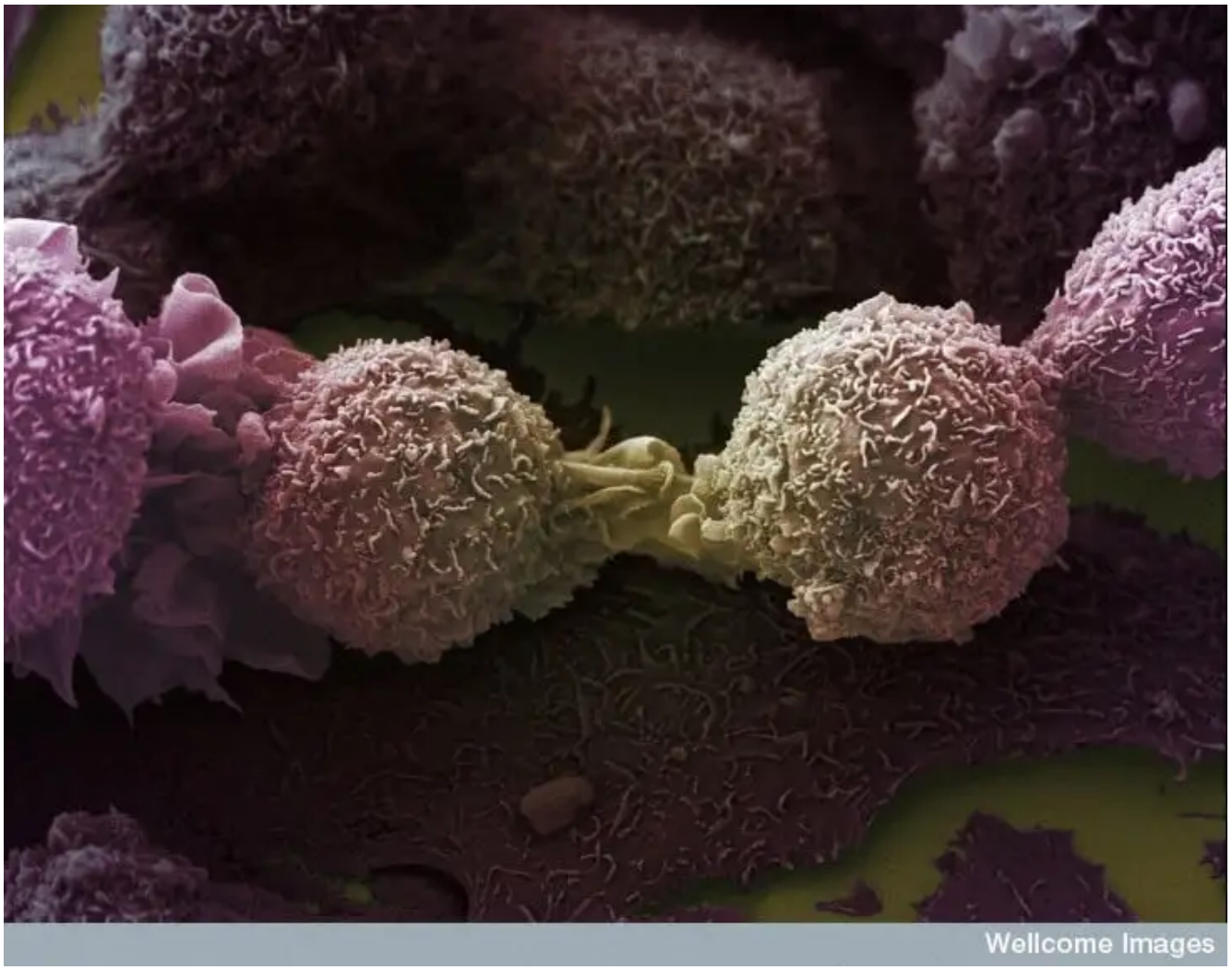
Archives (https://sciwri.club/archives/category/archives)

Onco-this-Week

April 29, 2018(https://sciwri.club/archives/date/2018/04/29)



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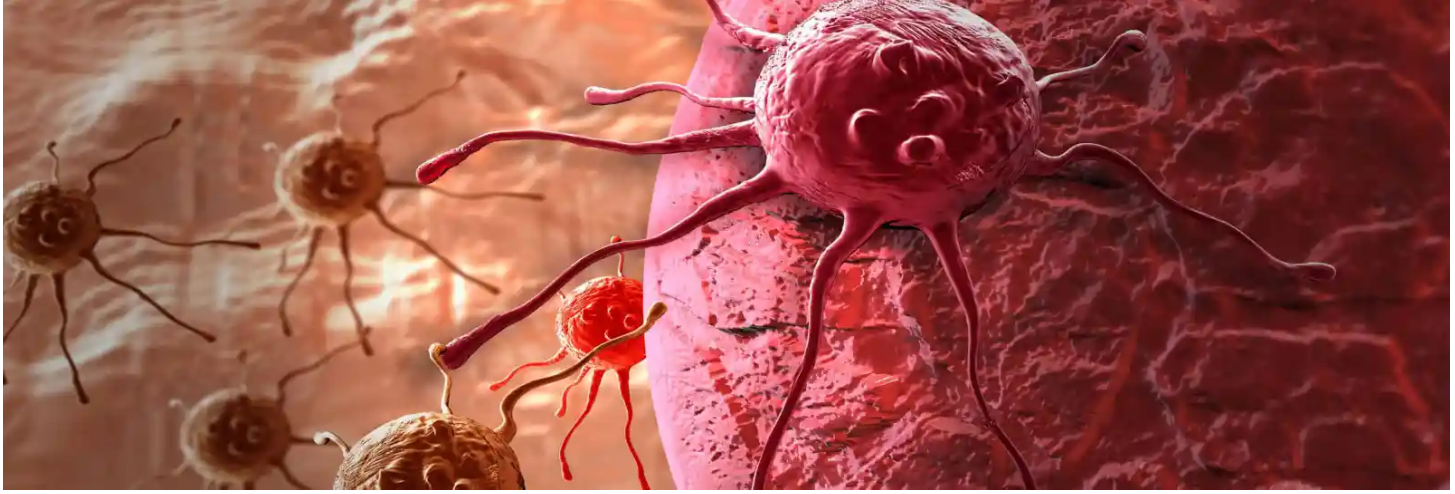
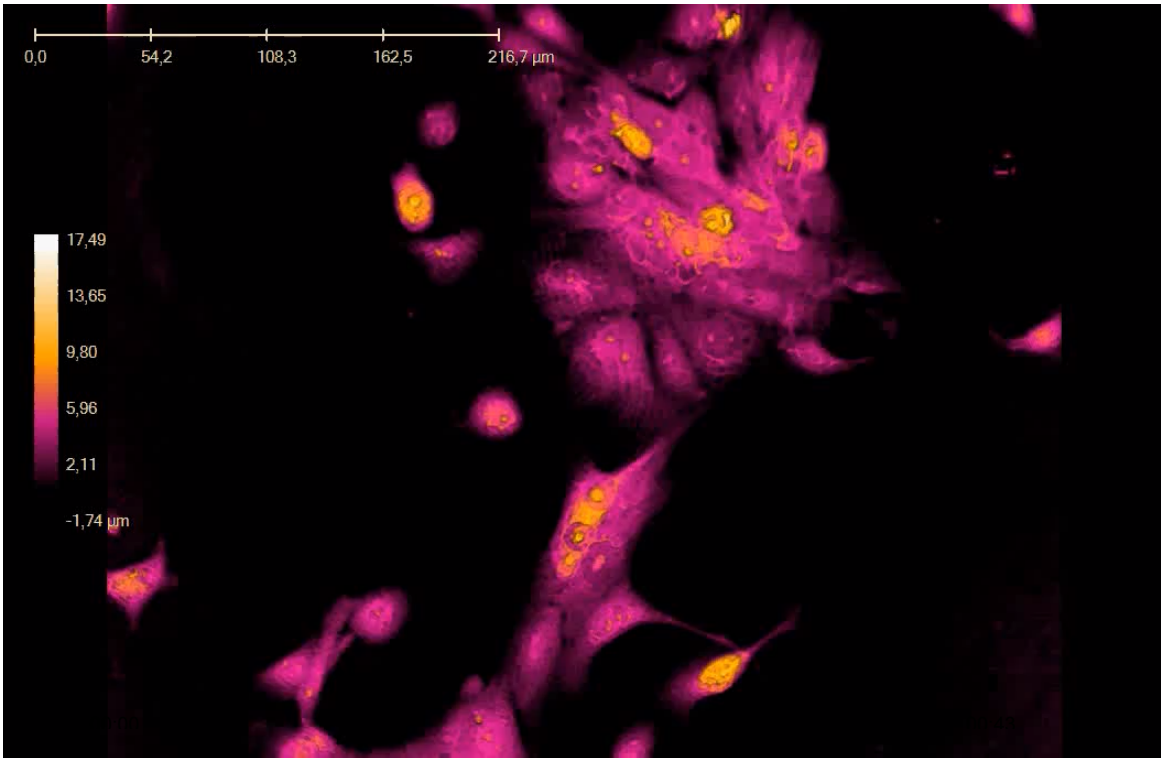


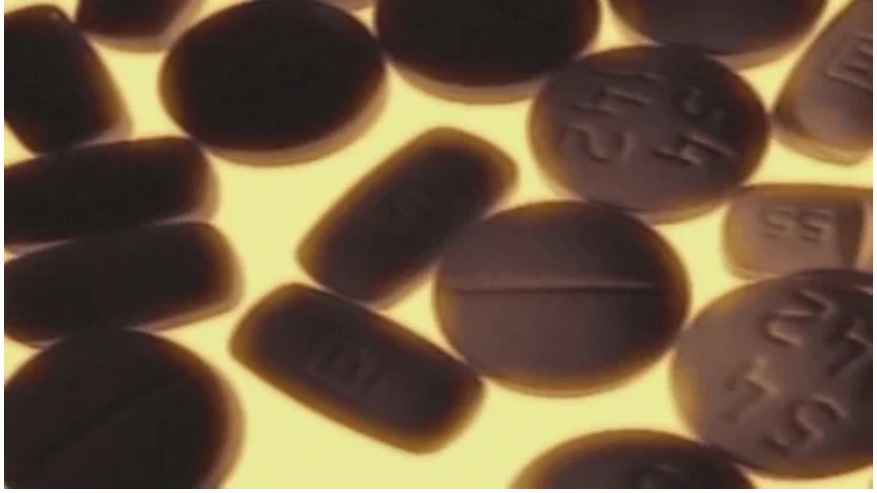
(https://i0.wp.com/sciwri.club/wp-content/uploads/2018/04/Cancer-cell.jpg?ssl=1)

Editor's Note: In Onco-this-Week, we have news about FDA approvals for a previously untreated form of leukemia (CD33+ AML) as well as the approval of Astra Zeneca's Targrisso, a first line treatment against EGFR-mutated NSCLC. Highlights in regulatory news include the fast-tracking of Immuno-Oncology candidate Balixafortide by FDA for metastatic breast cancer and a trial failure in Phase III for AstraZeneca immunotherpy combo durvalumab+ tremelimumab. Check out all this and more in an exhaustive issue of Onco-this-Week put together by Richa Tewari for bringing the latest in Oncology at your fingertips. Our educational video section demonstrates the cell proliferation process in breast cancer cells (a hallmark of cancer) and don't miss a detailed infographic on how innovations in oncology are changing the landscape of fight against cancer. We hope you enjoy this issue of Onco-this-Week and share the blog too!- Abhi Dey

Educational Video: Digital holographic microscopy video showing cell division of unlabeled JIMT-1 breast cancer cells. During the video, spanning over 72 hours, one cell divides into three daughter cells (seen on top of the cell cluster in the upper right portion of the image). One of the daughter cell dies, and two cells merge. The height of the cells is color coded by the vertical look up bar on the left of the image. (Source: Cell Image library (http://cellimagelibrary.org/images/43451) Public Domain)



DRUG APPROVALS



via GIPHY (https://giphy.com/gifs/pills-2xsMgBlSKS96U)

US FDA approves Osimertinib as 1L treatment for EGFR-mutated NSCLC (https://www.astrazeneca.com/media-centre/press-releases/2018/us-fda-approves-tagrisso-as-1st-line-treatment-for-EGFR-mutated-non-small-cell-lung-cancer.html)

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit at AstraZeneca, said: "Today's FDA approval of Tagrisso in the 1st-line setting is an exciting milestone for patients and our company. Tagrisso delivered unprecedented median progression-free survival data across all pre-specified patient subgroups, including patients with or without CNS metastases, and could prolong the lives of more patients without their tumours growing or spreading."

Dr. Suresh S. Ramalingam, Principal Investigator of the FLAURA trial, from Winship Cancer Institute of Emory University, Atlanta, said: "The approval of osimertinib in the 1st-line setting represents a major advance in the treatment of patients with EGFR mutations and a significant change in the treatment paradigm. Osimertinib provides robust improvements in progression-free survival with no unexpected safety signals compared to the previous generation of EGFR inhibitors."

> FDA Approves Osimertinib for Treatment of Non-Small Cell Lung Cancer https://t.co/ziuSapQIoy (https://t.co/ziuSapQIoy) pic.twitter.com/RqpZpcXsWA (https://t.co/RqpZpcXsWA)
>
> — SpecialtyPTimes (@SpecialtyPTimes) April 25, 2018 (https://twitter.com/SpecialtyPTimes/status/989172192884789251?ref_src=twsrc%5Etfw)

Gemtuzumab ozogamicin + chemotherapy approved for the treatment of previously untreated, *de novo*, CD33-positive AML (https://www.businesswire.com/news/home/20180423005633/en/MYLOTARG%E2%84%A2-Approved-EU-Treatment-Previously-Untreated-De)

"The marketing authorization of MYLOTARG provides a much-needed treatment option offering renewed hope for many acute myeloid leukemia patients in Europe," said Andreas Penk, M.D., regional president, Pfizer Oncology. "In clinical trials, the addition of MYLOTARG to standard chemotherapy resulted in deeper, more durable remission, thus providing an additional treatment option with the potential to prevent relapse for these patients."

"I am thrilled that MYLOTARG will be available soon in Europe as a first-line treatment for patients with acute myeloid leukemia," said Doctor Sylvie Castaigne, Professeur des Universités, Université de Versailles – Saint Quentin, Praticien Hospitalier, Centre Hospitalier de Versailles, and lead investigator of the ALFA-0701 study. "This important milestone is a result of close collaboration between Pfizer and clinical investigators around the world, particularly the ALFA investigators in France, who believed in the promise of this therapy. We thank all of

the investigators, nurses and patients who participated in these studies."

> ICYMI: The story of precision treatment of CD33-positive #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) with mylotarg, a Circle Series presentation by Fred Hutch #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) and transplantation experts Drs. Fred Appelbaum, Irv Bernstein and Soheil Meshinchi. https://t.co/ONmnUFaBk4 (https://t.co/ONmnUFaBk4) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/K2QvK09OhN (https://t.co/K2QvK09OhN)
>
> — Fred Hutch (@fredhutch) April 27, 2018 (https://twitter.com/fredhutch/status/989941416116666368?ref_src=twsrc%5Etfw)

LABEL UPDATE: EU approves Nivolumab four-week dosing schedule for advanced melanoma and previously treated RCC (https://news.bms.com/press-release/corporatefinancial-news/european-commission-approves-bristol-myers-squibbs-opdivo-nivo)

"This approval marks a significant achievement in our longstanding commitment to providing patients and healthcare providers with more flexible and convenient treatment options," said Fouad Namouni, M.D., head of development, Oncology, Bristol-Myers Squibb. "Bristol Myers-Squibb is dedicated to addressing the unique needs of patients, and with this approval, we will now be able to offer a range of dosing options for an Immuno-Oncology medicine approved in the European Union."

> European Commission Approves BristolMyers Squibbs Opdivo nivolumab FourWeek Dosing Schedule for Advanced Melanoma and Previously Treated Renal Cell Carcinoma: First and only PD1 inhibitor approved in the EU to offer every fourweek dosing Opdivo also now... https://t.co/FchlLSfvSY (https://t.co/FchlLSfvSY)
>
> — Diabetes News (@bioDiabetes) April 25, 2018 (https://twitter.com/bioDiabetes/status/989243388074516480?ref_src=twsrc%5Etfw)

REGULATORY NEWS

EMA validates Type II variation for 1L Pembrolizumab + Pemetrexed + Platinum chemotherapy in non-sq mNSCLC based on Ph III KEYNOTE-189 data (http://investors.merck.com/news/press-release-details/2018/European-Medicines-Agency-Validates-Type-II-Variation-for-Mercks-KEYTRUDA-pembrolizumab-in-Combination-with-Pemetrexed-ALIMTA-and-Platinum-Chemotherapy-as-First-Line-Therapy-in-Metastatic-Nonsquamo)

"EMA's acceptance of our application for review is based on data from the Phase 3 KEYNOTE-189 trial, which showed first-line treatment with KEYTRUDA in combination with pemetrexed and platinum chemotherapy significantly prolonged overall survival compared to chemotherapy alone in patients with metastatic nonsquamous non-small cell lung cancer, regardless of PD-L1 expression," said Dr. Roger M. Perlmutter, president, Merck Research Laboratories. "We are very pleased that the centralized review process is underway, and are hopeful that this new combination regimen will soon become available for appropriate patients in Europe who have been diagnosed with metastatic lung cancer."

$MRK (https://twitter.com/search?q=%24MRK&src=ctag&ref_src=twsrc%5Etfw) EMA Validates Type II Variation for KEYTRUDA® in Combo w/ Pemetrexed (ALIMTA®) and Platinum Chemotherapy as First-Line Therapy in Metastatic Nonsquamous #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw), Based on Phase 3 KEYNOTE-189 Trial https://t.co/6lXu1i8quo (https://t.co/6lXu1i8quo)

— Odi Bruckman (@odibro) April 23, 2018 (https://twitter.com/odibro/status/988516816015253504?ref_src=twsrc%5Etfw)

US FDA accepts sBLA for Nivolumab in previously treated SCLC patients, grants Priority Review, PDUFA: 16th Aug 2018 (https://news.bms.com/press-release/bristolmyers/us-food-and-drug-administration-accepts-supplemental-biologics-license-ap)

Sabine Maier, development lead, thoracic cancers, Bristol-Myers Squibb, commented, "Small cell lung cancer is a highly aggressive disease, one where most patients experience relapse within a year of diagnosis. The overall prognosis for this cancer remains poor, and there have been no new treatment advances in nearly 20 years. We are pleased with this important step forward in the FDA's consideration to expand the use of Opdivo to patients with small cell lung cancer who have received two or more lines of previous treatment."

RT TFTCS "The Week Ahead In Biotech: PDUFA Dates, Clinical Trials, Merck And Pfizer Earnings On Tap https://t.co/lLykpmCuoC (https://t.co/lLykpmCuoC) pic.twitter.com/R4zCVodP4m (https://t.co/R4zCVodP4m)"

— BullFan2016 (@BullFan2016) April 29, 2018 (https://twitter.com/BullFan2016/status/990669327266435072?ref_src=twsrc%5Etfw)

US FDA grants Fast Track designation to IO candidate Balixafortide (CXCR4 Antagonist) in combination with eribulin as 3L therapy for Metastatic Breast Cancer (https://www.polyphor.com/news/corporate-news-details/?newsid=1689641)

Giacomo Di Nepi, Chief Executive Officer of Polyphor: "We have already identified a development path for balixafortide with input from the FDA to conduct a single pivotal study in this indication. Fast Track designation is another positive step for the development of balixafortide and a recognition of the need for better treatments for this group of patients."

FDA granted fast track status to balixafortide (POL6326)-a selective blocker of the CXCR4 receptor- w/ Halaven (eribulin mesylate) to treat #metastaticBC (https://twitter.com/hashtag/metastaticBC?src=hash&ref_src=twsrc%5Etfw) HER2-. Polyphor pharmaceuticals is preparing Ph2 for patients HER2- #metastaticBC (https://twitter.com/hashtag/metastaticBC?src=hash&ref_src=twsrc%5Etfw) w/ a minimum of two chemotherapy regimens pic.twitter.com/L5y6e7OgM5 (https://t.co/L5y6e7OgM5)

— about_MBC (@about_MBC) April 23, 2018 (https://twitter.com/about_MBC/status/988431241832796160?ref_src=twsrc%5Etfw)

FDA Fast Track Designation Granted to CB-839 in Combination with Cabozantinib for Treatment of advanced RCC Patients (http://ir.calithera.com/news-releases/news-release-details/calithera-biosciences-announces-fda-fast-track-designation-0?field_nir_news_date_value[min]=)

"Despite a number of new therapies for the treatment of renal cell carcinoma, there remains a significant unmet need among advanced patients who have received prior treatment," said Susan Molineaux, PhD, President and Chief Executive Officer of Calithera. "We are pleased that CB-839 has been granted Fast Track designation, demonstrating the FDA's commitment to facilitate the development and expedite the review of our glutaminase

inhibitor as an important new therapy for patients with advanced or metastatic renal cell carcinoma who have failed prior systemic therapy."

> Calithera's CB-839 plus cabozantinib receives FDA Fast Track designation ... https://t.co/JOpjGkx11C (https://t.co/JOpjGkx11C) #Calithera (https://twitter.com/hashtag/Calithera?src=hash&ref_src=twsrc%5Etfw) #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) #renalcellcarcinoma (https://twitter.com/hashtag/renalcellcarcinoma?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/6UvcoNhoFx (https://t.co/6UvcoNhoFx)
>
> — TRM Oncology (@TRMoncology) April 26, 2018 (https://twitter.com/TRMoncology/status/989632818211966978?ref_src=twsrc%5Etfw)

Selinexor Granted Fast Track Designation by FDA for Penta-Refractory Multiple Myeloma (http://investors.karyopharm.com/news-releases/news-release-details/karyopharms-selinexor-receives-fast-track-designation-fda)

"The designation of Fast Track for selinexor represents important recognition by the FDA of the potential of this anti-cancer agent to address the significant unmet need in the treatment of patients with penta-refractory myeloma that has continued to progress despite available therapies," said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm. "We are fully committed to working closely with the FDA as we continue development of this potential new, orally-administered treatment for patients who currently have no other treatment options of proven benefit."

> Update: Selinexor has been granted Fast Track Designation by the FDA for patients with #MultipleMyeloma (https://twitter.com/hashtag/MultipleMyeloma?src=hash&ref_src=twsrc%5Etfw) that have already received 3 prior lines of therapy. Click here now https://t.co/cfzulQ9f70 (https://t.co/cfzulQ9f70) for more info. #mmsm (https://twitter.com/hashtag/mmsm?src=hash&ref_src=twsrc%5Etfw) #CancerResearch (https://twitter.com/hashtag/CancerResearch?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/QunBFJTfIZ (https://t.co/QunBFJTfIZ)
>
> — Targeted Oncology (@TargetedOnc) April 22, 2018 (https://twitter.com/TargetedOnc/status/988054960679145472?ref_src=twsrc%5Etfw)

FDA clearance of OBI-3424 IND application for a Ph I/II Study of OBI-3424 targeting AKR1C3 solid tumors (http://www.obipharma.com/2018/04/fda-clearance-of-obi-3424-ind-application-for-a-phase-i-ii-study-targeting-akr1c3-solid-tumors/)

OBI Pharma's Chief Medical Advisor, Tillman Pearce, M.D., noted, "This clinical trial intends to verify the safety and preliminary activity profile of OBI-3424, a novel first-in-class prodrug of a DNA alkylating cancer therapeutic that is selectively activated by AKR1C3, an enzyme that is overexpressed in a variety of solid and liquid tumors. We are delighted to conduct this first-in-man clinical trial at the University of Texas M.D. Anderson Cancer Center and The James Cancer Hospital and Solove Research Institute of Ohio State University, two of America's leading academic oncology research institutions."

Amy Huang, General Manager of OBI Pharma, added, "OBI Pharma is proud to further develop our unique targeted cancer pipeline, including targets like the Globo series and AKR1C3. OBI-3424 enhances OBI's pipeline in solid and liquid tumors for cancer patients who over-express AKR1C3. OBI is taking a first-step towards testing the safety and initial efficacy of a new class of AKR1C3 targeted therapy. We are excited to develop novel targeted therapeutics in the fight against cancers of unmet need."

FDA Approves IND for OBI Pharma's OBI-3424 for a Ph I/II Study in AKR1C3 Solid Tumors: OBI Pharma, Inc., a Taiwan biopharma company (TPEx: 4174), today announced that the U.S. Food and Drug Administration (FDA) has cleared an investigational new drug... https://t.co/tPByszSLDw (https://t.co/tPByszSLDw)

— cafepharma (@cafepharma) April 19, 2018 (https://twitter.com/cafepharma/status/986979724072181760?ref_src=twsrc%5Etfw)

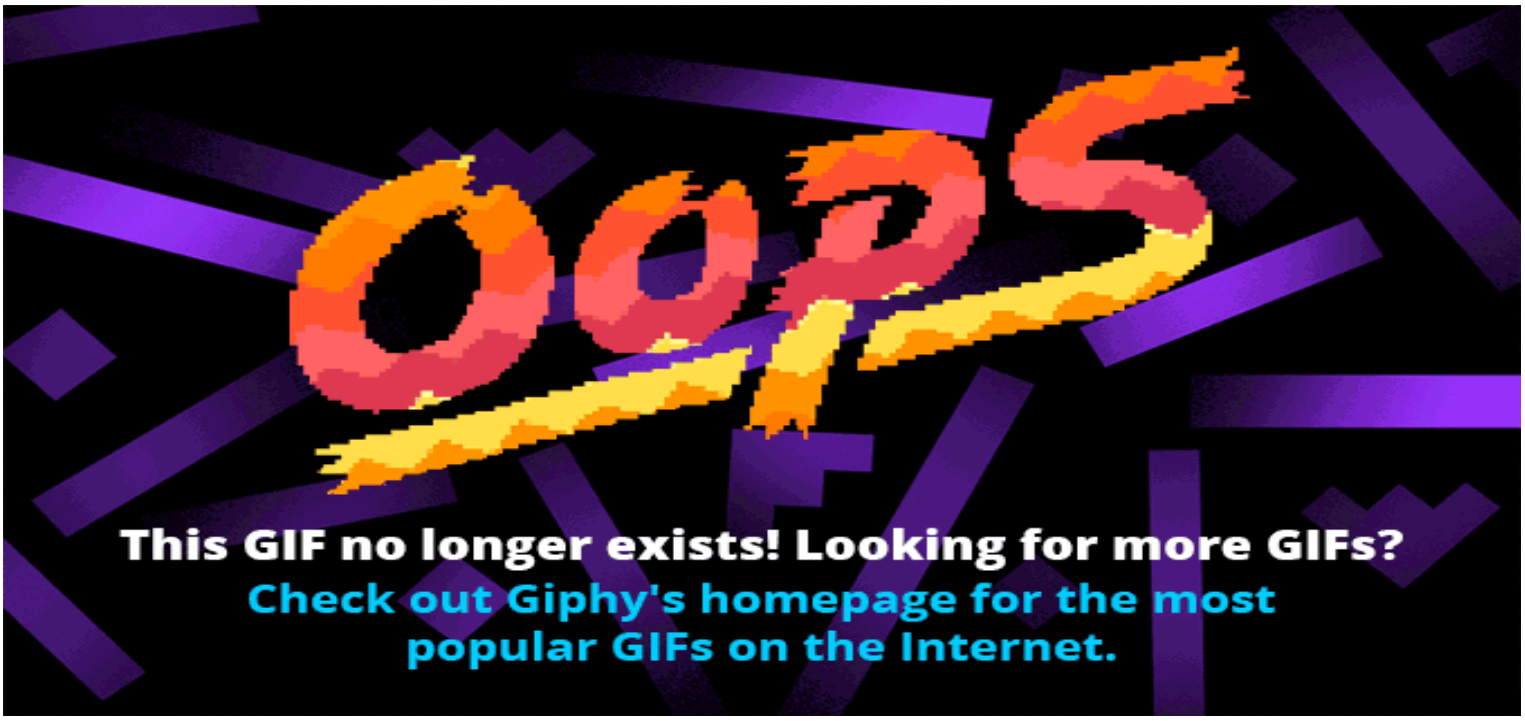
FDA grants orphan drug designation to LBS-007 for the treatment of ALL (https://www.prnewswire.com/news-releases/lin-bioscience-announces-fda-orphan-drug-designation-for-lbs-007-for-the-treatment-of-acute-lymphoblastic-leukemia-300635205.html)

"Our focus is to find treatments for untreatable diseases, and LBS-007 is the second candidate in our pipeline to receive Orphan Drug Designation in the last 6 months," stated Dr. Tom Lin, CEO of Lin BioScience. "We are pleased to reach this regulatory milestone with LBS-007 and we look forward to advancing the anti-cancer program into Phase 1 clinical trials later this year."

Lin BioScience Announces FDA Orphan Drug Designation for LBS-007 for the Treatment of Acute Lymphoblastic Leukemia https://t.co/U3BbFShj2F (https://t.co/U3BbFShj2F) pic.twitter.com/VGej42OCCX (https://t.co/VGej42OCCX)

— Hematopoiesis News (@Hema_News) April 26, 2018 (https://twitter.com/Hema_News/status/989605077252964352?ref_src=twsrc%5Etfw)

TRIAL RESULTS



via GIPHY (https://giphy.com/gifs/medicine-11XNfYm3Tt6Jwc)

TRIAL FAILURE: Durvalumab + Tremelimumab combo fails to meet primary endpoint of PFS and OS improvement in Ph III ARCTIC trial in PD-L1low/neg 3L NSCLC patients (https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2018/astrazeneca-reports-results-from-the-arctic-trial-in-third-line-non-small-cell-lung-cancer-24042018.html)

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "While we

are disappointed that the combination of *Imfinzi* plus tremelimumab did not result in a statistically-significant survival benefit in this heavily pre-treated patient population, we are encouraged by the activity of *Imfinzi* monotherapy observed in this trial and look forward to presenting the full data from the ARCTIC trial at an upcoming medical meeting."

> AstraZeneca immunotherpy combo durvalumab+ tremelimumab fails in Phase III ARCTIC trial in third-line non-small cell lung cancer https://t.co/HRPQQ5ssel (https://t.co/HRPQQ5ssel) pic.twitter.com/6u09z9TJhw (https://t.co/6u09z9TJhw)
>
> — Krishan Maggon (@kkmaggon) April 27, 2018 (https://twitter.com/kkmaggon/status/989829512258048000?ref_src=twsrc%5Etfw)

Additional Top-Line Results from Ramucirumab Ph III RANGE Study in Advanced or Metastatic Urothelial Cancer (https://investor.lilly.com/news-releases/news-release-details/lilly-reports-additional-top-line-results-cyramzar-ramucirumab)

"People with advanced urothelial carcinoma who experience disease progression urgently need treatment options that can control the disease – to help stop or slow the cancer from growing and spreading," said Levi Garraway, M.D., Ph.D., senior vice president, global development and medical affairs, Lilly Oncology. "Although this study didn't reach statistical significance for overall survival, we are encouraged by the totality of the RANGE results and look forward to reviewing the data with internal and external experts to determine next steps."

> Lilly announces topline results from ramucirumab-docetaxel combo ... https://t.co/EYPoZLnEtP (https://t.co/EYPoZLnEtP) #Lilly (https://twitter.com/hashtag/Lilly?src=hash&ref_src=twsrc%5Etfw) #bladdercancer (https://twitter.com/hashtag/bladdercancer?src=hash&ref_src=twsrc%5Etfw) #ramucirumab (https://twitter.com/hashtag/ramucirumab?src=hash&ref_src=twsrc%5Etfw) #Cyramza (https://twitter.com/hashtag/Cyramza?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/fqh6Or5Q7v (https://t.co/fqh6Or5Q7v)
>
> — TRM Oncology (@TRMoncology) April 26, 2018 (https://twitter.com/TRMoncology/status/989625293651488769?ref_src=twsrc%5Etfw)

HSP90 inhibitor XL888 + Vemurafenib combo shows tolerable side-effect profile in unresectable BRAF V600E mutant melanoma (http://clincancerres.aacrjournals.org/content/early/2018/04/19/1078-0432.CCR-18-0565)

XL888 in combination with vemurafenib has clinical activity in patients with advanced BRAFV600-mutant melanoma, with a tolerable side-effect profile. HSP90 inhibitors warrant further evaluation in combination with current standard-of-care BRAF plus MEK inhibitors in BRAFV600-mutant melanoma.

> An easier way to memorize BRAF V600E inhibitor – vemurafenib pic.twitter.com/E6lMQs5Pvz (https://t.co/E6lMQs5Pvz)
>
> — Simon Chiosea, MD (@chioseasi) April 13, 2017 (https://twitter.com/chioseasi/status/852521968045875200?ref_src=twsrc%5Etfw)

TLR9 Agonist CMP-001-Pembrolizumab Combination Shows Early Efficacy in Patients With Metastatic Melanoma Resistant to Anti-PD-1 (http://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1183#.WtoJSExuLIV)

"Checkpoint inhibition is quickly becoming a key tool for oncologists to treat cancer," said Mohammed Milhem, MBBS, clinical professor of internal medicine at the University of Iowa, Iowa City. "However, there are many

patients that either initially respond to checkpoint inhibition and then progress, or never respond to this therapy to begin with. Finding safe and effective therapies for these patients is critical."

Previous work has shown that tumors with an increase in interferon (IFN) gene expression are more responsive to PD-1 inhibition, explained Milhem. "The strongest known inducer of IFN production is the TLR9 pathway, so we thought that adding a TLR9 activator to anti-PD-1 therapy would elicit a response in patients who stopped or never responded to PD-1 inhibition," he noted.

> Ongoing phase 1b #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) clinical trial presented at @AACR (https://twitter.com/AACR?ref_src=twsrc%5Etfw) #AACR18 (https://twitter.com/hashtag/AACR18?src=hash&ref_src=twsrc%5Etfw) shows that the combination of TLR9 Agonist CMP-001/Pembrolizumab #Immunotherapy (https://twitter.com/hashtag/Immunotherapy?src=hash&ref_src=twsrc%5Etfw) Shows Early Efficacy in Patients With Metastatic #Melanoma (https://twitter.com/hashtag/Melanoma?src=hash&ref_src=twsrc%5Etfw) Resistant to Anti PD1 more @ASCOPost (https://twitter.com/ASCOPost?ref_src=twsrc%5Etfw) https://t.co/i9C3FJaR3y (https://t.co/i9C3FJaR3y) pic.twitter.com/RpbvQkwFEY (https://t.co/RpbvQkwFEY)
>
> — Gil Morgan (@weoncologists) April 18, 2018 (https://twitter.com/weoncologists/status/986470866472132608?ref_src=twsrc%5Etfw)

Dual Inhibition of IDO1 and PD-L1 safe in patients with advanced solid tumors as per ECHO-203 trial data (http://www.aacr.org/Newsroom/Pages/News-Release-Detail.aspx?ItemID=1184#.WtoJSExuLIV)

"Immune checkpoint inhibitors, including PD-1 and PD-L1 inhibitors, have provided meaningful clinical benefits for patients with cancer; however, novel immunotherapy combination treatments are needed to improve efficacy with limited additive toxicity," said Aung Naing, MD, FACP, associate professor, Department of Investigational Cancer Therapeutics, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center, Houston. "This is the first report of IDO1 inhibition in combination with PD-L1 antagonism, and we found that epacadostat plus durvalumab was generally well-tolerated in patients with advanced cancers, with a safety profile consistent with previous reports of durvalumab monotherapy."

"ECHO-203 is part of the broader ECHO clinical development program investigating efficacy and safety of epacadostat as a core component of combination therapy in a broad range of solid tumor types as well as hematological malignancies," said Naing. "Ongoing clinical studies are evaluating epacadostat in combination with PD-1 and PD-L1 inhibitors including pembrolizumab, nivolumab, and durvalumab."

> Dual IDO1, PD-L1 inhibition safe for advanced solid tumors, according to a presentation from Dr. @ANaingMD (https://twitter.com/ANaingMD?ref_src=twsrc%5Etfw) of @MDAndersonNews (https://twitter.com/MDAndersonNews?ref_src=twsrc%5Etfw) at #AACR18 (https://twitter.com/hashtag/AACR18?src=hash&ref_src=twsrc%5Etfw). https://t.co/YfkolQrf7U (https://t.co/YfkolQrf7U)#durvalumab (https://twitter.com/hashtag/durvalumab?src=hash&ref_src=twsrc%5Etfw) #epacadostat (https://twitter.com/hashtag/epacadostat?src=hash&ref_src=twsrc%5Etfw) @Incyte (https://twitter.com/Incyte?ref_src=twsrc%5Etfw) @AstraZenecaUS (https://twitter.com/AstraZenecaUS?ref_src=twsrc%5Etfw) pic.twitter.com/VB70XAVP57 (https://t.co/VB70XAVP57)
>
> — HemOnc Today (@HemOncToday) April 17, 2018 (https://twitter.com/HemOncToday/status/986294972168228864?ref_src=twsrc%5Etfw)

Encouraging response rates observed with SD-101+Pembrolizumab in advanced SCCHN patients (http://investors.dynavax.com/news-releases/news-release-details/dynavax-reports-interim-data-sd-101-combination-keytrudar)

“Results from our Phase 1b/2 trial of SD-101 in combination with KEYTRUDA are promising in head and neck cancer, a condition for which patients typically have a poor prognosis,” said Eddie Gray, Chief Executive Officer of Dynavax. “This is another tumor type in which SD-101, based on early data, has demonstrated encouraging activity while being well tolerated. As understanding of combination therapy matures we believe an effective immune stimulating agonist with an attractive tolerability profile will play a significant role in a wide range of tumors.”

> Dynavax Provides New Durability of Response Data for SD-101 in Combination with KEYTRUDA® (pembrolizumab) in Melanoma at the 2018 American Association for Cancer Research Annual Meeting https://t.co/4k4hnKNpLa (https://t.co/4k4hnKNpLa)
>
> — StockGuru (@StockGuruDotCom) April 17, 2018 (https://twitter.com/StockGuruDotCom/status/986236008059596800?ref_src=twsrc%5Etfw)

Novocure reports positive top-line results from STELLAR Ph II pilot trial in Mesothelioma (https://www.novocure.com/novocure-reports-positive-top-line-results-from-stellar-phase-2-pilot-trial-in-mesothelioma/)

“We are extremely pleased with these top-line results, which bring us one step closer to realizing the potential for a new treatment for mesothelioma patients in desperate need,” said Dr. Eilon Kirson, Novocure’s Chief Science Officer and Head of Research and Development. “Mesothelioma is the first torso indication for which Novocure will pursue FDA approval. The STELLAR data reinforce our belief that Tumor Treating Fields may be a broadly applicable platform technology for the treatment of solid tumors. We look forward to sharing the detailed results of the study with the lung cancer community at an upcoming medical conference.”

> Eilon Kirson, Novocure’s Chief Science Officer and Head of R&D, discusses the topline results of the STELLAR trial. https://t.co/nF5XaFem9d (https://t.co/nF5XaFem9d) pic.twitter.com/lQC2yw4aoQ (https://t.co/lQC2yw4aoQ)
>
> — Novocure (@Novocure) April 17, 2018 (https://twitter.com/Novocure/status/986306632543072256?ref_src=twsrc%5Etfw)

Niraparib meets primary endpoint in QUADRA trial of heavily pre-treated ovarian cancer patients (http://ir.tesarobio.com/news-releases/news-release-details/tesaro-announces-positive-top-line-results-quadra-trial-zejular?_ga=2.12416628.1938182024.1524588882-618476917.1523446779)

“These results demonstrated that ZEJULA is active as a late-line treatment for patients beyond those with *BRCA* mutations, which is the only treatment setting in which PARP inhibitors are approved today. In addition, the QUADRA data describe ZEJULA monotherapy activity in platinum-resistant/refractory patients, providing important context for our TOPACIO study of ZEJULA in combination with an anti-PD-1 inhibitor,” said Mary Lynne Hedley, President and COO of TESARO. “With QUADRA data in hand, we continue to advance our mission to provide all patients with ovarian cancer an opportunity to benefit from treatment with ZEJULA, and we are extremely grateful to the patients, caregivers, and investigators who took part in this study.”

> Niraparib met the primary endpoint of overall response as a fourth-line or later treatment in patients with ovarian cancer, regardless of BRCA status, according to top-line results from the QUADRA study #gyncsm (https://twitter.com/hashtag/gyncsm?src=hash&ref_src=twsrc%5Etfw) https://t.co/d3AIdnSbg9 (https://t.co/d3AIdnSbg9)
>
> — OncLive.com (@OncLive) April 25, 2018 (https://twitter.com/OncLive/status/989115611384045569?ref_src=twsrc%5Etfw)

TRIAL AND PROGRAM STATUSES

via GIPHY (https://giphy.com/gifs/medicine-uSZjg1PZoNBZe)

CellDex discontinues Glembatumumab development after the first in Class GPNMB Inhibitor fails in TNBC (http://ir.celldex.com/releasedetail.cfm?ReleaseID=1063842)

“Triple-negative breast cancer is a very difficult disease to treat, and we are extremely disappointed for patients that the METRIC Study was not successful,” said Anthony Marucci, Co-founder, President and Chief Executive Officer of Celldex Therapeutics. “On behalf of Celldex, I want to express our gratitude to the METRIC investigators, patients and families who participated in this study. Based on these results, we have also made the decision to discontinue the glembatumumab vedotin program across all indications and are currently prioritizing our pipeline, which includes five candidates in ongoing clinical studies. In line with this, we are evaluating our operational and workforce needs to extend our financial resources and direct them to continued pipeline advancement. Once we solidify these plans, we intend to update investors.”

> Celldex’s highly anticipated breast cancer drug fails to hit the mark in a midstage trial: Celldex’s shares are cratering in response to the news that its once promising triple negative breast cancer (TNBC) drug candidate, glembatumumab vedotin (glemba),... https://t.co/tSM6wEcGcl (https://t.co/tSM6wEcGcl)
>
> — cafepharma (@cafepharma) April 16, 2018 (https://twitter.com/cafepharma/status/985884011703619584?ref_src=twsrc%5Etfw)

Rocapuldencel-T Falls Short in mRCC (http://ir.argostherapeutics.com/news-releases/news-release-details/argos-therapeutics-reports-results-interim-analysis-adapt-trial)

Argos Therapeutics, Inc. (Nasdaq:ARGS), an immuno-oncology company focused on the development and commercialization of individualized immunotherapies based on the Arcelis® precision immunotherapy technology platform, today reported interim results from its randomized, active controlled, open-label, multi-center Phase 3 ADAPT trial of Rocapuldencel-T in combination with sunitinib/standard-of-care for the treatment of newly diagnosed metastatic renal cell carcinoma. Based on these results, the Company has decided to discontinue the trial.

The ADAPT trial investigating rocapuldencel-T in patients with mRCC has been stopped after findings revealed the immunotherapy was unlikely to meet any of the primary endpoints. More details here: https://t.co/xMyspcTFt6 (https://t.co/xMyspcTFt6) #RenalCellCarcinoma (https://twitter.com/hashtag/RenalCellCarcinoma?src=hash&ref_src=twsrc%5Etfw) #Carcinoma (https://twitter.com/hashtag/Carcinoma?src=hash&ref_src=twsrc%5Etfw) #CancerResearch (https://twitter.com/hashtag/CancerResearch?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/5a8ZKPYoja (https://t.co/5a8ZKPYoja)

— Targeted Oncology (@TargetedOnc) April 20, 2018 (https://twitter.com/TargetedOnc/status/987360366190628870?ref_src=twsrc%5Etfw)

Ph Ib trial of CMP-001 + Atezolizumab commences in NSCLC patients who progressed on prior anti-PD-1/PD-L1 therapy (http://checkmatepharma.com/pdf/release7.pdf)

"We are pleased to be advancing the clinical development of CMP-001 into a second tumor type," stated Art Krieg, founder and CEO of Checkmate Pharmaceuticals. "The mechanism of action of CMP001 should apply across most or all tumor types, and so we expect CMP-001 to reverse PD-1 resistance in NSCLC, just as we reported for PD-1 resistant advanced melanoma last week at the 2018 American Association of Cancer Research Annual Meeting in Chicago," noted Dr. Krieg.

In the second part of the trial, the combination of CMP-001 and atezolizumab therapy will be preceded by low-level radiation therapy to the target lesion. "In our ongoing melanoma trial we learned that patients whose tumors contain more plasmacytoid dendritic cells (pDC) appear to be more likely to respond to CMP-001 in combination with checkpoint inhibitor therapy. Low dose radiation therapy recruits pDC into tumors, and so we expect this triple combination regimen to increase the response rate to our therapy," explained Dr. Krieg. Patients will be monitored for safety and tolerability, as well as clinical response.

Read more on "PFS Benefit With Frontline Atezolizumab in NSCLC Sustained Across Biomarker-Driven Subgroups" here: https://t.co/aONPp60W8C (https://t.co/aONPp60W8C) #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) #LungCancer (https://twitter.com/hashtag/LungCancer?src=hash&ref_src=twsrc%5Etfw) #lcsm (https://twitter.com/hashtag/lcsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/O2OJs9Ohgo (https://t.co/O2OJs9Ohgo)

— Targeted Oncology (@TargetedOnc) April 25, 2018 (https://twitter.com/TargetedOnc/status/988960848008933376?ref_src=twsrc%5Etfw)

Two trials evaluating WT1 cancer peptide vaccine DSP-7888 (ombipepimut-S*) commenced in solid tumors (with Nivolumab/Atezolizumab) and GBM (with Bevacizumab) (http://www.bostonbiomedical.com/boston-biomedical-inc-initiates-two-studies-evaluating-wt1-cancer-peptide-vaccine-dsp-7888-ombipepimut-s/)

"Despite significant advances in cancer treatment, there remains a need for new, effective treatment options for many patients," said Patricia S. Andrews, Chief Executive Officer, Boston Biomedical, Inc. "We are exploring the potential of DSP-7888 to elicit an anti-tumor response in a number of high unmet need tumor types."

Boston Biomedical Inc. Initiates Two Studies Evaluating WT1 Cancer Peptide Vaccine DSP-7888 @BostonBioInc (https://twitter.com/BostonBioInc?ref_src=twsrc%5Etfw) https://t.co/WFlQXAgmon (https://t.co/WFlQXAgmon)

— CancerStemCell News (@cancerscnews) April 28, 2018 (https://twitter.com/cancerscnews/status/990254332867174400?ref_src=twsrc%5Etfw)

Mirati Therapeutics provides updated positive clinical trial results for Immuno-Oncology combination trials (http://ir.mirati.com/news-releases/news-release-details/mirati-therapeutics-announces-progress-lead-programs-and)

"The majority of NSCLC patients either do not respond to checkpoint inhibitor therapy or experience disease progression following treatment. These patients have limited treatment options and generally experience poor outcomes in response to standard of care chemotherapy," said Charles M. Baum, M.D., Ph.D., President and Chief Executive Officer. "The preliminary data from our Phase 2 study of sitravatinib plus nivolumab continue to highlight the promise of this combination to overcome resistance to initial checkpoint inhibitor therapy and provide a meaningful treatment option for this large and underserved patient population."

> $MRTX (https://twitter.com/search?q=%24MRTX&src=ctag&ref_src=twsrc%5Etfw) provides update for clinical trial of #sitravatinib (https://twitter.com/hashtag/sitravatinib?src=hash&ref_src=twsrc%5Etfw), stock falls -4.59%, #MiratiTherapeutics (https://twitter.com/hashtag/MiratiTherapeutics?src=hash&ref_src=twsrc%5Etfw) https://t.co/niqv342s3v (https://t.co/niqv342s3v)
>
> — News Quantified (@NewsQuantified) April 25, 2018 (https://twitter.com/NewsQuantified/status/988938138318983169?ref_src=twsrc%5Etfw)

ADC Therapeutics terminates ADCT-502 program targeting HER2 expressing solid tumors (http://adctherapeutics.com/)

Dr. Jay Feingold, Chief Medical Officer and Senior Vice President of Clinical Development at ADCT said: "We are very pleased with the efficacy and tolerability achieved with our lead hematological PBD-based ADC programs, but regrettably this has not been the case with our HER2 targeted ADC. PBD's (pyrrolobenzodiazepine dimers) are extremely potent and have a well characterized safety profile that includes fluid retention and pulmonary edema. For most PBD ADCs this can be managed by selecting dosing regimens that are efficacious with manageable toxicities. However, during dose escalation in this trial we did not achieve the necessary efficacy at tolerated doses required for patient benefit. This was possibly due to the extensive expression of HER2 in pulmonary tissue. Our next two solid tumor ADCs progressing into the clinic over the next nine months incorporate site specific conjugation technology which based on pre-clinical models has the potential to substantially improve tolerability and efficacy in difficult to treat solid tumors. Preclinical data on these programs was presented at the recent American Association of Cancer Research conference."

> ADC Therapeutics Announces the Termination of its ADCT-502 Program Targeting HER2 Expressing Solid Tumors @BusinessWire (https://twitter.com/BusinessWire?ref_src=twsrc%5Etfw) https://t.co/oL5O9XrsJU (https://t.co/oL5O9XrsJU) pic.twitter.com/WgAsTklek4 (https://t.co/WgAsTklek4)
>
> — Mammary Cell News (@MammaryCell) April 29, 2018 (https://twitter.com/MammaryCell/status/990390224483123200?ref_src=twsrc%5Etfw)

Ph I trial of first new gen precisely engineered ADC, STRO-001, initiated in myeloma and lymphoma patients (https://www.sutrobio.com/sutro-initiates-first-clinical-trial-of-cd74-targeting-adc-for-lymphoma-the-first-of-a-new-generation-of-precisely-engineered-adcs/)

"Based on preclinical research findings, we are hopeful that this Phase 1 study will demonstrate that STRO-001 has preliminary activity in patients with multiple myeloma and non-Hodgkin's lymphoma with progressive disease following standard of care therapies," said Bill Newell, Sutro's Chief Executive Officer.

"Ultimately, we aim to demonstrate that STRO-001 can be an important new treatment option to address an unmet need for targeted therapies for patients who have multiple myeloma and non-Hodgkin's lymphoma," Mr. Newell added.

Phase 1 Trial for Investigational Therapy STRO-001 Treats First Myeloma, Lymphoma Patients https://t.co/AF8MbugyFT (https://t.co/AF8MbugyFT) pic.twitter.com/oShWvEGL2E (https://t.co/oShWvEGL2E)

— BioNews Services (@bionewsservices) April 27, 2018 (https://twitter.com/bionewsservices/status/989935695954415617?ref_src=twsrc%5Etfw)

Ph I/Ib trial of anti-CD73 Ab CPI-006 as monotherapy or in combination with Atezolizumab or CPI-444 starts in patients with advanced cancer (http://investor.corvuspharma.com/phoenix.zhtml?c=254276&p=irol-newsArticle&ID=2344945)

"CPI-006 is an antibody engineered to completely inhibit the CD73 enzyme by binding to its active site. We look forward to evaluating this anti-CD73 antibody in our comprehensive Phase 1/1b trial, which we believe is the first human clinical trial in oncology to evaluate the effect of dual-blockade of the adenosine pathway by inhibiting both CD73 and the A2A receptor," said Richard A. Miller, M.D., an oncologist and co-founder, president and chief executive officer of Corvus. "This trial is designed to answer multiple important questions regarding the role of CD73 blockade and the adenosine pathway in patients with advanced cancer. With the initiation of this new trial and our ongoing Phase 1/1b clinical trial of CPI-444, we continue to reinforce our leadership position in this new therapeutic area."

Corvus Pharmaceuticals Announces Initiation of Phase 1/1b Clinical Trial of Investigational Anti-CD73 Antibody, CPI-006, in Patients with Advanced Cancer https://t.co/yQx94mzyoo (https://t.co/yQx94mzyoo)

— francis loos (@claoseun) April 26, 2018 (https://twitter.com/claoseun/status/989491864595324928?ref_src=twsrc%5Etfw)

COLLABORATIONS

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

Nektar and Takeda to evaluate combination of NKTR-214, a CD122-biased Agonist, and TAK-659, a Dual SYK and FLT-3 Inhibitor, in solid tumors and heme malignancies (http://ir.nektar.com/news-releases/news-release-details/new-oncology-clinical-collaboration-between-nektar-and-takeda)

"We look forward to collaborating with Takeda to explore a range of combination therapy approaches with

NKTR-214 and TAK-659 in liquid and solid tumor settings," said Jonathan Zalevsky, PhD, Chief Scientific Officer and Senior Vice President of Research, Nektar. "Importantly, this clinical collaboration will allow us to understand how we can increase the clinical benefit of immunotherapies for patients when we leverage multiple I-O modalities and target the immune cycle in complementary and novel ways."

"Based upon highly compelling preclinical data, we are looking forward to combining Nektar's unique CD122-biased agonist with TAK-659, which is a dual inhibitor of both SYK and FLT-3," said Phil Rowlands, PhD, Head, Oncology Therapeutic Area Unit, Takeda. "NKTR-214 is unique in that it can stimulate tumor-killing T-cells in the tumor micro-environment itself. By combining with TAK-659, we hope to target different stages of the cancer immunity cycle in a combination regimen. This collaboration is aimed at achieving our goal of allowing more patients with different types of cancer to benefit from immunotherapies."

> Oncology clinical collaboration between Nektar and Takeda https://t.co/QjRl3T8Ubu (https://t.co/QjRl3T8Ubu) pic.twitter.com/8pPNFApQVj (https://t.co/8pPNFApQVj)
>
> — Pharma Business Int (@PBIForum) April 27, 2018 (https://twitter.com/PBIForum/status/989785237298139137?ref_src=twsrc%5Etfw)

Immunovaccine and Incyte plan addition of Ph II component to ongoing Ph Ib rial of DPX-Survivac + Epacadostat in advanced ovarian cancer patients (http://ir.imvaccine.com/news-releases/news-release-details/immunovaccine-and-incyte-expand-clinical-collaboration)

"We were encouraged by the topline data we shared last December from the first dosing cohort of our trial, especially in this hard-to-treat population of ovarian cancer patients," said Frederic Ors, Chief Executive Officer at Immunovaccine. "We believe that these results further support the hypothesis that the unique mechanism of action underscoring our T cell activation technology can trigger tumor regressions, even in patients who typically don't respond well to current monotherapies. We are pleased to expand our collaboration with Incyte, and build on the initial demonstration of this combination in ovarian cancer."

> Phase 2 Study of DPX-Survivac Combo Doses First Lymphoma Patient https://t.co/1K3NCGrHmc (https://t.co/1K3NCGrHmc) pic.twitter.com/JG7AhHXfQN (https://t.co/JG7AhHXfQN)
>
> — BioNews Services (@bionewsservices) April 3, 2018 (https://twitter.com/bionewsservices/status/981239520933941248?ref_src=twsrc%5Etfw)

Tocagen licenses ApolloBio to develop and commercialize Toca 511 & Toca FC within the greater China region (http://ir.tocagen.com/phoenix.zhtml?c=254300&p=irol-newsArticle&ID=2343446)

"As an innovative biopharmaceutical company in China, ApolloBio is well positioned to leverage China's recent regulatory changes supporting the development of new medicines," said Marty Duvall, chief executive officer of Tocagen. "ApolloBio brings valuable regional expertise in product development, regulation and healthcare access, positioning our lead product to advance towards patients in the greater China region as quickly and efficiently as possible."

"We are committed to accelerating the availability of novel immuno-oncology treatments to patients with high unmet medical needs in the greater China region," said Dr. Weiping Yang, chief executive officer of ApolloBio. "Toca 511 & Toca FC is a highly promising, best-in-class cancer-selective immunotherapy and we look forward to working with Tocagen to advance this innovative late-stage product towards commercialization."

Read more about our licensing agreement with ApolloBio to help bring Toca 511 & Toca FC to patients in the greater China region. We'll receive up to $20M in upfront and near-term milestone payments & are eligible for an additional $107M in future payments. https://t.co/oAcGQK49dC (https://t.co/oAcGQK49dC) pic.twitter.com/TgQr44n4N4 (https://t.co/TgQr44n4N4)

— Tocagen (@Tocagen) April 19, 2018 (https://twitter.com/Tocagen/status/987071158091636736?ref_src=twsrc%5Etfw)

DIAGNOSTICS

via GIPHY (https://giphy.com/gifs/medicine-GS7zGHvGCSepa)

Roche expands indication for cobas® EGFR Mutation Test v2 as a companion diagnostic with Osimertinib (https://molecular.roche.com/news/roche-expands-indication-for-cobas-egfr-mutation-test-v2-as-a-companion-diagnostic-with-tagrisso/)

"The ability to provide confident patient test results in less than one day from sample preparation to report, provides clinicians the information necessary to choose the optimal therapy and avoid delays in getting their patients started on treatment," said Sid Scudder, MD, Senior Director, Clinical Research, Genomics & Oncology, Roche Molecular Diagnostics.

Roche expands indication for cobas® EGFR Mutation Test v2 as a companion diagnostic with TAGRISSO® #CDx (https://twitter.com/hashtag/CDx?src=hash&ref_src=twsrc%5Etfw) #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) @Roche (https://twitter.com/Roche?ref_src=twsrc%5Etfw) @AstraZeneca (https://twitter.com/AstraZeneca?ref_src=twsrc%5Etfw) https://t.co/vLXNvvfcIR (https://t.co/vLXNvvfcIR) pic.twitter.com/qQu4vy5wMX (https://t.co/qQu4vy5wMX)

— Market Ready Rx (@marketreadyrx) April 25, 2018 (https://twitter.com/marketreadyrx/status/989213771490095104?ref_src=twsrc%5Etfw)

Infographically Speaking!

Innovations In Oncology

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About the Author:


(https://i0.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: (From Cell Image Library) B0007213 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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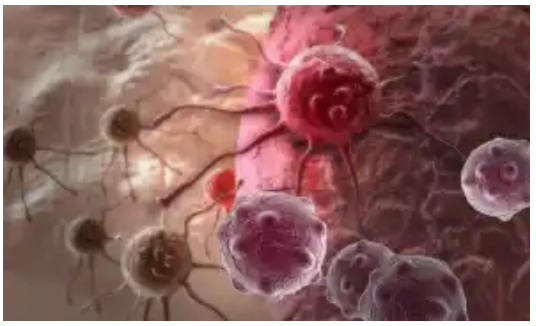

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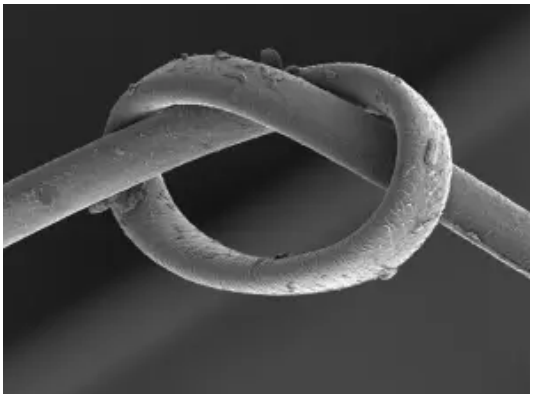

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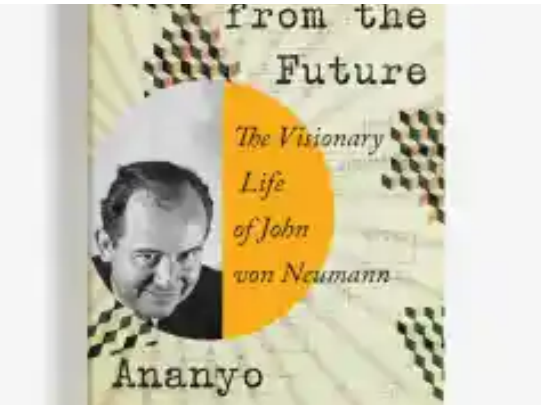

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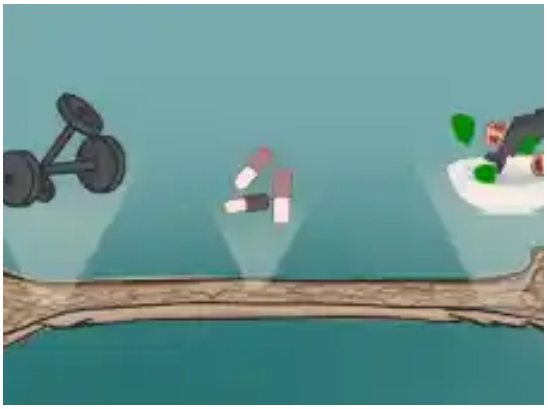

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