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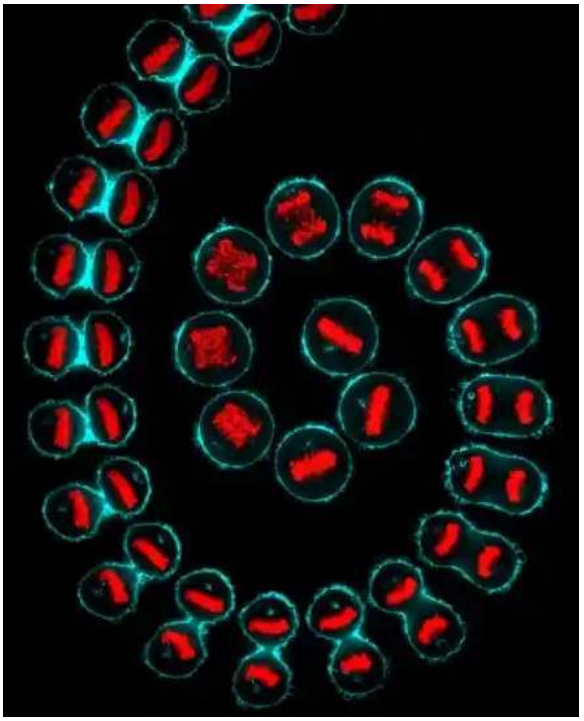
Onco-this-Week

August 11, 2018(https://sciwri.club/archives/date/2018/08/11)



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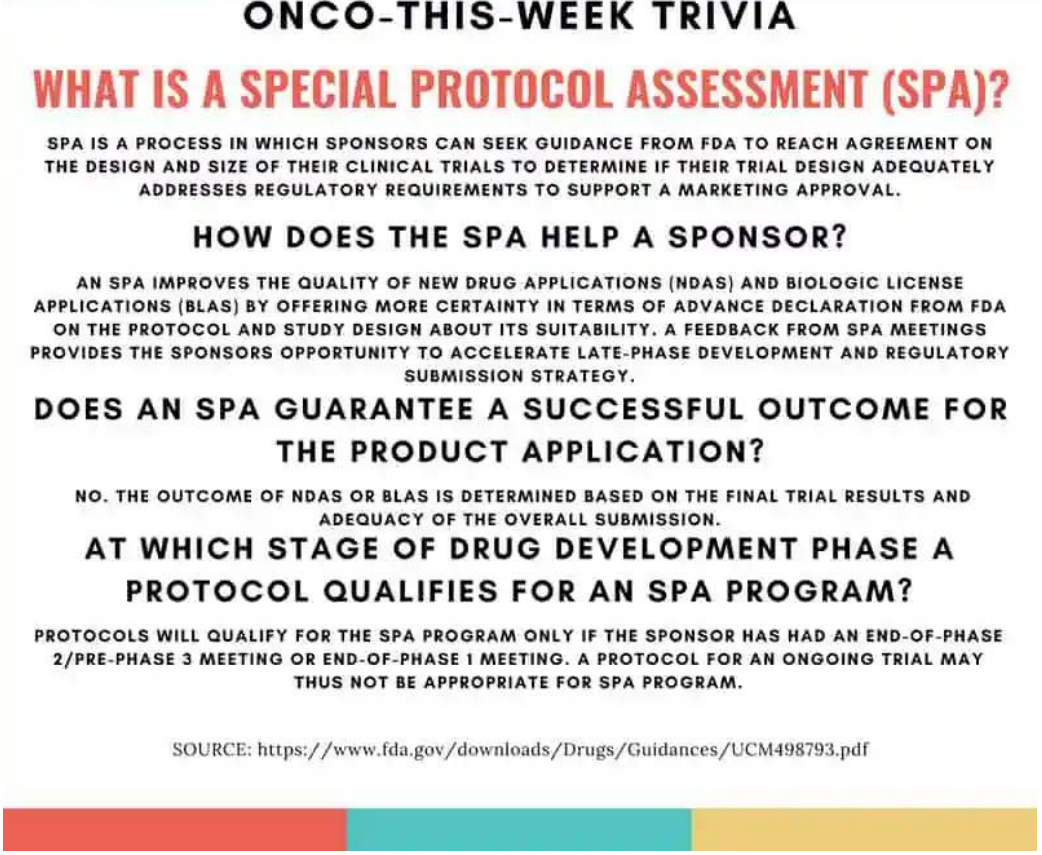
Highlights

FDA approval of CCR4 inhibitor Mogamulizumab in R/R mycosis fungoides (MF) or Sézary syndrome (SS), breakthrough designation to Encorafenib + Binimetinib + Cetuximab combo in BRAF V600E mutated mCRC patients, and Fast Track Designation to EpCAM-targeting ETA ADC Vicinium in NMIBC. Also check out the second quarter 2018 financial results and corporate updates from several key oncology companies.

- Mogamulizumab is the first FDA-approved therapy for SS, which together with MF, pose as difficult-to-treat subtypes of cutaneous T-cell lymphoma (CTCL), a class of non-Hodgkin lymphoma. The approval from a randomized trial (comparing Mogalizumab with Vorinostat) thus comes as a ray of hope for relapsed/refractory patients.
- It would be interesting to see if success of Encorafenib + Binimetinib combination in melanoma could be replicated in colorectal cancer patients too. The triple therapy (Encorafenib + Binimetinib + Cetuximab) got breakthrough designation in R/R mCRC patients based on data from the safety lead-in part of the BEACON CRC Ph III trial. Only the time would tell if the triplet therapy would go on to become the first FDA-approved therapy in this high unmet need patient population.
- With several IOs gaining their foothold in advanced bladder cancer, the early stage patients making up to ~80% of all bladder cancer cases become an attractive market for the drug makers. The EpCAM-targeting ETA ADC, Vicinium, targets BCG-treated high grade NMIBC patients from this pool. The fast track designation to Vicinium offers hope to patients for whom bladder removal is the recommended course after BCG.



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DRUG APPROVALS

Pfizer's TRASTUZUMAB biosimilar receives EU approval in HER2 overexpressing breast cancer and metastatic gastric or gastroesophageal junction adenocarcinoma (https://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_european_approval_for_oncology_biosimilar_trazimera_trastuzumab)

"TRAZIMERA has the potential to help many patients with HER2 overexpressing cancers, such as breast and gastric, which can correlate with poor outcomes and aggressive disease," said Professor Diana Lüftner, Charité Campus Benjamin Franklin and Member of the Presidency of the German Society of Hematology and Medical Oncology. "Today's approval will help enable greater access for patients and physicians across Europe, without compromising on quality, efficacy and safety."

> .@pfizer (https://twitter.com/pfizer?ref_src=twsrc%5Etfw) received EU approval for Trazimera, a #biosimilar (https://twitter.com/hashtag/biosimilar?src=hash&ref_src=twsrc%5Etfw) version of @Roche (https://twitter.com/Roche?ref_src=twsrc%5Etfw)'s best-selling oncology monoclonal #antibody (https://twitter.com/hashtag/antibody?src=hash&ref_src=twsrc%5Etfw), Herceptin. https://t.co/rAm7P3sZOo (https://t.co/rAm7P3sZOo) pic.twitter.com/QIbQBPD20g (https://t.co/QIbQBPD20g)
>
> — The 2018 American Pharma Outsourcing Summit (@PharmaOutSourc) August 1, 2018 (https://twitter.com/PharmaOutSourc/status/1024701564282384384?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Richard Blackburn, Global President, Pfizer Essential Health Europe, Africa/Middle East and Biosimilars said "The approval of TRAZIMERA, Pfizer's first oncology biosimilar, is another significant step in our quest to introduce more treatment options for patients in Europe. Pfizer is investing in developing and launching a range of biosimilars which can help to reduce healthcare costs and increase patient access to important medicines."

Mogamulizumab approved in USA in R/R mycosis fungoides (MF) or Sézary syndrome (SS), the two rare types of non-Hodgkin lymphoma (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm616176.htm)

"Mycosis fungoides and Sézary syndrome are rare, hard-to-treat types of non-Hodgkin lymphoma and this approval fills an unmet medical need for these patients," said Richard Pazdur, M.D., director of the FDA's Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "We are committed to continuing to expedite the development and review of this type of targeted therapy that offers meaningful treatments for patients."

> FDA approves GPCR-targeted antibody mogamulizumab for two rare types of non-Hodgkin lymphoma https://t.co/BJHlJeK9kJ (https://t.co/BJHlJeK9kJ) See https://t.co/HGbQUZUVod (https://t.co/HGbQUZUVod) for a review of the field pic.twitter.com/WI5AOl8NSc (https://t.co/WI5AOl8NSc)
>
> — Nature Rev Drug Disc (@NatRevDrugDisc) August 9, 2018 (https://twitter.com/NatRevDrugDisc/status/1027580039586611200?ref_src=twsrc%5Etfw)

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

REGULATORY NEWS

Janssen submits U.S. & EU regulatory applications seeking approval of Daratumumab split dosing regimen (https://www.janssen.com/janssen-submits-us-eu-regulatory-applications-seeking-approval-darzalex-daratumumab-split-dosing)

> Genmab Announces Submission of U.S. & EU Regulatory Applications Seeking Approval of DARZALEX® (Daratumumab) Split Dosing Regimen https://t.co/O1VuSaZYXb (https://t.co/O1VuSaZYXb)
>
> — Genmab (@Genmab) August 8, 2018 (https://twitter.com/Genmab/status/1027169015767040001?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are committed to exploring options that may improve the administration profile of DARZALEX® and the overall treatment experience for patients and physicians," said Craig Tendler, MD, Vice President, Clinical Development and Global Medical Affairs, Janssen Research & Development, LLC. "We look forward to reviewing the data in support of these applications with regulators and hope to make a DARZALEX® split-dose option available to patients and health care professionals to provide additional flexibility in administration of the initial infusion."

Karyopharm completes rolling submission of NDA for Selinexor in penta-refractory MM patients (http://investors.karyopharm.com/news-releases/news-release-details/karyopharm-completes-rolling-submission-new-drug-application-us)

> New Oral Compound, Selinexor – Selinexor can be safely combined with different drugs for efficacy https://t.co/CVAbOvoren (https://t.co/CVAbOvoren) pic.twitter.com/9ZYbBWNMr3 (https://t.co/9ZYbBWNMr3)
>
> — Oncology Tube (@oncologytube) August 11, 2018 (https://twitter.com/oncologytube/status/1028086600788402176?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"There is a substantial urgency for new therapies with novel mechanisms for patients with highly resistant, penta-refractory myeloma," said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm. "The completion of our first NDA submission marks a significant achievement for Karyopharm and brings oral selinexor one step closer to these patients. We are sincerely grateful to the patients, caregivers and investigators that have contributed to the selinexor program to date, the Agency for working with us with a sense of urgency and support, and to the entire Karyopharm team for their inexhaustible professionalism and dedication to advancing this NDA."

Angiochem Announces Special Protocol Assessment (SPA) with FDA (http://angiochem.com/angiochem-announces-special-protocol-assessment-spa-us-food-and-drug-administration-fda)

> Angiochem Announces Special Protocol Assessment SPA with US Food and Drug Administration FDA: MONTREAL Aug. 06 2018 GLOBE NEWSWIRE Angiochem Inc. Angiochem announced today that it has reached an agreement with the U.S. Food and Drug AdministrationÂFDA... https://t.co/JomPMBdghs (https://t.co/JomPMBdghs)
>
> — Food Safety News (@Food_Safety) August 6, 2018 (https://twitter.com/Food_Safety/status/1026429689861156865?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The SPA agreement is a major milestone for us as it represents the first clearly defined development and regulatory pathway for the approval of ANG1005 for the treatment of HER2- breast cancer patients with recurrent brain metastases and leptomeningeal carcinomatosis," said John Huss, Executive Chairman of Angiochem. "We look forward to initiating this trial as soon as possible and are excited to continue to work with all of the parties that have been and will be instrumental in our efforts to bring this important product to the market."

First Australian Ethics Approval to Initiate APOLLO-1 Ph I/II trial for HCC and RCC to be traeted with c-Met inhibitor + PD-1 inhibitor (https://www.cbtpharma.com/media/cbt-pharmaceuticals-receives-first-australian-ethics-approval-to-initiate-apollo-1-phase-1-2-clinical-trial-for-hepatocellular-and-renal-cell-carcinoma/)

> CBT Pharmaceuticals Receives First Australian Ethics Approval to Initiate APOLLO1 Phase 12 Clinical Trial for Hepatocellular and Renal Cell Carcinoma: PLEASANTON Calif. and HANGZHOU China Aug. 08 2018 GLOBE NEWSWIRE CBT Pharmaceuticals CBT a U.S. and... https://t.co/EGuppktqCD (https://t.co/EGuppktqCD) pic.twitter.com/iyAbylgAb7 (https://t.co/iyAbylgAb7)
>
> — Drug Approvals (@DrugApprovalBio) August 8, 2018 (https://twitter.com/DrugApprovalBio/status/1027181161678688256?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"Ethics approval is an essential element of the process to initiate a clinical trial in Australia as we prepare to launch our first combination study with our proprietary c-Met inhibitor and anti PD-1 immunotherapies," stated Sanjeev Redkar, PhD, President and Chief Executive Officer. "We are thrilled to partner with the world-leading oncologists and hepatologists in Australia who are highly experienced clinical trial investigators and share our commitment to the development of new combination approaches to treat cancer patients."

"Our c-Met inhibitor may improve responses to cancer immunotherapy in settings beyond c-MET-dependent tumors by eliminating resistance in the tumor microenvironment, reactivating T-cells to kill the tumor, and sustaining that T-cell response. We look forward to initiating the trial in the next few weeks," added Tillman Pearce, MD, Chief Medical Officer.

I-Mab Biopharma and MorphoSys Announce China IND Submission of TJ202/MOR202 for MM patients (http://www.i-mabbiopharma.com/en/shownews.asp?id=20&BigClass=News)

"The IND submission was done after a successful pre-submission consultation meeting with Center for Drug Evaluation (CDE) of CNDA, which is required under China's new drug regulation, unless waived," said Dr. Joan Shen, Head of R&D at I-Mab.

> I-Mab Biopharma, MorphoSys declares China IND Submission of monoclonal antibodyhttps://t.co/tDBnWrsW7U (https://t.co/tDBnWrsW7U) https://t.co/tDBnWrsW7U (https://t.co/tDBnWrsW7U)
>
> — MarksMan Healthcare (@MarksManHEOR) August 9, 2018 (https://twitter.com/MarksManHEOR/status/1027535835393155072?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"CNDA has endorsed the overall clinical and regulatory strategy, as well as the study designs, which should lead to the biologics license application (BLA)," said Dr. Joan Shen.Through a licensing agreement with MorphoSys AG in November 2017, I-Mab gained exclusive rights to develop and commercialize TJ202/MOR202 in Greater China territory, including mainland China, Hong Kong, Macau and Taiwan.

SPECIAL STATUSES

Breakthrough designation to Encorafenib + Binimetinib + Cetuximab combo in BRAF V600E m+ mCRC patients based on Ph III BEACON CRC trial data (https://arraybiopharma.gcs-web.com/news-releases/news-release-details/array-biopharma-receives-fda-breakthrough-therapy-designation)

> The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) has granted a breakthrough therapy designation to the combination of the BRAF inhibitor encorafenib, the MEK inhibitor binimetinib, and the EGFR inhibitor cetuximab for the treatment of patients with BRAF V600E–mutant mCRC #crcsm (https://twitter.com/hashtag/crcsm?src=hash&ref_src=twsrc%5Etfw) https://t.co/BXamhiYh3X (https://t.co/BXamhiYh3X)
>
> — OncLive.com (@OncLive) August 9, 2018 (https://twitter.com/OncLive/status/1027512352474886144?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are delighted that the FDA has recognized the potential of this combination for patients with *BRAF*^{V600E}-mutant metastatic colorectal cancer," said Victor Sandor, M.D., Chief Medical Officer. "As there are no regimens approved specifically for *BRAF*^{V600E}-mutant mCRC, this designation provides us with the opportunity to work closely with the FDA to potentially accelerate our effort to bring an important treatment option to these patients in critical need."

EpCAM-targeting ETA ADC Vicinium Granted Fast Track Designation by FDA for Treatment of NMIBC (http://ir.sesenbio.com/news-releases/news-release-details/sesen-bio-announces-vicinium-granted-fast-track-designation-fda)

> The granting of this designation is an important milestone for Sesen Bio, and we believe it exemplifies the urgent need for a new treatment option for people with NMIBC for whom bladder removal is the recommended course after BCG https://t.co/5wcjy8HAty (https://t.co/5wcjy8HAty)
>
> — American Patriot (@aslansroar) August 10, 2018 (https://twitter.com/aslansroar/status/1027934868565622784?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"The granting of this designation is an important milestone for Sesen Bio, and we believe it exemplifies the urgent need for a new treatment option for people with NMIBC for whom bladder removal is the recommended course after BCG," said Dr. Thomas Cannell, president and chief executive officer of Sesen Bio. "We are highly encouraged by the differentiated product profile of Vicinium in NMIBC, with a unique mechanism of action, positive three-month data presented earlier this year and favorable tolerability in patients treated to-date. With Fast Track designation, we look forward to determining the optimal registration path and assessing the opportunity for accelerated approval to bring Vicinium to patients as quickly as possible."

Orphan Drug designation granted to lurbinectedin in SCLC (https://www.pharmamar.com/wp-content/uploads/2018/08/PR_Lurbinectedin-orphan-drug-designation-FDA.pdf)

> #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) Approvals Week continues with an #orphandrug (https://twitter.com/hashtag/orphandrug?src=hash&ref_src=twsrc%5Etfw) designation granted to developer @PhrmMar (https://twitter.com/PhrmMar?ref_src=twsrc%5Etfw) for the treatment of small cell lung cancer. #Oncology (https://twitter.com/hashtag/Oncology?src=hash&ref_src=twsrc%5Etfw) indications make up a large percentage of approved orphan drugs each year. Read more HERE: https://t.co/OUkNKicEvO (https://t.co/OUkNKicEvO) #raredisease (https://twitter.com/hashtag/raredisease?src=hash&ref_src=twsrc%5Etfw)
>
> — BioPharmaGlobal (@biopharmaglobal) August 10, 2018 (https://twitter.com/biopharmaglobal/status/1027857190617534464?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"We are delighted to receive this orphan drug designation as it underscores the great need for innovative, effective treatments for this cancer, and recognizes the potential benefits that lurbinectedin may provide for patients with small cell lung cancer," said Luis Mora, Managing Director of the Oncology Business Unit of PharmaMar. "Receiving orphan drug designation for the treatment of small cell lung cancer (SCLC) is a significant regulatory milestone in the development of lurbinectedin", has added.

TRIAL STATUSES

Clovis Oncology announces first patient enrolled in the Ph III ATHENA trial (http://ir.clovisoncology.com/news-releases/news-release-details/clovis-oncology-announces-first-patient-enrolled-phase-3-athena)

"I am pleased the GOG and ENGOT are conducting the first trial designed to investigate whether the combination of a PARP inhibitor and PD-1 blocking antibody can demonstrate not only an improvement in progression-free survival in the first-line maintenance setting for women with advanced ovarian cancer, but also whether the combination can change the natural course of the disease by delaying or reducing recurrence following front-line therapy," said Brad Monk, M.D., FACS, FACOG, Arizona Oncology (US Oncology Network), Professor, Gynecologic Oncology at University of Arizona and Creighton University, Medical Director of US Oncology Research Gynecology program in Phoenix, Arizona and Lead Investigator of the ATHENA trial.

> Clovis Oncology Announces First Patient Enrolled in the Phase 3 ATHENA Trial – Business Wire (press release): Business Wire (press release) Clovis Oncology Announces First Patient Enrolled in the Phase 3 ATHENA Trial Business Wire (press release)... https://t.co/kf136ve88s (https://t.co/kf136ve88s) pic.twitter.com/2EHCO9fGQr (https://t.co/2EHCO9fGQr)
>
> — Oncology Board (@mb_Oncology) August 8, 2018 (https://twitter.com/mb_Oncology/status/1027183162449743872?ref_src=twsrc%5Etfw)

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"Rubraca combination trials such as ATHENA are encouraging to see, because the possible implications are particularly meaningful for women with advanced ovarian cancer, who need a wide range of treatment options," said Dr. Rebecca Kristeleit, Clinical Senior Lecturer and Consultant Medical Oncologist, University College London, U.K. and ATHENA ENGOT/Non-U.S. Lead Investigator. "The participation by the GOG and the ENGOT in the evaluation of a PARP inhibitor in combination with a PD-1 agent reflects the interest around this approach."

Several types of EGFR-expressing solid tumors targeted in New CAR T-Cell Immunotherapy Trial (http://www.seattlechildrens.org/media/press-releases/2018/Solid-Tumors-Targeted-in-New-CAR-T-Cell-Immunotherapy-Trial/)

"Despite employing modern treatments that offer more intensive therapy or new drug combinations for children with solid tumors, we've been unable to improve outcomes for our highest-risk patient groups," said Dr. Katie Albert (http://www.seattlechildrens.org/medical-staff/catherine-michelle-albert/), an oncologist at Seattle Children's and lead investigator for the STRIvE-01 trial. "It is those groups that push us to come up with innovative approaches so that we can see all of our patients cured of their cancer."

> STRIvE-01 CAR-T trial now open at Seattle Children's for children and young adults with R/R non-CNS tumors expressing EGFR. The target is the unique mAB806 epitope. The PI is our very own Dr. Katie Albert. https://t.co/6ex9xDhD11 (https://t.co/6ex9xDhD11)
>
> — R Orentas (@OrentasR) August 7, 2018 (https://twitter.com/OrentasR/status/1026893115141971968?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
"In order for this therapy to be effective against solid tumors and induce remission for our patients, we have to find a way to not only get the CAR T cells into the tumor microenvironment, but also ensure they can survive and thrive there," said Albert.

First patient dosed in Ph II pivotal trial of CD19-targeting PBD ADC, ADCT-402 (loncastuximab tesirine) in R/R DLBCL patients (https://adctherapeutics.com/)

"We are pleased to have dosed the first patient in our registrational Phase II clinical trial evaluating ADCT-402 in patients with DLBCL who have relapsed and have refractory disease after two or more multi-agent treatment regimens. Our Phase I clinical trial of ADCT-402 in non-Hodgkin lymphoma showed significant activity in patients with DLBCL and an acceptable safety profile," said Jay Feingold, MD, PhD, Chief Medical Officer and Senior Vice President of Clinical Development at ADC Therapeutics. "Unfortunately, there is no effective treatment for patients with multiple relapsed and refractory DLBCL, so we are excited about the potential to improve outcomes in these patients with ADCT-402 in a single-arm trial. We anticipate reporting results from the Phase II trial in the third quarter of 2019 and are hopeful that the data will support our submission of a BLA to the FDA."

> #ClinicalTrials (https://twitter.com/hashtag/ClinicalTrials?src=hash&ref_src=twsrc%5Etfw) (US): Study to Evaluate the Efficacy and Safety of #Loncastuximab (https://twitter.com/hashtag/Loncastuximab?src=hash&ref_src=twsrc%5Etfw) Tesirine in Patients With Relapsed or Refractory Diffuse Large B-Cell #Lymphoma (https://twitter.com/hashtag/Lymphoma?src=hash&ref_src=twsrc%5Etfw). https://t.co/Ne9TirgBvr (https://t.co/Ne9TirgBvr) https://t.co/jwMf4nBG45 (https://t.co/jwMf4nBG45)
>
> — William Avery Hudson (@wahwahnyc) July 19, 2018 (https://twitter.com/wahwahnyc/status/1019991296797233152?ref_src=twsrc%5Etfw)

https://platform.twitter.com/widgets.js (https://platform.twitter.com/widgets.js)
Alex Spira, MD, PhD, FACP, Director of Virginia Cancer Specialists Research Institute and Clinical Assistant Professor of Oncology at Johns Hopkins School of Medicine, added, "Patients with DLBCL who have relapsed or are refractory after second-line chemotherapy face a very poor prognosis. There is a significant unmet need for an effective new treatment option for this patient population, and we believe ADCT-402 has the potential to help impact patient outcomes in this disease."

Patient dosing started in Ph I trial of poplypeptide drug HPN424 in mCRPC patients (https://www.harpoontx.com/news/080618/)

"We are pleased to initiate Harpoon's first clinical trial with HPN424 in patients with advanced prostate cancer, an

important milestone that marks our transition to a clinical-stage company," said Jerry McMahon, PhD, President and Chief Executive Officer of Harpoon Therapeutics. "HPN424 is the first TriTAC compound to enter clinical testing and represents a novel class of T cell therapeutics aiming to achieve superior efficacy in penetrating and killing solid tumors. Data is expected in 2019, and should provide the safety assessment, pharmacokinetics and pharmacodynamics to determine the optimal dose and regimen for our additional planned trials in prostate cancer, the third leading cause of cancer deaths for men in the U.S."

> First Patient Advanced Prostate Cancer Treated with Harpoon Therapeutics' HPN424 https://t.co/IDtEozeTww (https://t.co/IDtEozeTww) pic.twitter.com/RYCnwcy01P (https://t.co/RYCnwcy01P)
>
> — BioNews Services (@bionewsservices) August 9, 2018 (https://twitter.com/bionewsservices/status/1027623957908938758?ref_src=twsrc%5Etfw)

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

Ph III ATLANTIS study of Lurbinectedin + doxorubicin reached the goal of patient recruitment in R/R SCLC patients (https://www.pharmamar.com/wp-content/uploads/2018/07/PR_ATLANTIS-end-patients-recruitment.pdf)

Anna Farago M.D., Ph.D., co-Principal Investigator of the ATLANTIS trial from Massachusetts General Hospital in Boston said, "The completion of enrollment to ATLANTIS marks an important moment for clinical trials in small cell lung cancer. New approaches for treating this aggressive cancer are sorely needed. We look forward to seeing the overall survival data from ATLANTIS soon, and we are hopeful that the combination lurbinectedin and doxorubicin will demonstrate a benefit compared to current standard of care therapy, and therefore provide a new option for patients with this terrible disease."

> Atlantis is a #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) with the goal to obtaining the efficacy of the combination of #lurbinectedin (https://twitter.com/hashtag/lurbinectedin?src=hash&ref_src=twsrc%5Etfw) plus #doxorubicin (https://twitter.com/hashtag/doxorubicin?src=hash&ref_src=twsrc%5Etfw) in patients with small-cell #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) Check all the info here: https://t.co/HIBNmUvkNs (https://t.co/HIBNmUvkNs) pic.twitter.com/vdJLZ2K6gl (https://t.co/vdJLZ2K6gl)
>
> — PharmaMar (@PhrmMar) April 23, 2018 (https://twitter.com/PhrmMar/status/988432367101644800?ref_src=twsrc%5Etfw)

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Luis Paz-Ares, M.D., Professor of Medicine, co-Principal Investigator of the ATLANTIS trial from Hospital Universitario 12 de Octubre, Madrid added, "The completion of the recruitment of the ATLANTIS clinical trial represents an important milestone. In a disease as relapsed small cell lung cancer, we are in need of new therapeutic opportunities for these patients and the results of this trial with lurbinectedin could help to change the therapeutic landscape in a setting in which, unfortunately, there have been no large advances in recent years. We are eagerly waiting for the trial data to mature and have the results available."

Luis Mora, Managing Director of PharmaMar´s Oncology Business Unit, said "we are pleased and excited that we have completed enrolment of this large trial. Between ATLANTIS and our monotherapy trial, we hope to deliver to regulators data sets that can lead to the approval of Lurbinectedin for this difficult to treat disease."

New Ph III trial initiated of PD-1 inhibitor Tislelizumab + Chemotherapy as 1L treatment for patients with advanced Squamous NSCLC in China (http://ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2363006)

"With the start of this important Phase 3 trial in China for patients with squamous NSCLC, our broad development program for tislelizumab, an advanced immuno-oncology therapy, continues to make great progress in China and globally. More than 1,500 patients have been enrolled in clinical trials with tislelizumab over the past three years, and we are excited to evaluate its potential when combined with both paclitaxel and carboplatin, the worldwide standard of care, or nab-paclitaxel (ABRAXANE®) and carboplatin, a newer regimen which has not yet gained approval in China but is approved in other geographies," commented Amy Peterson, M.D., Chief Medical Officer for Immuno-Oncology at BeiGene.

> BeiGene launches late-stage study of tislelizumab in first-line lung cancer https://t.co/MFFK67Nqqu (https://t.co/MFFK67Nqqu)
>
> — OncologyInfo (@OncologyInfo) August 9, 2018 (https://twitter.com/OncologyInfo/status/1027629963929956352?ref_src=twsrc%5Etfw)

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"Despite some recent developments, available data indicate that outcomes in patients with squamous NSCLC may be worse than those in patients with other forms of lung cancer. As shown by most recent data with other checkpoint inhibitors, combining immunotherapy and chemotherapy consisting of platinum and paclitaxel or nab-paclitaxel improves anti-tumor activity and significantly improves outcomes for patients with advanced squamous NSCLC. This Phase 3 study, in addition to our Phase 3 first line trial in China for patients with non-squamous NSCLC, will assess the impact of tislelizumab given in combination with chemotherapy, as a potential way to

improve outcomes in Chinese patients with advanced lung cancer, for whom prognoses are typically quite poor," commented Lai Wang, Ph.D., Head of China Development at BeiGene.

Recruitment completed in Ph II trial of pan-HER inhibitor Varlitinib in 1L gastric cancer (http://aslanpharma.com/2018/08/10/亞獅康varlitinib作為胃癌一線療法之全球二期臨床試驗完/)

Dr Bertil Lindmark, Chief Medical Officer, ASLAN Pharmaceuticals, said: "We are pleased to complete the patient recruitment for the first part of this important global phase 2/3 study for varlitinib in gastric cancer. We had initially planned to enrol 40 patients but strong recruitment allowed us to enrol the maximum of 52 patients. We expect to recruit an additional 350 patients as we progress on to the second part of the trial if the primary endpoint for phase 2 is met. With limited treatment options currently available, varlitinib has the potential to make a significant impact in one of the world's most prevalent and deadly cancers."

> ASLAN Pharmaceuticals Completes Recruitment for Global Phase 2 Study for Varlitinib in First Line Gastric Cancer https://t.co/vdnaaajhXE (https://t.co/vdnaaajhXE)
>
> — Crwe World (@CrweWorld) August 10, 2018 (https://twitter.com/CrweWorld/status/1027893607959687168?ref_src=twsrc%5Etfw)

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

COLLABORATIONS & LICENSING DEALS

Harbour BioMed to develop GBR 1302, a First-in-Class anti-HER2 x anti-CD3 bispecific antibody for treatment of HER2+ cancers in China (http://www.glenmarkpharma.com/sites/default/files/Pharmaceuticals-and-Harbour-BioMed-Sign-Agreement-for-Greater-China-toDevelop-GBR-1302.pdf)

"We are very pleased to begin this strategic relationship with Harbour BioMed for the development and commercialization of our bispecific antibody, GBR 1302 in Greater China, where the predominance of certain HER2 positive cancers presents a significant clinical need," said Glenn Saldanha, Chairman and Managing Director of Glenmark. "GBR1302 is representative of Glenmark's commitment to the discovery and development of innovative therapeutics for unmet medical need, and the opportunity to work collaboratively with Harbour BioMed on this program, which brings extensive local experience, is very important to Glenmark."

> #Glenmark (https://twitter.com/hashtag/Glenmark?src=hash&ref_src=twsrc%5Etfw) in deal with Chinese firm Harbour BioMed for innovative molecule https://t.co/PoJGAtqDJZ (https://t.co/PoJGAtqDJZ)
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> — Research Analyst (@mastersrock222) August 9, 2018 (https://twitter.com/mastersrock222/status/1027448172099129344?ref_src=twsrc%5Etfw)

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Dr. Jingsong Wang, founder and CEO of Harbour BioMed said: "We are looking forward to collaborating with Glenmark Pharmaceuticals to develop and commercialize this promising, novel bispecific antibody in Greater China to meet the significant unmet medical needs of Chinese cancer patients. This collaboration is aligned with our strategy to leverage our clinical development expertise by in-licensing highly innovative clinical stage assets. GBR 1302 is complementary to the internal portfolio we are building through our industry leading transgenic mouse platforms for generating innovative antibody-based therapeutics."

DIAGNOSTIC ASSAYS

Agilent Announces update on PD-L1 CE-IVD in Urothelial Carcinoma (https://www.agilent.com/about/newsroom/presrel/2018/08aug-ca18065.html)

"We are pleased that PD-L1 IHC 22C3 pharmDx will help physicians identify urothelial carcinoma patients for whom KEYTRUDA may be an appropriate first-line treatment option. Being able to support the use of immuno-oncology therapeutics by bringing their associated diagnostics to market is truly encouraging," said Sam Raha, president of Agilent's Diagnostics and Genomics Group.

Second Quarter 2018 Financial Results and Corporate Updates

Visit AstraZeneca (https://www.astrazeneca.com/media-centre/press-releases/2018/h1-2018-results-25072018.html), Merck (https://www.mrknewsroom.com/news-release/corporate-news/merck-announces-second-quarter-2018-financial-results), Boehringer Ingelheim (https://www.boehringer-ingelheim.com/press-release/halfyear1?), Bristol-Myers Squibb (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-reports-second-quarter-financial-result-0), Takeda Oncology (https://www.takeda.com/investors/reports/quarterly-announcements/quarterly-announcements-2018/), Roche (https://www.roche.com/investors/updates/inv-update-2018-07-26.htm), Merus (http://merus.nl/2018/08/10/merus-announces-financial-results-for-the-second-quarter-2018-mid-year-operating-results/), Beigene (http://phx.corporate-ir.net/phoenix.zhtml?c=254246&p=irol-newsArticle&id=2363005), Jounce Therapeutics (http://ir.jouncetx.com/phoenix.zhtml?c=254289&p=irol-newsArticle&ID=2363021), Loxo

Oncology (https://ir.loxooncology.com/press-releases/2363024-Loxo-oncology-reports-second-quarter-2018-financial-results), Aptevo Therapeutics (http://ir.aptevotherapeutics.com/news-releases/news-release-details/aptevo-therapeutics-reports-second-quarter-2018-financial), Cyclacel Pharmaceuticals (http://investor.cyclacel.com/news-releases/news-release-details/cyclacel-pharmaceuticals-reports-second-quarter-2018-financial), Asterias Biotherapeutics (http://asteriasbiotherapeutics.com/inv_news_releases_text.php?releaseid=2363196&date=August+09%2C+2018&title=Asterias+Biotherapeutics+Reports+Second+Quarter+Financial+Results+and+Recent+Dev Molecular Templates (http://ir.mtem.com/news-releases/news-release-details/molecular-templates-inc-reports-second-quarter-2018-financial), TRACON Pharmaceuticals (https://traconpharma.gcs-web.com/news-releases/news-release-details/tracon-pharmaceuticals-reports-second-quarter-2018-financial), CytomX Therapeutics (http://ir.cytomx.com/news-releases/news-release-details/cytomx-therapeutics-announces-second-quarter-2018-financial), G1 Therapeutics (http://investor.g1therapeutics.com/phoenix.zhtml?c=254335&p=irol-newsArticle&ID=2362851), Celldex (http://ir.celldex.com/news-releases/news-release-details/celldex-provides-corporate-update-and-reports-second-quarter), Ziopharm Oncology (http://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-reports-second-quarter-2018-financial-results), BioXcel Therapeutics (http://ir.bioxceltherapeutics.com/news/detail/49/bioxcel-therapeutics-reports-second-quarter-2018-financial-results-and-provides-business-update), Genmab (http://ir.genmab.com/news-releases/news-release-details/genmab-announces-financial-results-first-half-2018), Selecta Biosciences (https://selectabio.gcs-web.com/news-releases/news-release-details/selecta-biosciences-announces-second-quarter-2018-financial), Affimed (http://www.affimed.com/pdf/20180808_afmd_2q18_earnings_final.pdf), Cellular Biomedicine Group (http://www.cellbiomedgroup.com/newsroom/second-quarter-and-first-half-2018-financial-results-and-business-highlights/), Leap Therapeutics (http://www.investors.leaptx.com/phoenix.zhtml?c=254460&p=irol-newsArticle&ID=2362754), Trillium Therapeutics (https://trilliumtherapeutics.com/investors/news/Press-Release-Details/2018/Trillium-Therapeutics-Reports-Second-Quarter-2018-Financial-and-Operating-Results/default.aspx), Checkpoint Therapeutics (http://ir.checkpointtx.com/Cache/1001241130.PDF?O=PDF&T=&Y=&D=&FID=1001241130&iid=4660467), Aptose Biosciences (http://ir.aptose.com/phoenix.zhtml?c=116148&p=irol-newsArticle&ID=2362628), Aileron Therapeutics (http://investors.aileronrx.com/phoenix.zhtml?c=254548&p=irol-newsArticle&ID=2362608), Calithera Biosciences (http://ir.calithera.com/news-releases/news-release-details/calithera-biosciences-reports-second-quarter-2018-financial?field_nir_news_date_value%5bmin%5d=), Inovio Pharmaceuticals (http://ir.inovio.com/news-and-media/news/press-release-details/2018/Inovio-Pharmaceuticals-Reports-2018-Second-Quarter-Financial-Results/default.aspx), Bellicum Pharmaceuticals (http://ir.bellicum.com/node/8756), FibroGen, Inc. 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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.

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(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) Confocal micrograph showing a dividing cancer cell (HeLa) in time-lapse. Cellular structures have been visualised in cyan (cell membrane) and red (DNA). The spiral arrangement captures the journey of a cell as it divides and creates new cells. HeLa cells undergo cell division approximately once every 16 hours. The cell spends a substantial portion of this time preparing itself for division during interphase, and the actual process by which the cell physically divides takes approximately an hour. The cell in the center of the image has completed prophase and pro-metaphase by rounding and aligning its duplicated DNA in the center (metaphase). It is now ready to pull the identical copies of DNA to opposing ends of the cell (anaphase, approximately eight minutes). This is followed by cytokinesis (approximately 15-20 minutes), when the cell contraction in the middle and physically separates into two daughter cells. Wellcome Image Award 2012.Kuan-Chung Su, Mark Petronczki (2012) CIL:41732, Homo sapiens. CIL. Dataset. https://doi.org/doi:10.7295/W9CIL41732- Source (http://cellimagelibrary.org/images/41732)

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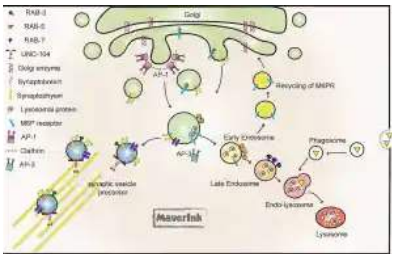

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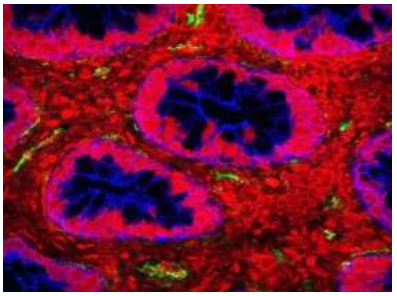

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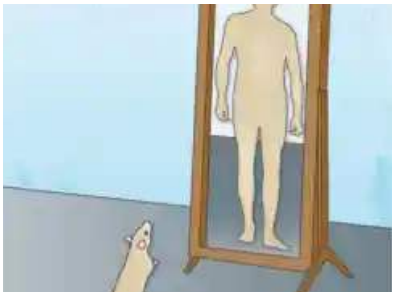

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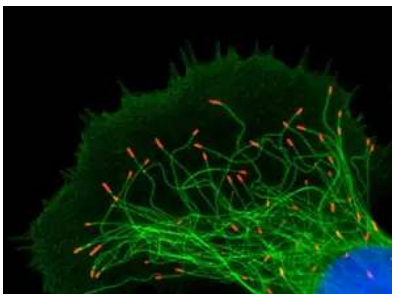

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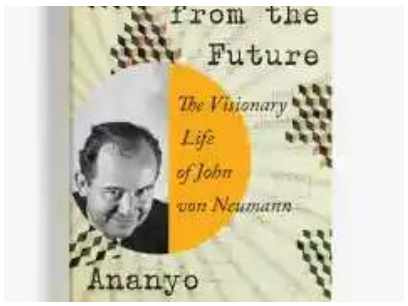

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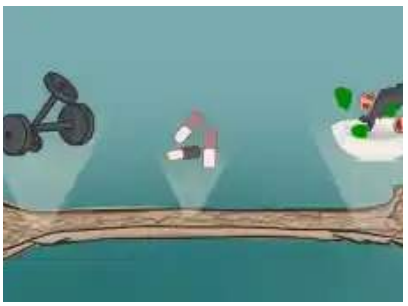

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