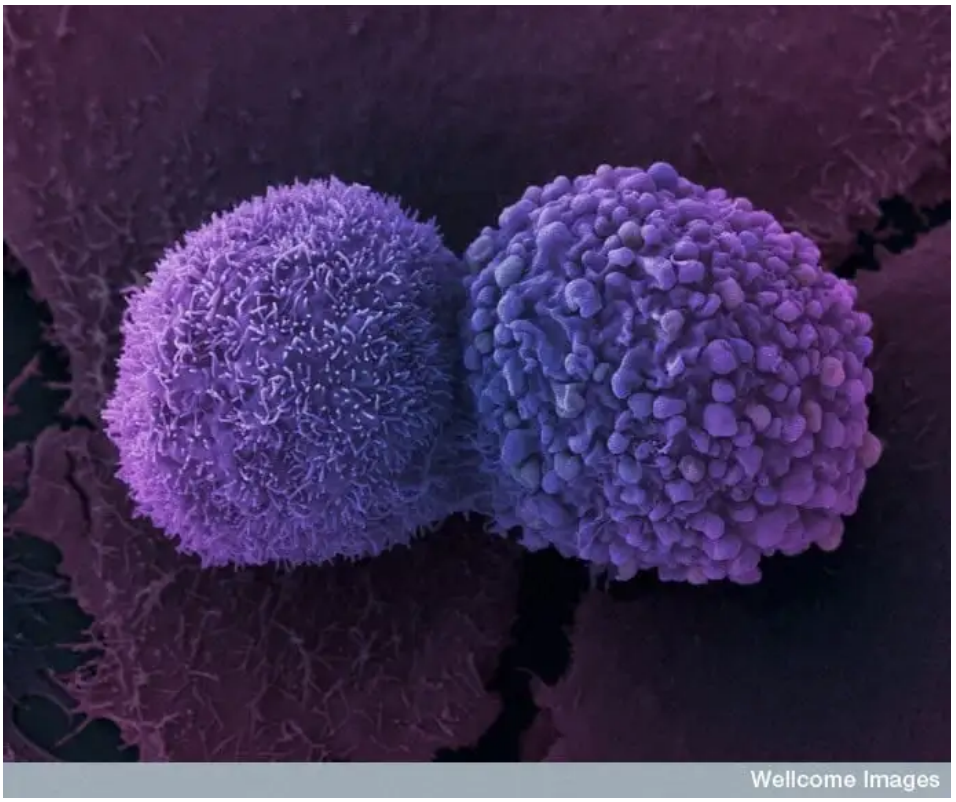
Onco-this-Week

July 13, 2018(https://sciwri.club/archives/date/2018/07/13)



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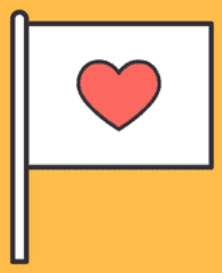
In the current edition of Onco-this-Week Richa Tewari highlights priority review to Pembrolizumab in previously treated Hepatocellular Carcinoma (HCC) patients; two approvals for Nivolumab – Ipilimumab combo – in first line (1L) metastatic Renal Cell Carcinoma (mRCC) patients and in previously-treated Microsatellite Instability High (MSI)-H/ deficient Mismatch Repair (dMMR) metastaic Colorectal Cancer (mCRC) patients; and removal of clinical hold from Ph II trial of Axalimogene filolisbac + Durvalumab. In our trivia section, find out what is a Fast Track designation by FDA and if you need info about any cancer-related term then key it in the NCI widget.

https://www.cancer.gov/publishedcontent/Js/TermDictionaryWidgetEnglish.js (https://www.cancer.gov/publishedcontent/Js/TermDictionaryWidgetEnglish.js)

ONCO-THIS-WEEK TRIVIA

WHAT IS A FAST TRACK DESIGNATION?



EXPEDITING THE REVIEW PROCESS

Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier.

HOW IS THE DRUG MAKING A DIFFERENCE?

Any drug being developed to treat or prevent a condition with no current therapy obviously is directed at an unmet need. If there are available therapies, a fast track drug must show some advantage over available therapy.

WHERE THE DRUG SHOULD SCORE?

- Showing superior efficacy
- Avoiding serious side effects
- Improving the diagnosis of a serious condition where early diagnosis results in an improved outcome
- Decreasing a clinical significant toxicity of an available therapy

HOW DOES FDA HELP?

- More frequent meetings with FDA to discuss the drug's development plan
- More frequent written communication from FDA about such things as the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval and Priority Review, if relevant criteria are met

WHAT MORE DOES FDA OFFER?

Rolling Review, which means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed.

SOURCE:
https://www.fda.gov/forpatients/approvals/fast/ucm405399.htm

(https://io.wp.com/sciwri.club/wp-content/uploads/2018/07/Onco-this-Week-Trivia-2.png?ssl=1)

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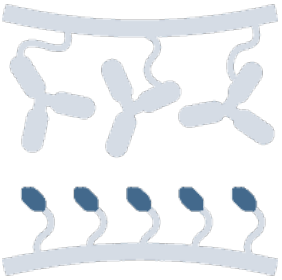

(https://io.wp.com/sciwri.club/wp-content/uploads/2018/07/ssoc_for_biochemistry.png?ssl=1)

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"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."

DRUG APPROVALS

Health Canada approves Osimertinib in 1L treatment for EGFR-mutated NSCLC based on Ph III FLAURA trial data (https://www.astrazeneca.ca/content/az-ca/media/press-releases/2018/health-canada-approves-tagrisso---osimertinib--as-first-line-tre.html)

"The approval of Tagrisso in this first-line setting represents a major advancement in the treatment of EGFR mutated lung cancer," said Dr. Glenwood Goss, Professor of Medicine, University of Ottawa, and Director of Clinical and Translational Research at the Ottawa Hospital Cancer Centre. "As an oncologist, I believe in using the best treatment first, and Tagrisso has shown to significantly extend progression-free survival and improve treatment of central nervous system metastases as a first-treatment of EGFR mutation positive non-small cell lung cancer. I am pleased to be able to offer this life-altering treatment as a first-line option to patients who need it."

> Dr. Suresh Ramalingam explains how the mechanisms of resistance to Osimertinib are different based on whether it's used in 1st line or 2nd line: https://t.co/XQ8VidwkJu (https://t.co/XQ8VidwkJu) #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) #LCSM (https://twitter.com/hashtag/LCSM?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/P47Y2PCa9V (https://t.co/P47Y2PCa9V)
>
> — OncologyEducation (@OncEd) July 13, 2018 (https://twitter.com/OncEd/status/1017755856513970176?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)

Health Canada approves Nivolumab + Ipilimumab in 1L mRCC patients based on Ph III CheckMate-214 data (https://www.bms.com/ca/en/media/press-release-listing/2005-09-15-press-release1.html)

"The incidence of RCC has steadily risen over the past decade and many patients still succumb to this disease," said Dr. Daniel Heng, medical oncologist, Tom Baker Cancer Center and clinical professor at the Cumming School of Medicine, University of Calgary. "For patients with intermediate and poor-risk prognosis which represents the majority of RCC patients, providing a treatment option that can significantly improve survival rates is an important advancement and has the potential to become a new standard of care."

Nivolumab + Ipilimumab approved in MSI-H/dMMR mCRC patients who progressed following treatment with a fluoropyrimidine, oxaliplatin and irinotecan based on CheckMate-142 trial data (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibbs-opdivo-nivolumab-low-dose-yervoy-ipilimu)

> Dr. Andre shared the results of the CheckMate-142 study in metastatic colorectal cancer, declaring this is only the beginning for immunotherapy in this treatment landscape.https://t.co/dyfojlWgXc (https://t.co/dyfojlWgXc)#ColorectalCancer (https://twitter.com/hashtag/ColorectalCancer?src=hash&ref_src=twsrc%5Etfw) #crcsm (https://twitter.com/hashtag/crcsm?src=hash&ref_src=twsrc%5Etfw)
>
> — Targeted Oncology (@TargetedOnc) July 10, 2018 (https://twitter.com/TargetedOnc/status/1016532511445405696?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)

"Bristol-Myers Squibb is pleased to bring forward *Opdivo* plus *Yervoy* as the first I-O/I-O combination therapy to be approved in this type of colorectal cancer," said Ian M. Waxman, M.D., development lead, gastrointestinal cancers, Bristol-Myers Squibb. "Our commitment to studying *Opdivo* plus *Yervoy*, which target distinct but complementary immune pathways, results from our strong belief that rational combinations in biomarker-selected populations may improve clinical benefit for patients."

REGULATORY NEWS

FDA lifted clinical hold on Ph II trial of Axalimogene filolisbac + Durvalumab in HPV-associated cervical and head and neck cancer patients (http://ir.advaxis.com/press-release/clinical-data-updates/advaxis-announces-fda-lifts-clinical-hold-phase-12-combination)

> Advaxis Announces FDA Lifts Clinical Hold on Phase 1/2 Combination Study of Axalimogene Filolisbac with Durvalumab https://t.co/zVXgX4EkcG (https://t.co/zVXgX4EkcG) pic.twitter.com/FbmBBtQ2P7 (https://t.co/FbmBBtQ2P7)
>
> — PharmaMKT (@PharmaMKTnet) July 13, 2018 (https://twitter.com/PharmaMKTnet/status/1017766528681463808?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)

"We are pleased to have resolved this issue with the FDA and will implement these guidelines across Advaxis' portfolio as needed, to ensure patient safety. We remain confident in the safety of axalimogene filolisbac based on our experience in treating approximately 400 patients and more than 1200 doses across multiple trials in HPV-associated cancers," said Kenneth A. Berlin, President and Chief Executive Officer of Advaxis.

Priority review granted to Pembrolizumab in previously treated HCC patients based on Ph II KEYNOTE-224 data; PDUFA: Nov. 9, 2018 (http://www.mrknewsroom.com/news-release/oncology-newsroom/fda-grants-priority-review-mercks-supplemental-biologics-license-ap-2)

> The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) has granted priority review for #Keytruda (https://twitter.com/hashtag/Keytruda?src=hash&ref_src=twsrc%5Etfw) (pembrolizumab) as a treatment for previously treated patients with advanced hepatocellular carcinomahttps://t.co/QVV8FKfMM3 (https://t.co/QVV8FKfMM3) pic.twitter.com/VetwdiiHrh (https://t.co/VetwdiiHrh)
>
> — AJMC (@AJMC_Journal) July 12, 2018 (https://twitter.com/AJMC_Journal/status/1017385586577903618?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"There continues to be a significant need for new options in the treatment of advanced hepatocellular carcinoma, which is the most common type of liver cancer," said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. "The data supporting our application provide a clear rationale for the advancement of the KEYTRUDA clinical program for hepatocellular carcinoma, and we are grateful for the opportunity to work with the FDA to potentially bring KEYTRUDA to patients living with this difficult-to-treat cancer."

sNDA submitted for Venetoclax in 1L AML patients ineligible for intensive chemotherapy based on data from M14-358 and M14-387 trials (https://news.abbvie.com/news/abbvie-announces-submission-supplemental-new-drug-application-to-us-fda-for-venetoclax-in-newly-diagnosed-acute-myeloid-leukemia-patients-ineligible-for-intensive-chemotherapy.htm)

> , @AbbVie (https://twitter.com/abbvie?ref_src=twsrc%5Etfw) has filed its #Venclexta (https://twitter.com/hashtag/Venclexta?src=hash&ref_src=twsrc%5Etfw) (#venetoclax (https://twitter.com/hashtag/venetoclax?src=hash&ref_src=twsrc%5Etfw)) and hopes it could change the treatment of one of the most aggressive #cancers (https://twitter.com/hashtag/cancers?src=hash&ref_src=twsrc%5Etfw) – #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) – #acute (https://twitter.com/hashtag/acute?src=hash&ref_src=twsrc%5Etfw) myeloid #leukaemia (https://twitter.com/hashtag/leukaemia?src=hash&ref_src=twsrc%5Etfw) – https://t.co/YVIAgByWjz (https://t.co/YVIAgByWjz) #pharma (https://twitter.com/hashtag/pharma?src=hash&ref_src=twsrc%5Etfw) #pharmanews (https://twitter.com/hashtag/pharmanews?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/IDMUeGP4mO (https://t.co/IDMUeGP4mO)
>
> — pharmaphorum (@pharmaphorum) July 13, 2018 (https://twitter.com/pharmaphorum/status/1017740576442249216?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"AML is an especially lethal and aggressive form of blood cancer with limited advances in care in three decades and few treatment options for patients ineligible for intensive chemotherapy," said Michael Severino, M.D., executive vice president of research and development and chief scientific officer, AbbVie. "The data submitted to the FDA may potentially reshape how AML is treated. We look forward to working with the FDA and other health authorities during the review of these data."

IND submitted for UGN-102 (VesiGel™) for the Treatment of Low-Grade NMIBC (http://investors.urogen.com/phoenix.zhtml?c=254372&p=irol-newsArticle&ID=2357799)

> UroGen Pharma Submits Investigational New Drug IND Application for UGN102 VesiGel: UroGen Pharma NasdaqURGN a clinicalstage biopharmaceutical company developing treatments to address unmet needs in the field of urology with a focus on urooncology today... https://t.co/BicqccC1Bo (https://t.co/BicqccC1Bo)
>
> — Urology News (@Urology_Bio) July 11, 2018 (https://twitter.com/Urology_Bio/status/1017097958007832576?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The IND submission of UGN-102 is a significant milestone for our RTGel™ technology platform. With UGN-102, we have a great opportunity to provide the first non-surgical alternative for patients suffering from chronically relapsing LG NMIBC," said Mark Schoenberg, M.D., Chief Medical Officer of UroGen. "The positive data observed in the Phase 3 trial of our lead product candidate, UGN-101 (MitoGel®), is a strong validation of our platform. We are encouraged by the efficacy and durability data generated in a Phase 2a European study of UGN-102 and if our IND is accepted, look forward to beginning the clinical trial in the United States."

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

> OBI Pharma's OBI-3424 is granted Orphan Drug Designation by FDA in ... https://t.co/ZiAa119dUf (https://t.co/ZiAa119dUf) #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) #livercancer (https://twitter.com/hashtag/livercancer?src=hash&ref_src=twsrc%5Etfw) #HCC (https://twitter.com/hashtag/HCC?src=hash&ref_src=twsrc%5Etfw) #OBI3424 (https://twitter.com/hashtag/OBI3424?src=hash&ref_src=twsrc%5Etfw) #OBIPharma (https://twitter.com/hashtag/OBIPharma?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/HbtddXCGpx (https://t.co/HbtddXCGpx)
>
> — TRM Oncology (@TRMoncology) July 13, 2018 (https://twitter.com/TRMoncology/status/1017564553352269824?ref_src=twsrc%5Etfw)

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Amy Huang, General Manager of OBI Pharma, noted, "The orphan drug designation for OBI-3424 by the FDA is a significant step in the development of this drug candidate. OBI-3424 is intended to treat a devastating form of Liver Cancer with limited therapeutic 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 this disease".

CLR 131 receives FDA orphan drug designation for treatment of Ewing's Sarcoma (https://www.cellectar.com/news-media/press-releases/detail/179/cellectars-clr-131-receives-fda-orphan-drug-designation)

> .@US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) grants orphan drug designation to CLR 131 for Ewing #sarcoma (https://twitter.com/hashtag/sarcoma?src=hash&ref_src=twsrc%5Etfw) @CellectarBio (https://twitter.com/CellectarBio?ref_src=twsrc%5Etfw) https://t.co/jzLT5PbgJc (https://t.co/jzLT5PbgJc)
>
> — HemOnc Today (@HemOncToday) July 10, 2018 (https://twitter.com/HemOncToday/status/1016740641987022849?ref_src=twsrc%5Etfw)

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"Ewing's sarcoma is the second most common bone malignancy among children and adolescents and there are limited treatment options for patients who relapse or become refractive to therapy," said John Friend, M.D., chief medical officer of Cellectar. "The ODD for Ewing's sarcoma represents another important milestone for our CLR 131 pediatric program as we work to bring new options to patients suffering from rare cancers."

TRIAL RESULTS

Tucatinib + T-DM1 show acceptable toxicity and preliminary antitumor activity in heavily pretreated patients with ERBB2/HER2-positive metastatic breast cancer with and without brain metastases (http://www.coloradocancerblogs.org/promising-clinical-trial-results-of-tucatinib-with-t-dm1-against-her2-breast-cancer/?utm_source=feedburner&utm_medium=email&utm_campaign=Feed%3A+ColoradoCancerBlogs+%28Colorado+Cancer+Blogs%29)

> Phase 1b clinical trial results of combining tucatinib with T-DM1 show promise for heavily pretreated HER2-positive breast cancer: https://t.co/vbDrKqgqia (https://t.co/vbDrKqgqia)
>
> — Omnia Education (@OmniaEducation) July 13, 2018 (https://twitter.com/OmniaEducation/status/1017801212131934208?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"At University of Colorado Cancer Center, we've worked with this drug since it was discovered by ARRAY BioPharma in Boulder. First it was ARRAY-380, then ONT-380 and now it's called tucatinib. Since then, our institution has taken a lead effort in bringing it into trials and now into places where we are seeing it provide real benefit for women," says Virginia Borges, MD, MMSc, director of the Breast Cancer Research Program and Young Women's Breast Cancer Translational Program at CU Cancer Center.

"One of the best things about this drug is that it combines well with nearly everything. It is so well tolerated that when you test tucatinib in combination with other drugs, it feels like you're just giving the other drug. It's a pill. It works. And it hardly causes side effects. It's really a doctor's dream," Borges says.

Ixazomib post-transplant maintenance improves PFS in MM patients; Ph III TOURMALINE-MM3 study meets its primary endpoint (https://www.takeda.com/newsroom/newsreleases/2018/phase-3-trial-of-ninlaro-ixazomib-as-maintenance-therapy-met-primary-endpoint-demonstrating-statistically-significant-improvement-in-progression-free-survival-in-patients-with-multiple-myeloma-post-transpla)

> Phase 3 Trial of NINLARO® (ixazomib) as Maintenance Therapy Met Primary Endpoint Demonstrating Statistically Significant Improvement in Progression-Free Survival in Patients with #MultipleMyeloma (https://twitter.com/hashtag/MultipleMyeloma?src=hash&ref_src=twsrc%5Etfw) Post-Transplant — CheckOrphan https://t.co/j9v1AYZUpO (https://t.co/j9v1AYZUpO)
>
> — Rare Diseases (@CheckOrphan) July 12, 2018 (https://twitter.com/CheckOrphan/status/1017423412124405760?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Within the maintenance setting, it is critical that we find agents that are efficacious, tolerable and convenient," said Jesús Gomez Navarro, M.D., Vice President, Head of Oncology Clinical Research and Development, Takeda. "The results of the TOURMALINE-MM3 trial represent an important step toward the goal of expanding the use of NINLARO as a maintenance therapy. This is the first and only Phase 3 placebo-controlled study evaluating a proteasome inhibitor in this setting and we look forward to discussions with Health Authorities around the world."

FAILED TRIAL: Ibrutinib didn't improve efficacy when added to R-CHOP in Ph III DBL3001 study (https://news.abbvie.com/news/press-releases/abbvie-provides-update-on-phase-3-study-ibrutinib-imbruvica-in-blood-cancer-diffuse-large-b-cell-lymphoma-dlbcl-and-ongoing-ibrutinib-clinical-program.htm)

> Phase 3 study evaluating #ibrutinib (https://twitter.com/hashtag/ibrutinib?src=hash&ref_src=twsrc%5Etfw) combined with R-CHOP for the treatment of #DLBCL (https://twitter.com/hashtag/DLBCL?src=hash&ref_src=twsrc%5Etfw) does not show additional efficacy compared with standard of care.
>
> Read more: https://t.co/MZru8mDjIo (https://t.co/MZru8mDjIo) pic.twitter.com/BqBZtFS07f (https://t.co/BqBZtFS07f)
>
> — Rare Disease Report (@RareDR) July 13, 2018 (https://twitter.com/RareDR/status/1017846627007004672?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Since its first U.S. FDA approval in 2013, IMBRUVICA has redefined standard of care in many different blood cancers – several of which had little to no treatment options available to patients before," said Thorsten Graef, M.D., Ph.D., Head of Clinical Development at Pharmacyclics LLC, an AbbVie company. "These medical achievements reflect our objective of focusing research where there is great unmet patient need and understanding that the nature of research is such that some studies succeed and others do not. We continue to believe that ibrutinib has great untapped potential as a cancer treatment alone or in combination. Together with our global partner Janssen, we are advancing our robust ibrutinib scientific development program and anticipate results from several studies in the future."

FAILED TRIAL: No PFS improvement seen in B-cell aNHL patients treated with gemcitabine + rituximab in Ph III (PIX306) trial (http://investors.ctibiopharma.com/phoenix.zhtml?c=92775&p=irol-newsArticle&ID=2357334)

> Dr. Craig said, "We would like to express our appreciation to the patients, families, and investigators who participated in the study," https://t.co/ZIwLitQDdB (https://t.co/ZIwLitQDdB) Read more on the results from the PIX306 trial. #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) #cancerresearch (https://twitter.com/hashtag/cancerresearch?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/5vQrNQtnTT (https://t.co/5vQrNQtnTT)
>
> — Targeted Oncology (@TargetedOnc) July 12, 2018 (https://twitter.com/TargetedOnc/status/1017227115274604544?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are disappointed with the outcome of the PIX306 trial and will proceed to conduct a thorough review of clinical data to assess the next steps for the PIXUVRI program," commented Adam Craig, MD, PhD, CEO of CTI BioPharma. "We would like to express our appreciation to the patients, families and investigators who participated in the study."

TRIAL STATUSES

First patient dosed in Ph II innovaTV 207 trial evaluating TF-targeting MMAE ADC, Tisotumab Vedotin, in Multiple Solid Tumors (http://investor.seattlegenetics.com/phoenix.zhtml?c=124860&p=RssLanding&cat=news&id=2357993)

> Seattle Genetics Announces First Patient Dosed in Phase 2 innovaTV 207 Trial Evaluating Tisotumab Vedotin in Multiple #SolidTumors (https://twitter.com/hashtag/SolidTumors?src=hash&ref_src=twsrc%5Etfw) — CheckOrphan https://t.co/APJWLBwC7r (https://t.co/APJWLBwC7r) @cancer (https://twitter.com/cancer?ref_src=twsrc%5Etfw) @AmericanCancer (https://twitter.com/AmericanCancer?ref_src=twsrc%5Etfw)
>
> — Rare Diseases (@CheckOrphan) July 13, 2018 (https://twitter.com/CheckOrphan/status/1017800974302408704?ref_src=twsrc%5Etfw)

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"The initiation of the phase 2 innovaTV 207 basket trial will enable us to explore the safety and activity of tisotumab vedotin in several tumor types where Tissue Factor is also expressed and is intended to inform a potentially broad development program that maximizes the opportunity for this ADC beyond cervical cancer," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics.

Positive outcome from Safety Review Committee for AST-VAC2; recommends continuation of trial in advanced NSCLC patients (http://asteriasbiotherapeutics.com/inv_news_releases_text.php?releaseid=2357777&date=July+11%2C+2018&title=Asterias+Biotherapeutics+Announces+Positive+Outcome+from+Safety+Review+Comm VAC2%3B+Recommends+Continuation+of+Clinical+Trial+in+Non-Sma)

> $AST (https://twitter.com/search?q=%24AST&src=ctag&ref_src=twsrc%5Etfw) Asterias up 26% premarket on advancement of AST-VAC2 https://t.co/cCkyfPdQ8P (https://t.co/cCkyfPdQ8P) pic.twitter.com/MaaQlDLOtP (https://t.co/MaaQlDLOtP)
>
> — Maria Chaudhry (@mchaudhry82) July 11, 2018 (https://twitter.com/mchaudhry82/status/1017018636953948160?ref_src=twsrc%5Etfw)

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"Based on its review of all available study data after five doses in the first patient, the Safety Review Committee's recommendation to continue the trial without modification reaffirms our belief that AST-VAC2 is safe and well-tolerated," commented Dr Edward Wirth, Chief Medical Officer of Asterias Biotherapeutics. "The committee concluded that the trial can proceed as planned per protocol – an important step as we continue the clinical development of AST-VAC2."

Ph II trial of CEA and MUC1-targeting vaccine CV301 + NIVOLUMAB starts in mCRC patients (http://www.bavarian-nordic.com/investor/news/news.aspx?news=5474)

> Bavarian Nordic Initiates Ph2 Trial of Combi of CV301 & Nivolumab in Metastatic Colorectal Cancer https://t.co/ows8lbokSo (https://t.co/ows8lbokSo) @BavarianNordic (https://twitter.com/BavarianNordic?ref_src=twsrc%5Etfw) More Scandinavian life science news at [LSE] at https://t.co/Nt55XtypAT (https://t.co/Nt55XtypAT) pic.twitter.com/HmCwd8GTyB (https://t.co/HmCwd8GTyB)
>
> — [iito] Life Science (@iitoLifeScience) July 11, 2018 (https://twitter.com/iitoLifeScience/status/1016987353137733632?ref_src=twsrc%5Etfw)

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"We are thrilled to see the first dose administered in this trial to evaluate the combination therapy of CV301 and nivolumab in patients with resectable, oligometastatic, microsatellite stable colorectal cancer (MSS)," said Paul Chaplin, President and CEO of Bavarian Nordic. "While checkpoint inhibitors have been impressive in some tumors, there are hundreds of thousands of cancer patients in dire need of new treatments, particularly in MSS. We are eager to explore how CV301 enhances the overall survival and lowers the risk of reoccurrence in these patients."

OncBioMune to commence Ph II Trial of ProscaVax for early stage prostate cancer patients (http://oncbiomune.com/2018/06/20/oncbiomune-to-commence-phase-2-trial-of-proscavax-for-early-stage-prostate-cancer-patients/)

> OncBioMunes Phase 2 Clinical Trial of ProscaVax for EarlyStage #prostate (https://twitter.com/hashtag/prostate?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) is Now Included on https://t.co/iUSGxpXivD (https://t.co/iUSGxpXivD): BATON ROUGE La. July 09 2018 GLOBE NEWSWIRE OncBioMune Pharmaceuticals Inc. OTCQBOBMP "OncBioMune" or the "Company" a... https://t.co/kgnKfsC7Wr (https://t.co/kgnKfsC7Wr)
>
> — Prostate Cancer News (@CancerProstate1) July 9, 2018 (https://twitter.com/CancerProstate1/status/1016352699783102464?ref_src=twsrc%5Etfw)

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“We are making the final preparations to initiate enrollment, including planned site visits,” commented Dr. Jonathan Head, Chief Executive Officer at OncBioMune. “Underscored by the compelling data derived from the successfully completed Phase 1a clinical trial and our other research, we are eager to proceed with this study. Our goal is simple: to provide a safe, nontoxic. front-line therapy for prostate cancer patients that are otherwise left with either no therapy or with much more invasive options that typically have very unpleasant side effects, such as impotence or urinary incontinence. I’d like to express my gratitude for all the shareholders that have supported us throughout the process to advance our company to this next stage of ProscaVax development. I believe there is a bright future ahead of us.”

Enrollment completed for the enfortumab vedotin EV-201 pivotal ph II trial cohort in locally advanced or metastatic urothelial cancer pts previously treated with both platinum chemotherapy and a checkpoint inhibitor (https://newsroom.astellas.us/2018-07-09-Seattle-Genetics-and-Astellas-Announce-Progress-in-Enfortumab-Vedotin-Urothelial-Cancer-Clinical-Development-Program)

> Seattle Genetics & Astellas urothelial #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) trial on enfortumab vedotin https://t.co/rcQtH1xu53 (https://t.co/rcQtH1xu53) #pharma (https://twitter.com/hashtag/pharma?src=hash&ref_src=twsrc%5Etfw) #health (https://twitter.com/hashtag/health?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/zgHl4gJGCN (https://t.co/zgHl4gJGCN)
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> — Pf Magazine (@Pharmafield) July 12, 2018 (https://twitter.com/Pharmafield/status/1017365209080565760?ref_src=twsrc%5Etfw)

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“With enfortumab vedotin, we have the opportunity to address some of the unmet need in advanced urothelial cancer,” said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics. “With our partners Astellas, we are pleased to advance the enfortumab vedotin clinical trial program with the vision of bringing a new treatment option to patients with advanced urothelial cancer worldwide.”

“Despite recent treatment advances, the unfortunate reality is that many patients with metastatic urothelial cancer currently find that their disease will progress after anti-PD-1 or PD-L1 therapy, highlighting the need to identify additional therapeutic options,” said Steven Benner, M.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development, Astellas. “Following encouraging results from our ongoing phase 1 study, we and our partners at Seattle Genetics decided to proceed with these registrational trials. We look forward to future clinical development milestones for enfortumab vedotin.”

COLLABORATIONS

Genmab and Immatics to discover and develop Next Generation Bispecific Cancer Immunotherapies (http://ir.genmab.com/news-releases/news-release-details/genmab-enters-strategic-partnership-immatics-discover-and)

> Good luck @Genmab (https://twitter.com/Genmab?ref_src=twsrc%5Etfw) and @immatics (https://twitter.com/immatics?ref_src=twsrc%5Etfw)! – #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) https://t.co/y9BSc9pAuQ (https://t.co/y9BSc9pAuQ)
>
> — Labiotech.eu (@Labiotech_eu) July 12, 2018 (https://twitter.com/Labiotech_eu/status/1017446034790809600?ref_src=twsrc%5Etfw)

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“This collaboration with Immatics gives us the opportunity to combine our unique technologies and expertise to create differentiated novel next-generation therapies. We very much look forward to this exciting partnership in the field of cancer immunotherapy,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Carsten Reinhardt, M.D., Ph.D., Chief Medical Officer and Managing Director of Immatics, commented: “We are very pleased to join forces with one of the world-leading biotechnology companies to develop and advance novel and highly active cancer therapeutics. This collaboration underpins Immatics’ leadership in intracellular tumor target identification and T-cell receptor engineering.” Dr. Reinhardt further said: “Our bispecific TCR technology exhibits exceptional potency and favourable pharmacokinetic properties by combining Immatics’ proprietary T-cell engaging format with our high-affinity and highly specific T-cell receptors as reported at AACR 2018.”

TRIO announces collaboration with Novartis on Phase III NATALEE trial of ribociclib (https://www.trioncology.org/news/trio-awarded-natalee-study-largest-single-phase-iii-breast-cancer-clinical-trial-in-its-history/)

> “This is just the beginning – it’s huge. This is a very exciting drug.” – Elgene Lim, #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) researcher & oncologist @GarvanInstitute (https://twitter.com/GarvanInstitute?ref_src=twsrc%5Etfw) @SVHSydney (https://twitter.com/SVHSydney?ref_src=twsrc%5Etfw) . Ribociclib (Kisqali) now available through the #PBS (https://twitter.com/hashtag/PBS?src=hash&ref_src=twsrc%5Etfw) @GregHuntMP (https://twitter.com/GregHuntMP?ref_src=twsrc%5Etfw) https://t.co/TkqsIlMAae (https://t.co/TkqsIlMAae) pic.twitter.com/aX8jn8qEcV (https://t.co/aX8jn8qEcV)
>
> — Garvan Institute (@GarvanInstitute) July 2, 2018 (https://twitter.com/GarvanInstitute/status/1013762792745140225?ref_src=twsrc%5Etfw)

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“Ribociclib in combination with hormonal therapy has been demonstrated to be an effective treatment for advanced breast cancer in three large, Phase III clinical trials as well as in clinical practice around the world,” says Samit Hirawat, MD, Executive Vice President, Head of Novartis Oncology Global Drug Development. “We are pleased to collaborate with TRIO, its study investigators and patients to advance ribociclib in combination with endocrine therapy as a potential new treatment option for patients with early-stage breast cancer.”

MabVax Therapeutics licenses its antibody development program targeting multiple solid tumor cancers to Boehringer Ingelheim (https://www.mabvax.com/news-media/press-releases/detail/132/mabvax-therapeutics-and-boehringer-ingelheim-sign-asset)

> MabVax Secures $11 Million from Boehringer Ingelheim for Antibody Development Program https://t.co/ZD9KkSZh27 (https://t.co/ZD9KkSZh27) pic.twitter.com/oHCNCUjO2h (https://t.co/oHCNCUjO2h)
>
> — Corixis (@Corixis) July 9, 2018 (https://twitter.com/Corixis/status/1016357812597764098?ref_src=twsrc%5Etfw)

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“We are very pleased to have Boehringer Ingelheim as a major industry partner to further develop one of our preclinical antibody assets based on our proprietary HuMab technology,” said David Hansen, President and CEO of MabVax Therapeutics. “This agreement with Boehringer Ingelheim recognizes the value of our innovative approach to discovering novel antibodies to diagnose and treat cancer. We have been committed since the founding of the Company to discovering and developing unique fully human antibodies to diagnose and treat patients with cancers where there remain significant unmet medical needs.”

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.

Cover Image: (Colorized scanning electron micrograph showing two lung cancer cells. These cells were grown using cell culture techniques. B0007782 Lung cancer cells. Wellcome Images available under the following creative commons usage http://creativecommons.org/licenses/by-nc-nd/2.0/uk/

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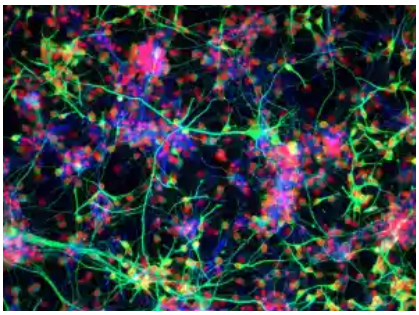

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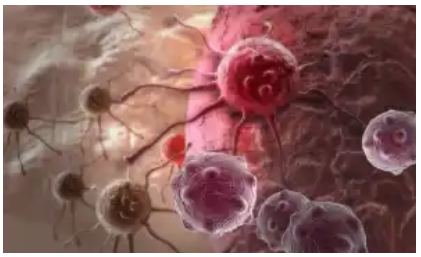

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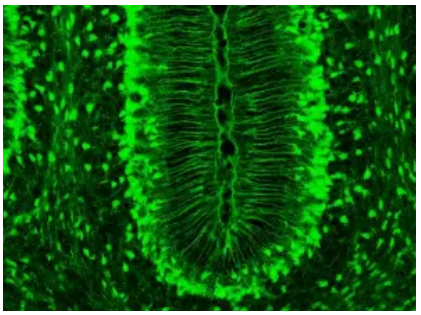

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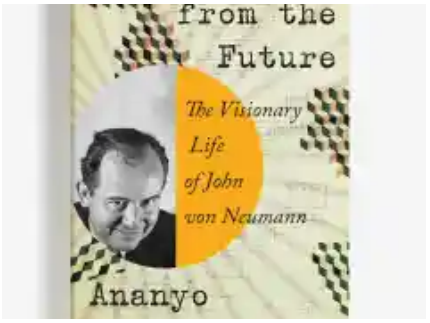

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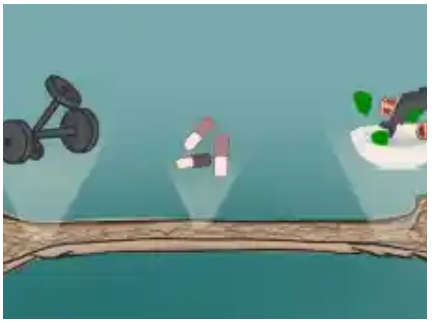

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