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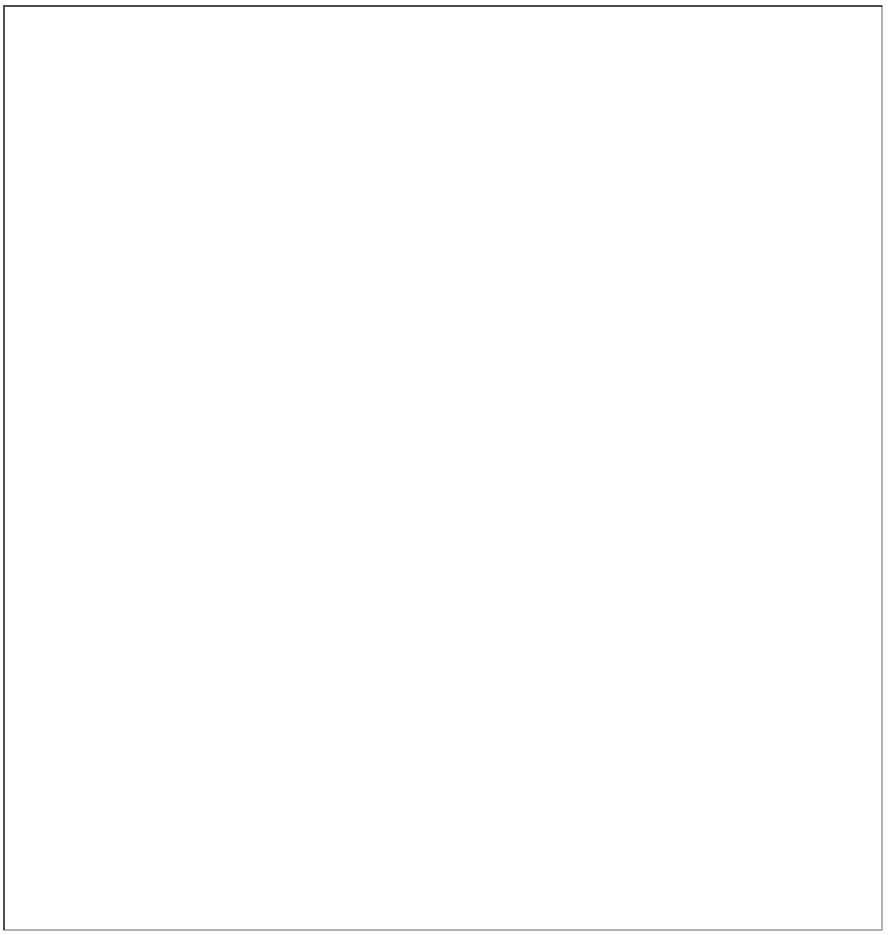
Onco-this-Week

March 3, 2019(https://sciwri.club/archives/date/2019/03/03)



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oTW in a Capsule

HIGHLIGHTS

1. FDA approval of LONSURF in 3L gastric or GEJ adenocarcinoma patients. Gastric cancer has always been a very aggressive indication to treat, (https://www.taihooncology.com/us/newsroom/press-releases/2019-02-25-LON-PM-US-1213-FDA-Approves-Gastric) with limited therapy options. The unmet need becomes even greater in relapsed/refractory patients, where average survival is dismal. Based on Ph III TAGS trial data, LONSURF received a FDA Priority Review designation earlier and its approval is going to provide another treatment option in this heavily pre-treated patient population.
2. Failure of Mirvetuximab in 3L platinum-resistant ovarian cancer patients. Immunogen's shares fell after its lead ADC candidate, Mirvetuximab soravtansine, failed to meet primary endpoints of PFS improvement in all comers. The treatment algo of ovarian cancer patients relies heavily on use of platinum and the failure of Mirvetuximab in platinum-resistant patients shut down the hope of finding a treatment option in these patients. Immunogen will try to salvage its Mirvetuximab program by relying heavily on combination trials.
3. Priority review to Lenalidomide + Rituximab in R/R FL and MZL. Lenalidomide and Ritumiab combination (dubbed as R²) was granted priority review this week based on Ph III AUGMENT trial data, and raised hopes of bringing a chemotherapy-free option to relapsed/refractory follicular lymphoma and marginal zone lymphoma patients.

DRUG APPROVALS

FDA approves subcutaneous Herceptin Hylecta (trastuzumab and hyaluronidase-oysk) in certain HER2-positive breast cancers based on Ph III HannaH, SafeHER and PrefHER trials (http://hugin.info/174806/R/2236131/881087.pdf)

"Over the past 20 years, Herceptin has significantly advanced treatment of HER2-positive breast cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "The approval of Herceptin Hylecta gives physicians and patients in the United States a new option to select treatment based on individual needs and preferences."

> Subcutaneous Herceptin Hylecta Gains #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) Approval
> Yesterday, the US Food and Drug Administration (FDA) approved Herceptin Hylecta, a new #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) therapeutic developed by #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) company, Halozyme, and Roche's Genentech.https://t.co/P1wGs609So (https://t.co/P1wGs609So)
>
> — Xtalks Webinars (@Xtalks) March 2, 2019 (https://twitter.com/Xtalks/status/1101640784175075329?ref_src=twsrc%5Etfw)

FDA recommends a pivotal trial planned for SM-88 in 3L pancreatic cancer patients with OS as primary endpoint (https://www.tymeinc.com/investors/news-releases/press-release-details/2019/TYME-Receives-FDA-Guidance-on-Pivotal-Trial-for-SM-88-in-Treatment-for-Advanced-Pancreatic-Cancer/default.aspx)

"We thank the FDA for its guidance, which provides instruction for our regulatory path forward in a patient population that has no standard of care and an expected prognosis of only a few months survival," said Steven Hoffman, Chairman and CEO at Tyme Technologies, Inc. "By leveraging our existing trial infrastructure from our TYME-88-Panc study, and the momentum generated from the first stage of that trial, we aim to advance a treatment that could offer both patients and physicians a needed option for third-line advanced pancreatic cancer as quickly as possible."

> TYME Chief Commercial Officer Michele Korfin is excited by the FDA's release of guidance on a pivotal trial for SM-88 in the treatment of pancreatic cancer. pic.twitter.com/8MPRekGZe5 (https://t.co/8MPRekGZe5)
>
> — Tyme Inc. (@tyme_inc) March 1, 2019 (https://twitter.com/tyme_inc/status/1101609590037327872?ref_src=twsrc%5Etfw)

LONSURF (trifluridine/tipiracil) gets approved in 2L+ gastric or gastroesophageal junction (GEJ) adenocarcinoma based on Ph III TAGS trial data (https://www.taihooncology.com/us/newsroom/press-releases/2019-02-25-LON-PM-US-1213-FDA-Approves-Gastric)

“The approval of LONSURF represents a significant milestone for patients living with advanced gastric or GEJ adenocarcinoma who have limited effective treatment options after standard treatment options have failed,” said Timothy Whitten, President and Chief Executive Officer, Taiho Oncology, Inc. “We thank all the patients and physicians who helped make this possible through their participation in LONSURF clinical trials.”

> Lonsurf gains metastatic gastric cancer indication https://t.co/MQVKeUiuCO (https://t.co/MQVKeUiuCO)
>
> — MPR (@eMPR) February 25, 2019 (https://twitter.com/eMPR/status/1100153795508604929?ref_src=twsrc%5Etfw)

REGULATORY NEWS

Positive CHMP opinion to Olaparib in gBRCA1/2-mutated HER2neg locally advanced or metastatic breast cancer based on Ph III OlympiAD trial data (https://www.astrazeneca.com/media-centre/press-releases/2019/lynparza-receives-positive-eu-chmp-opinion-for-use-in-germline-brca-mutated-her2-negative-advanced-breast-cancer-01032019.html)

Dave Fredrickson, Executive Vice President, Oncology, said: “Despite progress in treating patients with advanced breast cancer, there remains a significant unmet need for new treatment options. If approved, Lynparza will provide these patients with both a targeted and oral chemotherapy-free option. We now have evidence supporting the potential use of Lynparza in patients with BRCA-mutated breast, ovarian and pancreatic cancers, which demonstrates our ongoing commitment to improving patient outcomes in difficult-to-treat cancers.”

> LYNPARZA® (olaparib) Receives Positive EU CHMP Opinion For Use in Germline BRCA-Mutated HER2-Negative Advanced Breast Cancer https://t.co/Nk6222FZW5 (https://t.co/Nk6222FZW5) pic.twitter.com/Udr8vJnz9t (https://t.co/Udr8vJnz9t)
>
> — Latest News from Business Wire (@NewsFromBW) March 1, 2019 (https://twitter.com/NewsFromBW/status/1101479970814091264?ref_src=twsrc%5Etfw)

NDA filed for ARi Darolutamide in nmCRPC patients based on Ph III ARAMIS trial data (https://www.bayer.us/en/newsroom/press-releases/article/?id=123282)

“We are grateful to the patients, their families and the clinical investigators who have made this important study possible,” said Scott Z. Fields, M.D., senior vice president and head of Oncology Development at Bayer’s Pharmaceutical Division. “The NDA submission is a key milestone bringing us closer to providing darolutamide as a potential treatment option for men with nmCRPC.”

> Bayer reported its key phase 3 clinical trials in developing darolutamide in patients with non-metastatic castrated resistant prostate cancer (nmCRPC). It significantly increased the patient’s metastasis-free survival and reduced the risk of cancer metastasis or death by 59%. pic.twitter.com/dXqgUjwhym (https://t.co/dXqgUjwhym)
>
> — Sinoway Industrial (@sinowaychem) March 2, 2019 (https://twitter.com/sinowaychem/status/1101814462896455680?ref_src=twsrc%5Etfw)

Priority review granted to Lenalidomide + Rituximab in R/R FL and MZL based on Ph III AUGMENT trial data;

PDUFA: Jun 2019 (https://ir.celgene.com/press-releases/press-release-details/2019/Celgene-Corporation-Announces-Key-Regulatory-Updates-for-REVLIMID-in-Lymphoma-and-Luspatercept-in-MDS-and-Beta-Thalassemia/default.aspx)

"R2 has the potential to offer patients with previously treated follicular lymphoma and marginal zone lymphoma a chemotherapy free option" said Jay Backstrom, M.D., Chief Medical Officer and Head of Global Regulatory Affairs for Celgene. "We look forward to working with the FDA to bring the R2 regimen to patients as quickly as possible."

> Lenalidomide and rituximab combination for R/R PCNSL-DLBCL patients. Read more here https://t.co/b4l6uhO3g0 (https://t.co/b4l6uhO3g0) #lymsm (https://twitter.com/hashtag/lymsm?src=hash&ref_src=twsrc%5Etfw) #lymphoma (https://twitter.com/hashtag/lymphoma?src=hash&ref_src=twsrc%5Etfw) #hematology (https://twitter.com/hashtag/hematology?src=hash&ref_src=twsrc%5Etfw) @lymphomahub (https://twitter.com/lymphomahub?ref_src=twsrc%5Etfw) pic.twitter.com/e9dCPSM9vB (https://t.co/e9dCPSM9vB)
>
> — Lymphoma Hub (@lymphomahub) February 22, 2019 (https://twitter.com/lymphomahub/status/1098945769976016897?ref_src=twsrc%5Etfw)

ODAC against accelerated approval to Selinexor in triple refractory MM based on Ph IIb STORM trial data; recommends waiting for results of Ph III BOSTON trial (https://investors.karyopharm.com/news-releases/news-release-details/karyopharm-announces-outcome-fda-advisory-committee-meeting)

"While we are disappointed with ODAC's recommendation to delay the potential approval of selinexor, we plan to work with the FDA to evaluate the best path forward as they continue to review our NDA. Karyopharm remains committed to improving the outcomes of patients with cancer, including those with relapsed refractory multiple myeloma," said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm. "Patients with triple class refractory multiple myeloma have disease which has progressed following treatment with the most effective myeloma drugs approved to date and are in desperate need of new treatment options. Karyopharm has assembled and submitted a compelling, comprehensive clinical data package to the FDA supporting the request for accelerated approval for selinexor. We are committed to working with the FDA, patients, and the myeloma community with the goal to provide selinexor as an option for those patients with no other options of known clinical benefit."

> There is no better way to learn about the conscientious review of drugs than to read @FDA (https://twitter.com/FdA?ref_src=twsrc%5Etfw) ODAC transcripts and background documents. Example:
> Oncologic Drugs Advisory Committee Meeting February 26, 2019
> NDA 212306 Selinexor https://t.co/DB6gNAKVmy (https://t.co/DB6gNAKVmy) pic.twitter.com/3qhCQKmUEX (https://t.co/3qhCQKmUEX)
>
> — Lymphomation.org (@Lymphomation) March 1, 2019 (https://twitter.com/Lymphomation/status/1101495031226134529?ref_src=twsrc%5Etfw)

SPECIAL STATUSES

Fast Track Designation granted to adoptive cell therapy LN-145 for Cervical Cancer based on Ph II C-145-04 trial data (http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2389051)

"We are pleased to have received Fast Track designation for LN-145 for the treatment of cervical cancer in patients who have failed chemotherapy treatment," commented Maria Fardis, Ph.D., MBA, president and chief executive officer of Iovance Biotherapeutics. "The designation is an important positive step for the development

of LN-145 in a serious and unmet medical need patient population. We are excited about the clinical data for LN-145 in cervical cancer patients and look forward to a closer collaboration with the FDA as we advance the clinical development of LN-145 for the treatment of cervical cancer."

> Iovance Biotherapeutics announces fast track designation for LN-145 from FDA https://t.co/ZH2nrhtSdm (https://t.co/ZH2nrhtSdm)
>
> — AwesomeCapital (@AwesomeCapital) February 26, 2019 (https://twitter.com/AwesomeCapital/status/1100406580124692480?ref_src=twsrc%5Etfw)

TRIAL RESULTS

Failed trial: Ph III FORWARD I trial of Mirvetuximab soravtansine in 3L platinum resistant ovarian cancer fails to meet endpoints (http://investor.immunogen.com/news-releases/news-release-details/immunogen-announces-top-line-results-phase-3-forward-i-study)

"Even though FORWARD I did not meet its primary endpoint, I continue to be impressed with the efficacy and tolerability of mirvetuximab soravtansine in ovarian cancer patients, especially in the subset with high FRα expression," said Dr. Kathleen Moore, Associate Director of Clinical Research at the Stephenson Cancer Center at the University of Oklahoma. "I look forward to continuing to work with ImmunoGen to analyze the Phase 3 data and determine the most appropriate path to bringing mirvetuximab soravtansine to those patients who benefit most from it."

> Phase III failure of mirvetuximab soravtansine in ovarian Cancer touches off stock price plunge for ImmunoGenInc httpow.lyUe3030nT4FSÂ: Phase III failure of mirvetuximab soravtansine in ovarian Cancer touches off stock price plunge for ImmunoGenInc... https://t.co/c30BbE1401 (https://t.co/c30BbE1401)
>
> — Ovarian Cancer News (@OvarianC_bio) March 1, 2019 (https://twitter.com/OvarianC_bio/status/1101619641200197632?ref_src=twsrc%5Etfw)

Ph II CALGB 10403 trial results justify use of pediatric regimen from AALL0232 trial in 1L AYA ALL patients (https://www.cancer.gov/news-events/cancer-currents-blog/2019/aya-leukemia-pediatric-regimen-effective?cid=eb_govdel)

"The pediatric regimen will become the new standard treatment for young adults who are newly diagnosed with ALL," Dr. Seibel said. "And, as we try to improve the treatment for ALL, this regimen will be the treatment against which other therapies are compared."

> AYA studies are an important part of the #NCTN (https://twitter.com/hashtag/NCTN?src=hash&ref_src=twsrc%5Etfw) trial portfolio! Check out the recent results from CALGB 10403, an important @ALLIANCE_org (https://twitter.com/ALLIANCE_org?ref_src=twsrc%5Etfw) NCTN study setting a new treatment standard for AYA ALL: https://t.co/eqjchyw73f (https://t.co/eqjchyw73f) (Sub Required) pic.twitter.com/YXqdSedJ1R (https://t.co/YXqdSedJ1R)
>
> — NCI CTEP Clinical Research (@NCICTEP_ClinRes) January 25, 2019 (https://twitter.com/NCICTEP_ClinRes/status/1088813749610401792?ref_src=twsrc%5Etfw)

Ph III POLO trial of Olaparib meets primary endpoint of PFS improvement in 1L maintenance settings in gBRCA m+ pancreatic cancer (https://www.astrazeneca.com/media-centre/press-releases/2019/lynparza-significantly-delayed-disease-progression-as-1st-line-maintenance-treatment-in-germline-brca-mutated-metastatic-pancreatic-cancer-26022019.html)

José Baselga, Executive Vice President, Research and Development, Oncology, said: "This is the first positive Phase III trial of any PARP inhibitor in germline BRCA-mutated metastatic pancreatic cancer, a devastating disease with critical unmet need. The results of POLO provide further evidence of the clinical benefit of Lynparza across a variety of BRCA-mutated tumour types. We will discuss these results with global health authorities as soon as possible."

> AstraZeneca & Merck Report Result of Lynparza (olaparib) in P-III POLO Trial for BRCA-Mutated Metastatic Pancreatic Cancer @AstraZeneca (https://twitter.com/AstraZeneca?ref_src=twsrc%5Etfw) https://t.co/MavwKHJ07L (https://t.co/MavwKHJ07L) pic.twitter.com/lwtKhXZ2ec (https://t.co/lwtKhXZ2ec)
>
> — PharmaShots (@Pharmashot) February 28, 2019 (https://twitter.com/Pharmashot/status/1100985004417581056?ref_src=twsrc%5Etfw)

Deep and durable responses observed in Ph I trial of Ivosidenib + Azacitidine in 1L IDH1 m+ AML patients (https://agiospharmaceuticalsinc.gcs-web.com/node/12226)

"With longer follow up from the ongoing Phase 1 study, the ivosidenib and azacitidine combination data in newly diagnosed AML patients are striking, with a 65% CR+CRh rate, 57% CR rate and the majority of CR patients achieving IDH1 mutation clearance," said Courtney DiNardo, M.D., lead investigator and assistant professor, department of leukemia at the University of Texas MD Anderson Cancer Center. "The combination regimen showed a 12-month survival rate of 82%, which is impressive given the age and comorbidities associated with patients who are not eligible for intensive chemotherapy. From a safety perspective, results from the combination were consistent with the safety profiles of each drug used alone and cytopenias were in line with those seen for azacitidine alone and favorable compared with other emerging hypomethylating agent combinations."

> Agios Reports Updated Data from Phase 1 Study of Ivosidenib in Combination with Azacitidine Demonstrating Deep and Durable Responses in Newly Diagnosed IDH1 Mutant Acute Myeloid Leukemia AML Patients: Overall Response Rate of 78 CRCRh Rate of 65 and... https://t.co/2kX1rFdOkx (https://t.co/2kX1rFdOkx)
>
> — Leukemia News (@Leukemia_bio) February 25, 2019 (https://twitter.com/Leukemia_bio/status/1100004999482900480?ref_src=twsrc%5Etfw)

Positive top-line data announced from Ph II trial of CLR 131 in RRMM patients (https://www.cellectar.com/news-media/press-releases/detail/202/cellectar-reports-positive-top-line-response-rate-of-30)

"We are encouraged by the 30% response rate and continued positive results in our ongoing Phase 2 study of CLR 131," said James Caruso, president and CEO of Cellectar. "This represents the second cohort of patients who have demonstrated encouraging responses to our lead drug candidate while receiving sub-optimal single doses. We look forward to the availability of additional data this year and will continue to aggressively enroll patients and dose at higher levels that have the potential to generate increased efficacy."

Cellectar's phase II clinical trial is evaluating CLR-131 in patients with relapsed or refractory multiple #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw). https://t.co/jTiqnaZdpX (https://t.co/jTiqnaZdpX) #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) #mmsm (https://twitter.com/hashtag/mmsm?src=hash&ref_src=twsrc%5Etfw) @myelomacrowd (https://twitter.com/myelomacrowd?ref_src=twsrc%5Etfw) pic.twitter.com/YoFZW7E2XB (https://t.co/YoFZW7E2XB)

— SparkCures (@SparkCures) March 1, 2019 (https://twitter.com/SparkCures/status/1101589296392429568?ref_src=twsrc%5Etfw)

Ph III COLUMBA trial of SC Daratumumab meets both co-primary endpoints of ORR and Ctrough in RRMM patients (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-positive-topline-results-phase-iii-columba)

"With the data from each of the key clinical studies we learn more about the difference that daratumumab potentially can make to the lives of patients suffering with multiple myeloma. I am particularly excited about the results from this study as it may support a much quicker and far more convenient administration of daratumumab, which would provide an important benefit for many patients and their families," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Genmab Announces Positive Topline Results in Phase III Study of Subcutaneous Daratumumab in Multiple Myeloma: Copenhagen Denmark; February 25 2019 ÂGenmab AS Nasdaq Copenhagen GEN announced today topline results from the Phase III COLUMBA study MMY3012... https://t.co/uzFazT8NMK (https://t.co/uzFazT8NMK) pic.twitter.com/hwz09iuqEg (https://t.co/hwz09iuqEg)

— Clinical Trials News (@ClinicalPhase) February 25, 2019 (https://twitter.com/ClinicalPhase/status/1100110213888106497?ref_src=twsrc%5Etfw)

TRIAL STATUSES

First patient dosed in Ph II/III ORIENT-32 trial of PD-1 inh Sintilimab in 1L HCC patients (http://innoventbio.com/en/#/news/134)

"HCC is the fourth most common cancer and the second leading cause of cancer related death in China. The five-year survival rate is about 10%, and only 20-30% of patients have the opportunity for curative surgery. Current targeted therapies have only shown limited responses in HCC. Immune checkpoint inhibitors have brought new hope to patients with this life-threatening disease. We hope to validate the therapeutic potential of Tyvyt® in combination with IBI305 in the ORIENT-32 trial," said Professor Fan Jia, President of Zhongshan Hospital, and an academician of the Chinese Academy of Sciences.

First Patient Dosed in a Clinical Trial of Tyvyt® (Sintilimab injection) in Combination with IBI305 https://t.co/dye09KSXB2 (https://t.co/dye09KSXB2)

— Patient Daily (@patient_daily) March 2, 2019 (https://twitter.com/patient_daily/status/1101757779327574017?ref_src=twsrc%5Etfw)

Patient enrolment completed in Ph II ILLUMINATE-204 trial of TLR9 agonist tilsotolimod + ipilimumab in PD-1-refractory metastatic melanoma patients (http://ir.iderapharma.com/news-releases/news-release-details/idera-pharmaceuticals-completes-enrollment-illuminate-204-trial)

"We made tremendous progress with the clinical development of tilsotolimod in the second half of 2018, and enrollment in the phase 3 study in patients with melanoma progressing on PD-1 therapy is tracking to complete by the end of 2019." stated Joanna Horobin, M.B. Ch.B, Idera's Chief Medical Officer. "Oncologists are enthusiastic to extend the use of tilsotolimod to potentially improve the outcome of immuno-therapy for other patient populations, such as head and neck cancer, and in microsatellite stable CRC where so far immunotherapy outcomes have not been optimal."

> $IDRA (https://twitter.com/search?q=%24IDRA&src=ctag&ref_src=twsrc%5Etfw) Completes Enrollment Into the ILLUMINATE204 Trial of the Combination of Tilsotolimod and Ipilimumab for Unresectable or Metastatic Melanoma. Results expected Q4 19 httpsglobenewswire.comnewsrelease20190227174327oenIderaPharmaceutic: $IDRA... https://t.co/qzcB5LTZbo (https://t.co/qzcB5LTZbo)
>
> — Drug Discovery News (@DiscoveryDrug) February 27, 2019 (https://twitter.com/DiscoveryDrug/status/1100781990163312640?ref_src=twsrc%5Etfw)

Ph I trial of novel anti-CD47/ anti-CD19 Bispecific Antibody TG-1801 initiated in R/R B-cell lymphoma patients (http://ir.tgtherapeutics.com/news-releases/news-release-details/tg-therapeutics-announces-initiation-phase-i-first-human)

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We are extremely pleased to announce the commencement of clinical development for TG-1801, our proprietary first-in-class anti-CD47/CD19 bispecific antibody which we licensed from Novimmune last year." Mr. Weiss continued, "CD47 targeted therapy has yielded promising early clinical results, and we look forward to exploring the potential of this dual targeted immunotherapy with a long-term goal of combining TG-1801 with our other in-house immunotherapies and targeted agents to create novel treatment options for patients with B-cell cancers."

> #TGTherapeutics (https://twitter.com/hashtag/TGTherapeutics?src=hash&ref_src=twsrc%5Etfw) Announces Initiation of Phase I First-in-Human Clinical Trial of its #AntiCD47 (https://twitter.com/hashtag/AntiCD47?src=hash&ref_src=twsrc%5Etfw)/#CD19BispecificAntibody (https://twitter.com/hashtag/CD19BispecificAntibody?src=hash&ref_src=twsrc%5Etfw), #TG1801 (https://twitter.com/hashtag/TG1801?src=hash&ref_src=twsrc%5Etfw), in Patients with Relapsed or Refractory #BcellLymphoma (https://twitter.com/hashtag/BcellLymphoma?src=hash&ref_src=twsrc%5Etfw) $TGTX (https://twitter.com/search?q=%24TGTX&src=ctag&ref_src=twsrc%5Etfw) https://t.co/oIDjKi4twU (https://t.co/oIDjKi4twU)
>
> — 1stOncology (@1stOncology) February 27, 2019 (https://twitter.com/1stOncology/status/1100755092058329088?ref_src=twsrc%5Etfw)

First patient in second cohort dosed with COTI-2 + Cisplatin in ongoing Ph Ib/IIa trial in solid tumors (http://globenewswire.com/news-release/2019/02/26/1742721/0/en/Cotinga-Pharmaceuticals-Doses-First-Patient-in-Second-Cohort-of-Phase-1b-2a-Combination-Trial-of-COTI-2-in-Solid-Tumors.html?ev=1)

1st Patient Dosed in Phase 1/2 Trial of COTI-2 Plus Chemo for Gynecological and Other Solid Cancers https://t.co/xekD73QTdv (https://t.co/xekD73QTdv) pic.twitter.com/6ueuVt7OAa (https://t.co/6ueuVt7OAa)

— BioNews Services (@bionewsservices) February 15, 2019 (https://twitter.com/bionewsservices/status/1096477485687099394?ref_src=twsrc%5Etfw)

"We are pleased to report that the DEC voted unanimously to continue dose escalation in our combination trial, with the new dosage level of 1.0 mg/kg, an increase from the 0.5 mg/kg level of cohort 1", said Alison Silva, Cotinga's President & CEO. "We are pleased with the Committee's recommendation and trial advancement. Additionally, we continue to be encouraged by the enthusiasm of our investigators who have been working diligently to screen and enroll patients for this and upcoming cohorts. The patients in our ongoing Phase 1b/2a trial are suffering from a wide spectrum of cancers with little to no therapeutic options, and we are hopeful that combining existing chemotherapy regimens with COTI-2 could be a potential treatment as we have demonstrated and published in a number of preclinical studies. We remain committed to advancing the clinical development of COTI-2, and we will continue to provide key updates as the trial progresses."

Ph I/II ASTISTRY-2 trial of SC IL-2R-binding fusion protein ALKS 4230 +/- Pembrolizumab initiated in solid tumor patients (http://phx.corporate-ir.net/phoenix.zhtml?c=92211&p=RssLanding&cat=news&id=2388952)

Alkermes Initiates Clinical Study of ALKS 4230 Administered Subcutaneously in Patients With Advanced Solid Tumors: OnceWeekly and OnceEveryThreeWeek Dosing of ALKS 4230 to be Evaluated as Monotherapy and in Combination With Pembrolizumab ARTISTRY2 is... https://t.co/FynW8gjDMq (https://t.co/FynW8gjDMq)

— CRO Contract Res. (@cro_bio) February 26, 2019 (https://twitter.com/cro_bio/status/1100464021281501185?ref_src=twsrc%5Etfw)

"The initiation of our clinical subcutaneous dosing study represents an important milestone for the ALKS 4230 program as we explore new regimens that may offer patients a more convenient alternative to daily IV dosing that is complementary to checkpoint inhibitor regimens," said Craig Hopkinson, M.D., Chief Medical Officer and Senior Vice President of Medicines Development and Medical Affairs at Alkermes. "Based on the emerging profile of ALKS 4230, we've rapidly expanded our clinical development program in recent months to evaluate combination therapy, potential efficacy in new tumor types and dosing optionality. The expansion of this program reflects our belief in the significant potential of ALKS 4230 and our recognition of the urgent and persistent need that exists for patients with cancer."

First patient dosed in Ph Ib/II trial of TLR9 agonist AST-008 + pembrolizumab in advanced or metastatic solid tumor patients (http://investors.exicuretx.com/phoenix.zhtml?c=254193&p=irol-newsArticle&ID=2388720)

We dosed the 1st patient in our multicenter, open label, Phase 1b/2 study of AST-008 combined with pembrolizumab. We're enrolling patients w superficial injectable tumors in advanced or metastatic solid tumor conditions such as Merkel cell carcinoma. https://t.co/FgM5RVB96q (https://t.co/FgM5RVB96q)

— Exicure (@exicure) February 25, 2019 (https://twitter.com/exicure/status/1100003580713598977?ref_src=twsrc%5Etfw)

"We believe that combining our immune system agonist drug with checkpoint inhibitors is an important strategy for leveraging the patient's own immune system to fight cancer. We are excited to bring this approach into cancers like Merkel cell carcinoma, where patients have limited success using currently available treatments," said Exicure CEO Dr. David Giljohann. "It is also an important milestone for Exicure in the development of our platform technology, which allows us to digitally design drug candidates and potentially bring them into clinic faster."

First patient completes treatment in Ph II Ovarian cancer trial of autologous dendritic cells (http://aivitabiomedical.com/news/aivita-completes-treatment-of-first-patient-in-phase-2-ovarian-cancer-trial/)

"Interest amongst oncologists has been extremely high, as our therapy complements standard of care and has such a high efficacy rate," said Dr. Robert Dillman, Chief Medical Officer at AIVITA. "Of the eight subjects currently randomized in our trial we have been successful in manufacturing treatments for all eight, further evidencing that this technology can be quickly and reliably produced for the treatment of multiple cancer types."

AIVITA BIOMEDICAL, INC.: Completes Treatment of First Patient in Phase 2 Ovarian Cancer Trial https://t.co/xxji9FRpbc (https://t.co/xxji9FRpbc)

— Patient Daily (@patient_daily) February 24, 2019 (https://twitter.com/patient_daily/status/1099779216533532673?ref_src=twsrc%5Etfw)

First in Human Nanomedicine Drug, BXQ-350, progresses to Ph I Part 3 in rare cancers and GIST (https://www.prnewswire.com/news-releases/bexion-pharmaceuticals-announces-the-opening-of-phase-i-part-3-first-in-human-trial-using-bxq-350-for-the-treatment-of-cancer-300800359.html)

"By enrolling patients in Part 3, we hope to gain a better understanding of the potential of BXQ-350 in treating cancer," stated Dr. Ray Takigiku, Founder and CEO of Bexion.

Bexion Pharmaceuticals Announces the Opening of Phase I Part 3 First-in-Human Trial Using BXQ-350 for the Treatment of Cancer https://t.co/vuA50qR7r7 (https://t.co/vuA50qR7r7)

— DEALBOSSwires (@DealbosSwires) February 22, 2019 (https://twitter.com/DealbosSwires/status/1098985889177522177?ref_src=twsrc%5Etfw)

COMPANION Dx

BRACAnalysis CDx® successfully identifies BRCA+ metastatic pancreatic cancer patients to benefit with olaparib in Ph III POLO trial; sPMA planned (https://myriad.com/investors/news-release/news-release-detail/?newsItemId=20306)

"The results of the POLO trial strongly support use of the BRACAnalysis CDx test to help inform treatment

decisions in the metastatic pancreatic cancer setting and will expand the patient population who can benefit from BRCA testing," said Johnathan Lancaster, M.D., Ph.D., chief medical officer of Myriad Genetics. "This study underscores Myriad's commitment to our pharmaceutical partners and to advancing the field of personalized medicine for patients with cancer."

RESULTS ALERT // AACR 2019

> Congratulations to the 2019 AACR NextGen Stars: https://t.co/soE6ooiM1t (https://t.co/soE6ooiM1t) #AACR19 (https://twitter.com/hashtag/AACR19?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/R4F5xy3uJY (https://t.co/R4F5xy3uJY)
>
> — AACR (@AACR) February 27, 2019 (https://twitter.com/AACR/status/1100878290099888134?ref_src=twsrc%5Etfw)

1. Syndax Pharmaceuticals present clinical updates from Entinostat program (http://ir.syndax.com/news-releases/news-release-details/syndax-announces-clinical-data-its-entinostat-immuno-oncology)
2. Oncopeptides AB to present clinical updates from HORIZON and ANCHOR trials (https://www.oncopeptides.se/en/data-from-oncopeptides-clinical-trials-horizon-and-anchor-evaluating-melflufen-in-rrmm-selected-for-presentation-at-the-aacr-annual-meeting/)
3. Updates from Ph II study of NLG207 to be presented (http://investors.linkp.com/news-releases/news-release-details/newlink-genetics-announces-clinical-trial-abstract-presentation)
4. Data from lead clinical programs of Onvansertib in AML and mCRPC to be presented (http://trovageneoncology.investorroom.com/2019-02-28-Trovagene-to-Present-Data-from-Lead-Clinical-Programs-of-Onvansertib-in-AML-and-mCRPC-at-the-American-Association-for-Cancer-Research-Annual-Meeting)
5. First clinical results of placental-derived natural killer (PNK) cells PNK-007 to be presented (https://www.marketwatch.com/press-release/first-clinical-results-evaluating-allogeneic-off-the-shelf-placental-derived-cells-to-be-presented-by-celularity-at-2019-aacr-annual-meeting-2019-02-27)
6. Positive outcome from Ph IIb UNITY-NHL trial of Umbralisib in CD20 inhibitor-treated R/R MZL to be presented; primary endpoint of ORR met (http://ir.tgtherapeutics.com/news-releases/news-release-details/tg-therapeutics-announces-positive-outcome-unity-nhl-phase-2b)
7. Next gen CAR-T platform and CART-mesothelin clinical results to be presented by Atara Biotherapeutics (http://investors.atarabio.com/news-releases/news-release-details/atara-biotherapeutics-announces-presentations-highlighting-next)
8. Updates from STING agonist ADU-S100, and anti-APRIL antibody BION-1301 to be presented (http://investors.aduro.com/phoenix.zhtml?c=242043&p=irol-newsArticle&ID=2389463)

FINANCIAL NEWS // Fourth quarter and year-end 2018 financial results

1. Karyopharm Therapeutics Inc. (https://investors.karyopharm.com/news-releases/news-release-details/karyopharm-reports-fourth-quarter-and-full-year-2018-financial)
2. Iovance Biotherapeutics (http://ir.iovance.com/phoenix.zhtml?c=254507&p=irol-newsArticle&ID=2389304)
3. NewLink Genetics (http://investors.linkp.com/news-releases/news-release-details/newlink-genetics-reports-fourth-quarter-year-end-2018-financial)
4. Nektar Therapeutics (https://ir.nektar.com/news-releases/news-release-details/nektar-therapeutics-reports-fourth-quarter-and-year-end-2018)
5. Nordic Nanovector ASA (http://www.nordicnanovector.com/investors-and-media/press-releases?page=/press/perma/1663167)
6. Tocagen (http://ir.tocagen.com/phoenix.zhtml?c=254300&p=irol-newsArticle&ID=2389303)
7. Sierra Oncology (http://investor.sierraoncology.com/2019-02-28-Sierra-Oncology-Reports-2018-Year-End-Results)
8. Mirati Therapeutics (http://ir.mirati.com/news-releases/news-release-details/mirati-therapeutics-reports-fourth-quarter-financial-results)
9. Genmab (https://ir.genmab.com/static-files/2d42acad-9313-4900-9e0e-12c6cf16f10d)
10. Halozyme (https://www.halozyme.com/investors/news-releases/news-release-details/2019/Halozyme-Reports-Fourth-Quarter-And-Full-Year-2018-Results/default.aspx)
11. Mersana Therapeutics (http://ir.mersana.com/news-releases/news-release-details/mersana-therapeutics-host-conference-call-announcing-fourth-0)
12. BioXcel Therapeutics (https://ir.bioxceltherapeutics.com/press-releases/detail/70/bioxcel-therapeutics-to-host-fourth-quarter-full-year)
13. Celldex Therapeutics, Inc. (https://ir.celldex.com/news-releases/news-release-details/celldex-report-full-year-2018-businessfinancial-results-and-host)
14. Fate Therapeutics, Inc. (https://ir.fatetherapeutics.com/news-releases/news-release-details/fate-therapeutics-webcast-conference-call-reporting-fourth-4)
15. Aravive, Inc. (https://ir.aravive.com/news-releases/news-release-details/aravive-report-fourth-quarter-and-full-year-2018-financial)
16. Radius Health, Inc. (https://ir.radiuspharm.com/news-releases/news-release-details/radius-health-announces-fourth-quarter-and-full-year-2018)
17. TRACON Pharmaceuticals, Inc. (https://traconpharma.gcs-web.com/news-releases/news-release-details/tracon-report-fourth-quarter-and-full-year-2018-company)
18. G1 Therapeutics (http://investor.g1therapeutics.com/news-releases/news-release-details/g1-therapeutics-reports-fourth-quarter-and-full-year-2018)
19. Jounce Therapeutics (https://ir.jouncetx.com/news-releases/news-release-details/jounce-therapeutics-announce-fourth-quarter-and-full-year-2018)
20. Aeglea BioTherapeutics (http://ir.aegleabio.com/events/event-details/aeglea-biotherapeutics-fourth-quarter-and-full-year-2018-financial-results-and)
21. Sunesis Pharmaceuticals (http://ir.sunesis.com/news-releases/news-release-details/sunesis-pharmaceuticals-host-conference-call-march-7th-discuss)
22. Sierra Oncology (http://investor.sierraoncology.com/2019-02-28-Sierra-Oncology-Reports-2018-Year-End-Results?platform=hootsuite)

OTW Trivia

ODAC

Q: What is ODAC?

A: ODAC is FDA's Oncologic Drugs Advisory Committee.

Q: What ODAC does?

A: ODAC reviews and evaluates the safety and efficacy data of both marketed and investigational cancer drugs – it then makes appropriate recommendations to FDA.

Q: How many people form the committee?

A: ODAC has thirteen voting members, coming from the fields like general oncology, haematological malignancies, pediatric oncology, immunoncology, biostatistics etc., one of whom possesses the technical expertise of concerned disease area. The committee will have a non-voting member with industry interests as well.

Q: Give an example of latest ODAC action in oncology?

A: Last week, ODAC against accelerated approval to Selinexor in triple refractory MM based on Ph IIb STORM trial data due to concerns over safety. It recommended waiting for results of Ph III BOSTON trial to confirm the benefit from Selinexor in this patient population.

(Source: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/default.htm (https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/default.htm))

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:

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. Currently, he is a Lead Scientist at MicroCures Inc. Previously, he served as 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 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: "Maximum intensity projection of intracellularly labeled astrocytes in stratum radiatum of CA1. See Fig. 7 in Bushong et al. (2002)" Source (http://cellimagelibrary.org/images/CCDB_28)

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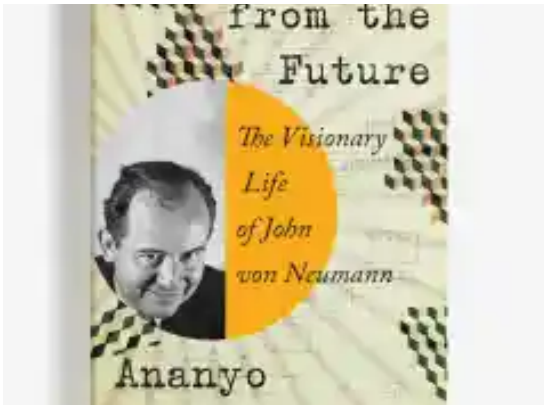

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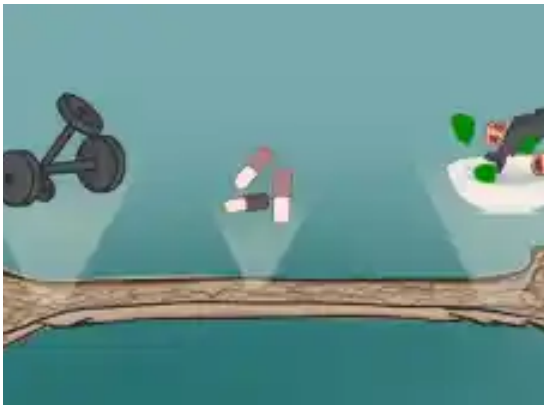

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