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Onco-this-Week

March 17, 2018(https://sciwri.club/archives/date/2018/03/17)

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This edition of Onco-this-Week brings to you a sneak peak at the upcoming breakthroughs being presented at American Association for Cancer Research (AACR) Annual Meeting 2018 (Chicago, IL) and if you are wondering what's up with PALOMA-2 and MONALEESA-7, then read-on as Richa Tewari updates you about these and several other oncology clinical trials, FDA buzz, Regulatory issues, Program updates, Collaborations and Financial Results that made news this week.

(For detailed info, click on the headline of each story to get directed to the original news source)

America

(https://visual.ly/community/infographic/health/americas-cancer-clusters/?utm_source=visually_embed)

by NowSourcing (http://nowsourcing.com?utm_source=visually_embed).
From Visually (https://visual.ly?utm_source=content-embed&utm_medium=embed).

RESULTS

(https://io.wp.com/sciwri.club/wp-content/uploads/2018/03/rawpixel-com-561404-unsplash.jpg?ssl=1)

Photo by rawpixel.com (https://unsplash.com/photos/iJBU8Ra8h3c?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText) on Unsplash (https://unsplash.com/search/photos/results?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText)

PERSIST-2 trial results published in JAMA Oncology; Pacritinib reduces spleen volume and total symptom score in Ruxolitinib-treated myelofibrosis patients with thrombocytopenia (http://investors.ctibiopharma.com/phoenix.zhtml?c=92775&p=RssLanding&cat=news&id=2337281)

> When you have myelofibrosis, the genetic code, or DNA, inside one of your stem cells gets damaged. Learn more: https://t.co/euodRvoGH4 (https://t.co/euodRvoGH4) pic.twitter.com/3GRHQaVQDe (https://t.co/3GRHQaVQDe)
>
> — WebMD (@WebMD) March 9, 2018 (https://twitter.com/WebMD/status/971951532412424192?ref_src=twsrc%5Etfw)

“Pacritinib was shown to reduce both spleen volume and total symptom score, two very important clinical measures, in myelofibrosis patients with thrombocytopenia including those patients who received prior treatment with ruxolitinib,” stated John Mascarenhas, M.D., Adult Leukemia Program, Tisch Cancer Institute, Icahn School of Medicine at Mount Sinai. “Clinical improvements in hemoglobin levels and reduction in transfusions were also seen in patients who received pacritinib, and pacritinib had a generally manageable safety profile.”

Encouraging complete remission rates observed in AML patients treated with CX-01 + Chemotherapy (http://www.cantex.com/content/news/releases/BloodAdvances.htm)

> WHAT IS ACUTE MYELOID LEUKAEMIA? – Acute myeloid leukaemia (AML) is a type of blood cancer ... https://t.co/RpqG6D5QRd (https://t.co/RpqG6D5QRd) via @DailyMailUS (https://twitter.com/DailyMailUS?ref_src=twsrc%5Etfw)
>
> — Hematology Oncology (@koduri_oncology) March 5, 2018 (https://twitter.com/koduri_oncology/status/970663053334401025?ref_src=twsrc%5Etfw)

Stephen Marcus, M.D., Chief Executive Officer of Cantex and a co-author of the paper, stated, "Results from the pilot study suggest that CX-01 in combination with chemotherapy could provide a potentially efficacious therapy for the treatment of AML. Not only did the study produce highly encouraging remission rates after a single induction cycle of chemotherapy, but the therapy also suggested a more rapid white blood cell and platelet count recovery, which is important to recovery from intensive chemotherapy."

Low rates of cancer recurrence, encouraging DFS and OS rates observed in pediatric AML patients treated with BPX-501 (http://ir.bellicum.com/news-releases/news-release-details/bellicum-announces-interim-results-showing-low-rates-cancer)

Data from the ongoing BP-004 trial suggest that BPX-501 T cells may contribute to a durable anti-leukemic effect in patients with AML. In the study, 38 pediatric AML patients in their first (n=13) or second (n=25) complete response underwent a haplo-HSCT followed by treatment with BPX-501. With a median follow-up of one year, rates of relapse-free survival and overall survival were 91.5% and 97.3%, respectively. This compares to one-year rates reported in the literature in pediatric AML patients undergoing alternate-donor HSCT of 60% to 80%.

"The recurrence of cancer is one of the most serious risks to AML patients receiving a stem cell transplant. These impressive results in children with AML suggest that BPX-501 may be effectively reducing or eradicating residual cancer cells following a haplo-transplant procedure," commented Neena Kapoor, M.D., Director of the Blood and Marrow Transplantation Program at Children's Hospital of Los Angeles and an investigator in the BP-004 trial.

> Interim clinical data from the ongoing BP-004 trial suggest that @BellicumPharma (https://twitter.com/BellicumPharma?ref_src=twsrc%5Etfw)'s BPX-501 reduces cancer recurrence rates in pediatric patients with AML and primary immunodeficiencies.https://t.co/qNnsyjQIc4 (https://t.co/qNnsyjQIc4) pic.twitter.com/ZblDK7FgAl (https://t.co/ZblDK7FgAl)
>
> — Rare Disease Report (@RareDR) March 13, 2018 (https://twitter.com/RareDR/status/973564119340273669?ref_src=twsrc%5Etfw)

Deeper analysis of Ph III PALOMA-2 trial shows significant efficacy with Palbociclib + Letrozole in 1L ER+ve HER2-neg postmenopausal metastatic breast cancer patients (http://www.oncnursingnews.com/web-exclusives/palbociclib-combo-effective-in-frontline-treatment-of-er-her2-postmenopausal-metastatic-breast-cancer)

"In the subgroup analysis, we evaluated benefit based on prior endocrine and prior chemotherapy, both of which would have been given in the neoadjuvant or adjuvant setting," lead author of the subgroup analysis Richard Finn, MD, from the David Geffen School of Medicine at UCLA, told *OncLive®*, a sister publication to *Oncology Nursing News®*. "The take-home message is that regardless of these prior therapies, there is still a significant improvement tin PFS with the addition of palbociclib to letrozole."

"There are now 3 CDK 4/6 inhibitors approved in this indication, but only PALOMA-2 included patients who relapsed on prior endocrine therapy in less than 12 months, as long as it was not a non-steoridal AI," he added.

> Dr. Kevin Kalinsky discusses PALOMA-2 positive trial results in metastatic #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) at #ASCO16 (https://twitter.com/hashtag/ASCO16?src=hash&ref_src=twsrc%5Etfw) #bcsm (https://twitter.com/hashtag/bcsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/dhvbTonzab (https://t.co/dhvbTonzab)
>
> — NewYork-Presbyterian (@nyphospital) June 7, 2016 (https://twitter.com/nyphospital/status/739997555711475718?ref_src=twsrc%5Etfw)

Ph III MONALEESA-7 trial shows PFS improvement with Ribociclib's combination with AI or tamoxifen in HR+ve, HER2-neg metastatic breast cancer (http://www.oncnursingnews.com/web-exclusives/ribociclib-benefits-premenopausal-women-with-advanced-breast-cancer)

"The MONALEESA-7 trial is the first large randomized trial in advanced breast cancer in nearly 20 years focusing specifically on premenopausal women. While the use of ovarian suppression has been used with endocrine therapy, this trial was dedicated to assessing the CDK 4/6 inhibitor ribociclib compared to placebo in combination with ovarian suppression using goserelin along with either AI or tamoxifen," Debu Tripathy, MD, professor and chair, Department of Breast Medical Oncology at the University of Texas MD Anderson Cancer Center, said in an interview with *OncLive®,* a sister company to *Oncology Nursing News®*.

"It confirmed a significant benefit in progression free-survival and response rate, and also showed comparable efficacy with either AI or tamoxifen—both findings representing important advances in the treatment of this population of patients," added Tripathy.

> Debu Tripathy, MD, on HR+, HER2– Breast Cancer: Results From the MONALEESA-7 Trial https://t.co/jiQ8lTot6d (https://t.co/jiQ8lTot6d) #SABCS17 (https://twitter.com/hashtag/SABCS17?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #bcsm (https://twitter.com/hashtag/bcsm?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/V3jVE80TOq (https://t.co/V3jVE80TOq)
>
> — The ASCO Post (@ASCOPost) December 7, 2017 (https://twitter.com/ASCOPost/status/938805804634959875?ref_src=twsrc%5Etfw)

MorphoSys reports updated data from Ph II L-MIND Study of MOR208 + Lenalidomide in Aggressive Lymphoma (r/r DLBCL) (https://www.morphosys.com/media-investors/media-center/morphosys-reports-updated-data-from-l-mind-study-of-mor208-plus)

"We are truly excited about this data and our productive discussions with FDA under the current breakthrough therapy designation on the path to market for MOR208, including the possibility of an expedited regulatory submission and approval for MOR208 based primarily on the L-MIND study. We look forward to continuing the analysis of maturing data from the L-MIND trial and to maintaining our interactions with the FDA," commented Dr. Malte Peters, Chief Development Officer of MorphoSys AG.

"There is a very high unmet medical need for patients with r/r DLBCL who, after having failed initial therapies, are ineligible for high-dose chemotherapy and autologous stem cell transplantation," said Dr. Simon Moroney, Chief Executive Officer of MorphoSys AG. "We are very encouraged by our most recent clinical data from the ongoing L-MIND trial, which support our plan to develop MOR208 in combination with lenalidomide as a chemo-free treatment option for this patient population."

> L-mind trial MOR-208 + lenalidomide in r/r DLCBL. Phase II data @MorphoSys (https://twitter.com/MorphoSys?ref_src=twsrc%5Etfw) #ASCO17 (https://twitter.com/hashtag/ASCO17?src=hash&ref_src=twsrc%5Etfw) $MOR (https://twitter.com/search?q=%24MOR&src=ctag&ref_src=twsrc%5Etfw) pic.twitter.com/Z5AuZdoCvI (https://t.co/Z5AuZdoCvI)
>
> — EdisonHealthcare (@EdisonHealth) June 5, 2017 (https://twitter.com/EdisonHealth/status/871767901283524608?ref_src=twsrc%5Etfw)

Long-lasting immune responses and safety data from Ph 1 trial of TPIV200 in Ovarian and breast cancer published (https://tapimmune.com/2018/03/tapimmune-announces-publication-of-clinical-trial-results-for-the-tpiv200-cancer-vaccine-in-clinical-cancer-research/)

Peter Hoang, President and CEO of TapImmune, stated, "Although this safety trial was not designed to evaluate clinical efficacy outcomes, all patients remained alive at last follow-up, at least two years following initiation of immunization, and the large majority of vaccinated patients developed lasting immune responses against multiple FRa epitopes. The potential PFS benefit observed in women with ovarian cancer in first remission is very intriguing to TapImmune and our clinical investigators, especially in the context of our ongoing Phase 2 study of TPIV200, which is enrolling patients at the same stage of disease. While our population of 10 patients in ovarian first remission cannot be deemed to be statistically significant, the observed median PFS of 528 days is certainly an interesting result, particularly in light of the historical data where patients receiving stand-of-care in this setting had a median PFS in the 313-day range. Should we see a similar result in our larger ongoing randomized, double-blind, controlled Phase 2 trial, we believe that TPIV200 has a viable pathway toward potential approval in this indication. Enrollment in the study is currently ongoing, and we expect to conduct an interim analysis by mid-2019, once the data from the first half of enrollment is achieved."

> TapImmune's T-cell pollen candidate TPIV200 shows encouraging action in early-phase Cancer... https://t.co/2GFKMAYxRr (https://t.co/2GFKMAYxRr)
>
> — Health For All (@em6323787) March 16, 2018 (https://twitter.com/em6323787/status/974621687374376960?ref_src=twsrc%5Etfw)

RESULTS ALERT // AACR 2018

(https://io.wp.com/sciwri.club/wp-content/uploads/2018/03/DXvg483U0AAotDL.jpg?ssl=1)

Blueprint Medicines to present proof-of-concept data from ongoing Ph 1 BLU-667 trial in RET-Altered solid tumors patients (http://ir.blueprintmedicines.com/phoenix.zhtml?c=253931&p=irol-newsArticle&ID=2338129)

Presentation Title: Highly potent and selective RET inhibitor, BLU-667, achieves proof-of-concept in a Phase I study of advanced, *RET*-altered solid tumors
Session Title: Advances in Precision Cancer Medicine
Session Date & Time: Sunday, April 15, 2018 from 3:00 – 5:00 p.m. CT (4:00 – 6:00 p.m. ET)
Abstract Number: 9226
Location: N Hall C – McCormick Place North (Level 1)

> Don't miss the BLU-667 Phase 1 trial results @AACR (https://twitter.com/AACR?ref_src=twsrc%5Etfw) annual meeting in a Clinical Trial Plenary Session next month. BLU-667 is our investigational medicine for RET fusions and mutations – presentation will be on April 15, from 3-5 PM CT: https://t.co/cjeWvLtsjO (https://t.co/cjeWvLtsjO) pic.twitter.com/Dvcsyo4tuG (https://t.co/Dvcsyo4tuG)
>
> — Blueprint Medicines (@BlueprintMeds) March 14, 2018 (https://twitter.com/BlueprintMeds/status/974034972280545280?ref_src=twsrc%5Etfw)

OncoSec to present ImmunoPulse® IL-12 data in TNBC patients at AACR (https://ir.oncosec.com/press-releases/detail/1938/oncosecs-intratumoral-il-12-in-metastatic-triple-negative)

Details of the oral poster presentation are as follows:

Abstract Title: *Intratumoral plasmid IL-12 and electroporation in pre-treated inoperable locally advanced or recurrent triple-negative breast cancer (TNBC)* (Abstract #CT022)

Session Title: Phase I Clinical Trials 1

Date and Time: Sunday, April 15, 2018 1:00 PM – 5:00 PM EST

Location: McCormick Place South, Hall A, Poster Section 42

> In another collaboration, $AVCT (https://twitter.com/search?q=%24AVCT&src=ctag&ref_src=twsrc%5Etfw) makes deal to pair their Affirmer platform with $ONCS (https://twitter.com/search?q=%24ONCS&src=ctag&ref_src=twsrc%5Etfw) #GeneDelivery (https://twitter.com/hashtag/GeneDelivery?src=hash&ref_src=twsrc%5Etfw) technology ImmunoPulse https://t.co/qmawG42VXn (https://t.co/qmawG42VXn)
>
> — CBPartners (@CBPartners) January 26, 2018 (https://twitter.com/CBPartners/status/957020342018543616?ref_src=twsrc%5Etfw)

MabVax Therapeutics to present interim results from Ph 1 trial of MVT-1075, radioimmunotherapy, in R/R pancreatic cancer patients (https://www.mabvax.com/news-media/press-releases/detail/118/mabvax-therapeutics-announces-acceptance-of-three-poster)

Sunday April 15, 2018 from 1:00 PM – 5:00 PM CDT:
Title: *A fully human antibody binds Tn and sTn carbohydrate antigens specifically on serine residues, without need for polypeptide interaction*
Session Location: Poster Section 43
Abstract Number: LB-002, Poster Board Number 2
Presenting Author: Jonah Rainey, Ph.D., Executive Director, Antibody Research MabVax Therapeutics

> Our CEO David Hansen provides an update on $MBVX (https://twitter.com/search?q=%24MBVX&src=ctag&ref_src=twsrc%5Etfw)'s lead development programs MVT-1075 and MVT-5873. For the full release visit: https://t.co/wyjoT4k3yS (https://t.co/wyjoT4k3yS) pic.twitter.com/nCNt2TW6sv (https://t.co/nCNt2TW6sv)
>
> — MabVax Therapeutics (@MabVaxThera) January 17, 2018 (https://twitter.com/MabVaxThera/status/953700996039020545?ref_src=twsrc%5Etfw)

Tuesday April 17, 2018 from 8:00 AM – 12:00 PM CDT:
Title: *Phase I dose escalation study of 177Lu-HuMab-5B1 (MVT-1075) in combination with MVT-5873 as radioimmunotherapy (RIT) in subjects with relapsed / refractory pancreatic cancer or other CA19-9+ malignancies*

Session Location: McCormick Place South, Hall A, Poster Section 42
Abstract Number: CT140, Poster Board Number 23
Presenting Author: Paul Maffuid, Ph.D., Executive Vice President, Research & Development MabVax Therapeutics

> $MBVX (https://twitter.com/search?q=%24MBVX&src=ctag&ref_src=twsrc%5Etfw)'s lead product candidate, MVT-1075, is a human #antibody (https://twitter.com/hashtag/antibody?src=hash&ref_src=twsrc%5Etfw)-based RIT product being evaluated in a Ph 1 trial for the treatment of #PanCan (https://twitter.com/hashtag/PanCan?src=hash&ref_src=twsrc%5Etfw), colon, and lung #cancers (https://twitter.com/hashtag/cancers?src=hash&ref_src=twsrc%5Etfw) with interim data expected Q1 '18. Learn more about MVT-1075 & our Ph 1a clinical trial: https://t.co/61XxMhzT6p (https://t.co/61XxMhzT6p) pic.twitter.com/U2eJkzWarr (https://t.co/U2eJkzWarr)
>
> — MabVax Therapeutics (@MabVaxThera) February 8, 2018 (https://twitter.com/MabVaxThera/status/961622415427166208?ref_src=twsrc%5Etfw)

Tuesday April 17, 2018 from 8:00 AM – 12:00 PM CDT:
Title: *PEGylated Hyaluronidase Increases Tumor Uptake of ^{89}Zr-DFO-HuMab-5B1 (MVT-2163) in a CA19-9 Positive Hyaluronan-Accumulating Pancreatic Cancer Model*
Session Location: McCormick Place South, Hall A, Poster Section 1
Abstract Number: 3036, Poster Board Number 9
Co-presenting Authors: Paul Maffuid, Ph.D., Executive Vice President, Research & Development and Jonah Rainey, MabVax Therapeutics Executive Director, Antibody Research MabVax Therapeutics

> $MBVX (https://twitter.com/search?q=%24MBVX&src=ctag&ref_src=twsrc%5Etfw)'s lead product candidate, MVT-1075, is a human #antibody (https://twitter.com/hashtag/antibody?src=hash&ref_src=twsrc%5Etfw)-based RIT product being evaluated in a Ph 1 trial for the treatment of #PanCan (https://twitter.com/hashtag/PanCan?src=hash&ref_src=twsrc%5Etfw), colon, and lung #cancers (https://twitter.com/hashtag/cancers?src=hash&ref_src=twsrc%5Etfw) with interim data expected Q1 '18. Learn more about MVT-1075 & our Ph 1a clinical trial: https://t.co/61XxMhzT6p (https://t.co/61XxMhzT6p) pic.twitter.com/U2eJkzWarr (https://t.co/U2eJkzWarr)
>
> — MabVax Therapeutics (@MabVaxThera) February 8, 2018 (https://twitter.com/MabVaxThera/status/961622415427166208?ref_src=twsrc%5Etfw)

Tocagen to present Toca 6 Ph I data at AACR 2018 (http://ir.tocagen.com/phoenix.zhtml?c=254300&p=irol-newsArticle&ID=2338235)

Presentation Type: Poster (Abstract: CT067)
Title: A phase 1b study of Toca 511, a retroviral replicating vector, followed by Toca FC in patients with advanced cancer (http://www.abstractsonline.com/pp8/#!/4562/presentation/11204)
Presenter: Jaime Merchan, M.D., director, Phase 1 clinical trials program at Sylvester Comprehensive Cancer Center, part of UHealth, the University of Miami Health System; associate professor of medicine at the University of Miami Miller School of Medicine
Date and Time: Monday, April 16, 8:00 a.m. – 12:00 p.m. CT

Presentation Type: Poster (Abstract: 5630)

#BrainTumorThursday (https://twitter.com/hashtag/BrainTumorThursday?src=hash&ref_src=twsrc%5Etfw) #Toca511 (https://twitter.com/hashtag/Toca511?src=hash&ref_src=twsrc%5Etfw) #TocaFC (https://twitter.com/hashtag/TocaFC?src=hash&ref_src=twsrc%5Etfw) #clinicaltrials (https://twitter.com/hashtag/clinicaltrials?src=hash&ref_src=twsrc%5Etfw) #btsm (https://twitter.com/hashtag/btsm?src=hash&ref_src=twsrc%5Etfw)
Injecting live virus in brain tumors may fight cancer https://t.co/c9zy9hQ3i3 (https://t.co/c9zy9hQ3i3)

— Debi Cirasole (@DebiCasserole) September 29, 2016 (https://twitter.com/DebiCasserole/status/781498989812322304?ref_src=twsrc%5Etfw)

Title: Immune profile of tumor microenvironment helps predict response in patients treated with an investigational immunotherapeutic consisting of a retroviral replicating vector (Toca 511) and an extended-release formulation of 5-fluorocytosine (Toca FC) (http://www.abstractsonline.com/pp8/#!/4562/presentation/8617)
Presenter: Derek Ostertag, Ph.D., senior director of R&D Diagnostics at Tocagen
Date and Time: Wednesday, April 18, 8:00 a.m. – 12:00 p.m. CT

Download our new app note exploring the tumor microenvironment using the Chromium Single Cell Immune Profiling Solution to measure TCR, B-cell Ig, & 5' gene expression in the same samples https://t.co/oQxua4YOJl (https://t.co/oQxua4YOJl) pic.twitter.com/Yn9HcEfZWj (https://t.co/Yn9HcEfZWj)

— 10x Genomics (@10xgenomics) February 27, 2018 (https://twitter.com/10xgenomics/status/968577483980312577?ref_src=twsrc%5Etfw)

BerGenBio to present AXLi Bemcentinib's preclinical data (http://www.bergenbio.com/bergenbio-promising-data-highlighting-bemcentinibs-potential-to-improve-efficacy-of-checkpoint-inhibitors-to-be-presented-at-aacr-annual-meeting/)

Poster presentation: Tuesday Apr 17, 2018 8:00 AM – 12:00 PM, McCormick Place South, Exhibit Hall A, Poster Section 32

$BGBIO (https://twitter.com/search?q=%24BGBIO&src=ctag&ref_src=twsrc%5Etfw) – presents Q4 and FY results:
Looking forward to an exciting year ahead.

Six phII #clinicaltrials (https://twitter.com/hashtag/clinicaltrials?src=hash&ref_src=twsrc%5Etfw) ongoing with selective AXL inhibitor #bemcentinib (https://twitter.com/hashtag/bemcentinib?src=hash&ref_src=twsrc%5Etfw) (#BGB324 (https://twitter.com/hashtag/BGB324?src=hash&ref_src=twsrc%5Etfw)) in #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw), #TNBC (https://twitter.com/hashtag/TNBC?src=hash&ref_src=twsrc%5Etfw), #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw), #MDS (https://twitter.com/hashtag/MDS?src=hash&ref_src=twsrc%5Etfw) and #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw). Interim read-outs mid-2018. https://t.co/njL9fYcB3S (https://t.co/njL9fYcB3S) pic.twitter.com/djoES5YRvd (https://t.co/djoES5YRvd)

— BerGenBio (@BGenBio) February 13, 2018 (https://twitter.com/BGenBio/status/963291687073218561?ref_src=twsrc%5Etfw)

Bristol-Myers Squibb to present preclinical and clinical data at AACR (https://news.bms.com/press-release/corporatefinancial-news/research-bristol-myers-squibbs-innovative-oncology-development)

#DYK (https://twitter.com/hashtag/DYK?src=hash&ref_src=twsrc%5Etfw) #LungCancer (https://twitter.com/hashtag/LungCancer?src=hash&ref_src=twsrc%5Etfw) is the most common cancer in the world? #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) makes up the vast majority of diagnoses. https://t.co/2zUSEPddRX (https://t.co/2zUSEPddRX) #AACR18 (https://twitter.com/hashtag/AACR18?src=hash&ref_src=twsrc%5Etfw) #LCSM (https://twitter.com/hashtag/LCSM?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/BSW7u17UcB (https://t.co/BSW7u17UcB)

— Bristol-Myers Squibb (@bmsnews) March 15, 2018 (https://twitter.com/bmsnews/status/974284090294890499?ref_src=twsrc%5Etfw)

Key late-breaking and oral presentations representing the breadth of the Company's leading translational and basic research include:

- **Nivolumab + ipilimumab versus platinum-doublet chemotherapy as first-line treatment for advanced non-small cell lung cancer: initial results from CheckMate -227**
  Author: M. Hellmann
  Abstract #CT077
  Session: CTPL03 – Immunotherapy Combinations: The New Frontier in Lung Cancer
  Monday, April 16, 10:30 AM-12:30 PM CDT, N Hall B (Plenary Hall, Level 3)
- **Tumor mutation burden (TMB) as a biomarker for clinical benefit from dual immune checkpoint blockade with nivolumab + ipilimumab in first-line non-small cell lung cancer: identification of TMB cutoff from CheckMate -568**
  Author: S. Ramalingam
  Abstract #CT078
  Session: CTPL03 – Immunotherapy Combinations: The New Frontier in Lung Cancer
  Monday, April 16, 10:30 AM-12:30 PM CDT, N Hall B (Plenary Hall, Level 3)
- **Nivolumab versus docetaxel in a predominantly Chinese patient population with previously treated advanced non-small cell lung cancer: results of the Phase 3 CheckMate -078 study**
  Author: Y-L. Wu
  Abstract #CT114
  Session: CTMS02 – Updates in Immuno-Oncology Trials
  Monday, April 16, 3-5 PM CDT, N Hall C (Level 1)
- **Nivolumab versus investigator's choice in recurrent or metastatic squamous cell carcinoma of the head and neck: 2-yr outcomes in the overall population and PD-L1 subgroups of CheckMate -141**
  Author: R. Ferris
  Abstract #CT116
  Session: CTMS02 – Updates in Immuno-Oncology Trials
  Monday, April 16, 3-5 PM CDT, N Hall C (Level 1)
- **Nivolumab monotherapy in patients with advanced platinum-resistant urothelial carcinoma: Efficacy and safety update and association between biomarkers and overall survival in CheckMate -275**
  Author: P. Sharma
  Abstract #CT178
  Session: CTMS03 – Biomarkers in Immuno-Oncology
  Tuesday, April 17 2:45-5 PM CDT, N Hall C (Level 1)
- **Preliminary Phase 1 profile of BMS-986179, an anti-CD73 antibody, in combination with nivolumab in patients with advanced solid tumors**
  Author: L. Siu
  Abstract #CT180
  Session: CTMS03 – Biomarkers in Immuno-Oncology
  Tuesday, April 17, 2:45-5 PM CDT, N Hall C (Level 1)

Additional data to be presented include:

Gastrointestinal Malignancies

> Gastrointestinal Cancer Drug Market Trends, outlook and Opportunity Analysis 2023 https://t.co/ZxNVeXRIq5 (https://t.co/ZxNVeXRIq5) pic.twitter.com/vQPLmlc2mh (https://t.co/vQPLmlc2mh)
>
> — Eric Bendic (@ericbendic24) December 21, 2017 (https://twitter.com/ericbendic24/status/943749133411725312?ref_src=twsrc%5Etfw)

- **Exploratory analysis of Janus kinase 1 loss-of-function mutations in patients with DNA mismatch repair-deficient/microsatellite instability-high metastatic (dMMR/MSI-H) colorectal cancer treated with nivolumab + ipilimumab in CheckMate -142**
  Author: S. Kopetz
  Abstract #2603
  Session: PO.CL10.04 – Biomarkers of Therapeutic Response in Clinical Trials
  Monday, April 16, 1-5 PM CDT, Exhibit Hall A, Poster Section 26, Board #4
- **Integrated analysis of colorectal carcinoma by co-extraction of RNA, DNA and protein from FFPE tumor samples**
  Author: V. Patel
  Abstract #2707
  Session: PO.CH03.01 – Cancer Biology Insights Emerging from Proteomic Investigations
  Monday, April 16, 1-5 PM CDT, Exhibit Hall A, Poster Section 31, Board #17

Genitourinary Cancers

> Immunotherapy in genitourinary malignancies. https://t.co/CE3ZtlBloZ (https://t.co/CE3ZtlBloZ) #News (https://twitter.com/hashtag/News?src=hash&ref_src=twsrc%5Etfw) #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/byFg69eA5E (https://t.co/byFg69eA5E)
>
> — Dra Catalina Solano (@miurologa) February 27, 2018 (https://twitter.com/miurologa/status/968442445120790528?ref_src=twsrc%5Etfw)

- **Double positive CD4+CD8+ T cells with an exhausted phenotype in renal cell carcinoma patients**
  Author: L. Menard
  Abstract #4687
  Session: PO.IM01.01 – Adaptive Immunity in Tumors
  Tuesday, April 17, 1-5 PM CDT, Exhibit Hall A, Poster Section 32, Board #20

Melanoma

> A type of vaccine is being tested to treat #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw) and epithelial tumors in a new#clinicaltrial from the @NCI_CCR_SB (https://twitter.com/NCI_CCR_SB?ref_src=twsrc%5Etfw) https://t.co/288CQ5tiAJ (https://t.co/288CQ5tiAJ) pic.twitter.com/01yATe1zep (https://t.co/01yATe1zep)
>
> — NCICancerTrials (@NCICancerTrials) March 16, 2018 (https://twitter.com/NCICancerTrials/status/974782363723943936?ref_src=twsrc%5Etfw)

- **Use of adjuvant interferon alfa-2b or ipilimumab 10mg/kg for high-risk patients with melanoma, and associated adverse events and duration of therapy**
  Author: A. Tarhini
  Abstract #3641
  Session: PO.CL06.04 – Immune Checkpoints 3
  Tuesday, April 17, 8 AM-12 PM CDT, Exhibit Hall A, Poster Section 26, Board #19

- **Matching-adjusted indirect comparison of nivolumab + ipilimumab and BRAF+MEK inhibitors for the treatment of BRAF-mutant treatment-naïve advanced melanoma**
  Author: M. Atkins
  Abstract #3639
  Session: PO.CL06.04 – Immune Checkpoints 3
  Tuesday, April 17, 8 AM-12 PM CDT, Exhibit Hall A, Poster Section 26, Board #17

Non-Small Cell Lung Cancer

> Does the Amount of #Malignant (https://twitter.com/hashtag/Malignant?src=hash&ref_src=twsrc%5Etfw) Pleural Effusion affect the #Survival (https://twitter.com/hashtag/Survival?src=hash&ref_src=twsrc%5Etfw) in #Patients (https://twitter.com/hashtag/Patients?src=hash&ref_src=twsrc%5Etfw) with Non-small Cell #Lung_Cancer (https://twitter.com/hashtag/Lung_Cancer?src=hash&ref_src=twsrc%5Etfw) – https://t.co/KrLaKNDEvH (https://t.co/KrLaKNDEvH) pic.twitter.com/MuKggbtQXj (https://t.co/MuKggbtQXj)
>
> — lungcancer (@lungcanc123) March 16, 2018 (https://twitter.com/lungcanc123/status/974506253907935232?ref_src=twsrc%5Etfw)

- **Tumor intrinsic properties associate with differential effects on CD8+ tumor-infiltrating lymphocyte density and immune gene expression in non-small cell lung cancer samples**
  Author: C. Hedvat
  Abstract #1024
  Session: PO.TB06.04 – Adaptation and Checkpoints in Tumorigenesis
  Monday, April 16, 8 AM-12 PM CDT, Exhibit Hall A, Poster Section 1, Board #26
- **Evaluation of tumor mutation burden as a biomarker for immune checkpoint inhibitor efficacy: A calibration study of whole exome sequencing with FoundationOne ®**
  Author: J. Szustakowski
  Abstract #5528
  Session: PO.CL10.05 – Diagnostic and Prognostic Biomarkers in Clinical Trials
  Wednesday, April 18, 8 AM-12 PM CDT, Exhibit Hall A, Poster Section 24, Board #1

Early Assets


(https://io.wp.com/sciwri.club/wp-content/uploads/2018/03/yair-mejia-318376-unsplash.jpg?ssl=1)

Photo by Yair Mejía (https://unsplash.com/photos/DoScpguhoJ8?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText) on Unsplash (https://unsplash.com/search/photos/assets?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText)

- **From bench to bedside: Exploring OX40 receptor modulation in a Phase 1/2a study of the OX40 agonist BMS-986178 ± nivolumab or ipilimumab in patients with advanced solid tumors**
  Author: R. Wang
  Abstract #LB-127
  Session: LBPO.IM01 – Late-Breaking Research: Immunology 1
  Monday, April 16, 8 AM-12 PM CDT, Poster Section 45, Board #24
- **Examining the dynamic regulation of OX40 following receptor agonism and T cell activation: Implications**

for antibody-mediated enhancement of T cell function
Author: M-C. Gaudreau
Abstract #2782
Session: PO.IM02.11 – Therapeutic Antibodies, Including Engineered Antibodies 2
Monday, April 16, 1-5 PM CDT, Exhibit Hall A, Poster Section 34, Board #15

- **A Phase 1b/2 study of BMS-813160, a CC chemokine receptor 2/5 dual antagonist, in combination with chemotherapy or nivolumab in patients with advanced pancreatic or colorectal cancer**
  Author: D. Le
  Abstract #CT124
  Session: Phase I Trials in Progress
  Tuesday, April 17, 8 AM-12 PM CDT, Exhibit Hall A, Poster Section 42, Board #7
- **Preclinical antitumor activity of a CC chemokine receptor 2/5 dual antagonist as monotherapy and in combination with immune checkpoint blockade**
  Author: Q. Zhao
  Abstract #3760
  Session: PO.IM02.07 – Immunomodulatory Agents and Interventions 1
  Tuesday, April 17, 8 AM-12 PM CDT, Exhibit Hall A, Poster Section 32, Board #10
- **Preclinical antitumor activity of BMS-986158, an oral BET inhibitor, for the treatment of cancer**
  Author: S. Wee
  Abstract #5792
  Session: PO.ET06.10 – Canonical Targets 2
  Wednesday, April 18, 8 AM-12 PM CDT, Exhibit Hall A, Poster Section 36, Board #18
- **Discovery of clinical candidate BMS-986158, an oral BET inhibitor, for the treatment of cancer**
  Author: A. Gavai
  Abstract #5789
  Session: PO.ET06.10 – Canonical Targets 2
  Wednesday, April 18, 8 AM-12 PM CDT, Exhibit Hall A, Poster Section 36, Board #15

<u>Clinical Collaborations</u>


(https://io.wp.com/sciwri.club/wp-content/uploads/2018/03/rawpixel-com-565454-unsplash.jpg?ssl=1)

Photo by rawpixel.com (https://unsplash.com/photos/gUpbcU58B70?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText) on Unsplash (https://unsplash.com/search/photos/collaborations?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText)

- **A novel heterologous prime boost vaccine system drives tumor specific and potent CD8 T cell responses for cancer immunotherapy**
  Author: W. Blair
  Abstract #724

Session: PO.IM02.13 – Vaccines 1
Sunday, April 15, 1-5 PM CDT, Exhibit Hall A, Poster Section 34, Board #9

- **Antitumor activity associated with dual targeting of CD38 and PD-1 pathways in preclinical models**
  Author: N. Bezman
  Abstract #1727
  Session: PO.IM02.05 – Immune Response to Therapies 2
  Monday, April 16, 8 AM-12 PM CDT, Exhibit Hall A, Poster Section 32, Board #22
- **Prophylactic TNFa blockade unplugs toxicity and efficacy in immunotherapy anti-PD-1 + anti-CTLA-4 combination**
  Author: E. Perez-Ruiz
  Abstract #LB-151
  Session: LBPO.CL01 – Late-Breaking Research: Clinical Research 1
  Monday, April 16, 1-5 PM CDT, Exhibit Hall A, Poster Section 43, Board #18
- **The immunosuppressive tumor microenvironment in nasopharyngeal carcinoma: implications for immunotherapy**
  Author: A. Duffield
  Abstract #4750
  Session: PO.IM01.02 – New Immunosuppressive Mechanisms in Cancer
  Tuesday, April 17, 1-5 PM CDT, Exhibit Hall A, Poster Section 34, Board #24
- **Characterization of the tumor immune microenvironment in head and neck squamous cell carcinoma**
  Author: F. Succaria
  Abstract #4693
  Session: PO.IM01.01 – Adaptive Immunity in Tumors
  Tuesday, April 17, 1-5 PM CDT, Exhibit Hall A, Poster Section 32, Board #26

SPECIAL STATUS

(https://io.wp.com/sciwri.club/wp-content/uploads/2018/03/jon-tyson-420512-unsplash.jpg?ssl=1)

Photo by Jon Tyson (https://unsplash.com/photos/82ZEOTntP8g?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText) on Unsplash (https://unsplash.com/search/photos/leader?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText)

Priority review to Pembrolizumab in Cervical cancer, PDUFA: June 28, 2018 (http://www.mrknewsroom.com/news-release/oncology-newsroom/fda-grants-priority-review-mercks-supplemental-biologics-license-ap-1)

This is the first filing acceptance and Priority Review granted for an anti-PD-1 therapy in cervical cancer and the 14th regulatory submission accepted by the FDA for KEYTRUDA. The FDA has set a PDUFA, or target action, date of June 28, 2018.

"Advanced cervical cancer is an illness with a poor prognosis and a high unmet medical need. We look forward to working with the FDA on the review of this application to help bring KEYTRUDA to previously-treated patients with advanced cervical cancer," said Dr. Roger Dansey, senior vice president and therapeutic area head, oncology late-stage development, Merck Research Laboratories.

> FDA Grants Pembrolizumab Priority Review for Treatment of Cervical Cancerhttps://t.co/x8pWpD6MwZ (https://t.co/x8pWpD6MwZ) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #fda (https://twitter.com/hashtag/fda?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/mF6WtCoe7G (https://t.co/mF6WtCoe7G)
>
> — OncologyNursingNews (@OncNursingNews) March 13, 2018 (https://twitter.com/OncNursingNews/status/973639873251995648?ref_src=twsrc%5Etfw)

FDA Breakthrough Therapy Designation for Erdafitinib in the treatment of metastatic urothelial cancer (http://www.janssen.com/janssen-announces-us-fda-breakthrough-therapy-designation-erdafitinib-treatment-metastatic)

"For patients diagnosed with urothelial cancer, outcomes are unfortunately disheartening due to the aggressiveness of the disease," said Peter Lebowitz, MD, PhD, Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. "Through the continued development of erdafitinib, and working closely with the FDA, we look forward to bringing a potential new treatment option to patients."

The Breakthrough Therapy Designation is based on data from a multicenter, open-label Phase 2 clinical trial evaluating the efficacy and safety of erdafitinib in the treatment of adult patients with locally advanced or metastatic urothelial cancer, whose tumors have certain fibroblast growth factor receptor (FGFR) genetic alterations. The Phase 2 study BLC2001 presented at the 2018 ASCO Genitourinary Cancers Symposium showed an overall response rate of 42 percent in 59 patients with relapsed/refractory metastatic urothelial cancer whose tumors harbored actionable FGFR mutations (ASCO-GU abstract #411).

> Erdafitinib Granted FDA Breakthrough Therapy Designation for Urothelial Carcinoma https://t.co/szjt3uZtxv (https://t.co/szjt3uZtxv) via @CancerTherAdvsr (https://twitter.com/CancerTherAdvsr?ref_src=twsrc%5Etfw)
>
> — Wafik El-Deiry MDPhD (@weldeiry) March 16, 2018 (https://twitter.com/weldeiry/status/974788348303826944?ref_src=twsrc%5Etfw)

REGULATORY NEWS

(https://io.wp.com/sciwri.club/wp-content/uploads/2018/03/mark-duffel-422279-unsplash.jpg?ssl=1)

Photo by Mark Duffel (https://unsplash.com/photos/U5y077qrMdI?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText) on Unsplash (https://unsplash.com/search/photos/rules?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText)

FDA Clears IND Application for Actimab-A + CLAM-G Combination Therapy in R/R AML patients (http://www.raredr.com/news/fda-clears-ind-application-actimab-a)

"The use of our actinium-225 – anti-CD33 ARC in combination with cytotoxic therapies such as CLAG-M has the potential to improve outcomes for a significant number of patients," said Dr. Mark Berger, Actinium's Chief Medical Officer in a press release (http://globenewswire.com/news-release/2018/03/13/1421165/0/en/Actinium-Announces-FDA-Clearance-of-IND-For-Phase-1-trial-of-Actimab-A-in-Combination-with-CLAG-M-for-Patients-with-Relapsed-or-Refractory-AML.html?ev=1). "We believe our ARC approach, which has shown to be potent while having minimal extramedullary toxicities in over 100 patients to date, has the potential to be synergistic with cytotoxic chemotherapy agents. CLAG-M has shown compelling results in patients with relapsed or refractory disease and we believe that the combination with our ARC can improve response rates, transplant rates and overall survival for patients."

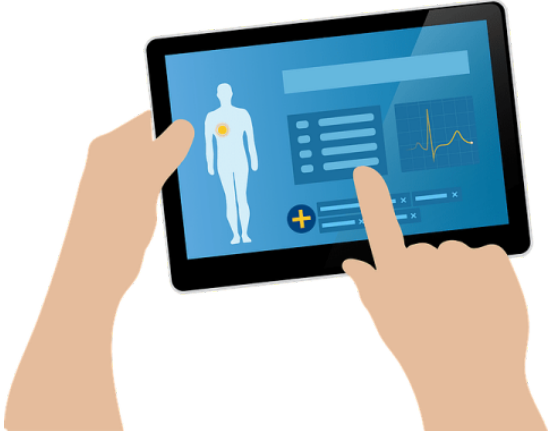
> – @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) grants Investigational New Drug clearance for #actimab (https://twitter.com/hashtag/actimab?src=hash&ref_src=twsrc%5Etfw)-A in combination with #CLAG (https://twitter.com/hashtag/CLAG?src=hash&ref_src=twsrc%5Etfw)-M for R/R #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) patients https://t.co/FKmVBDAInI (https://t.co/FKmVBDAInI) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/NZvxNBukc1 (https://t.co/NZvxNBukc1)
>
> — AML Global Portal (@AGP_hematology) March 15, 2018 (https://twitter.com/AGP_hematology/status/974298705380724738?ref_src=twsrc%5Etfw)

Cabozantinib sNDA submitted on basis of Ph III CELESTIAL data in previously treated advanced HCC (http://ir.exelixis.com/phoenix.zhtml?c=120923&p=irol-newsArticle&ID=2338226)

"We look forward to working closely with regulatory authorities through the review process in anticipation of bringing CABOMETYX to people diagnosed with advanced hepatocellular carcinoma, an underserved patient community that urgently needs new treatment options," said Gisela Schwab, M.D., President, Product Development and Medical Affairs and Chief Medical Officer, Exelixis. "We would sincerely like to thank the study patients and clinicians who participated in the CELESTIAL trial as well as our dedicated clinical development, medical and regulatory teams for bringing us another step closer to our goal of fully exploring the potential of CABOMETYX and making it accessible to every patient who may benefit from its use."

> Cabometyx sNDA for hepatocellular carcinoma indication submitted to FDA: https://t.co/5mSl6bjla3 (https://t.co/5mSl6bjla3) pic.twitter.com/XTgdr01can (https://t.co/XTgdr01can)
>
> — MPR (@eMPR) March 15, 2018 (https://twitter.com/eMPR/status/974353566646390784?ref_src=twsrc%5Etfw)

TRIAL STATUS



(https://io.wp.com/sciwri.club/wp-content/uploads/2018/03/ehr-1476525_640.png?ssl=1)

AstraZeneca announces final analysis of OS in MYSTIC trial now expected in the second half of 2018 (https://www.astrazeneca.com/media-centre/press-releases/2018/astrazeneca-provides-update-on-mystic-trial-timeline-12032018.html)

AstraZeneca and MedImmune, its global biologics research and development arm, today announced an updated timeline for the final analysis of the Phase III MYSTIC trial of *Imfinzi* (durvalumab) as monotherapy and in combination with tremelimumab, versus platinum-based standard-of-care (SoC) chemotherapy in previously-untreated patients with metastatic (Stage IV) 1st-line non-small cell lung cancer (NSCLC).

MYSTIC is an event-driven clinical trial and continues per protocol. Based on current predictions, the final analysis of overall survival (OS) is now expected in the second half of 2018 (previously anticipated in the first half).

> AZ`s #Mystic (https://twitter.com/hashtag/Mystic?src=hash&ref_src=twsrc%5Etfw) trial hits another snag, delaying #Imfinzi (https://twitter.com/hashtag/Imfinzi?src=hash&ref_src=twsrc%5Etfw)`s lung cancer expansion https://t.co/2C4lVC5Vgc (https://t.co/2C4lVC5Vgc)
>
> — Research Analyst (@mastersrock222) March 14, 2018 (https://twitter.com/mastersrock222/status/973836062035505152?ref_src=twsrc%5Etfw)

Enrollment completed in the VISTA Ph III registrational trial of EpCAM-targeting ADC, Vicinium, in BCG-unresponsive NMIBC patients (http://ir.elevenbio.com/news-releases/news-release-details/enrollment-completed-phase-3-registration-trial-non-muscle)

"Bladder cancer is one of the most prevalent cancers in the United States, yet there has been limited development of new therapeutic options for patients in more than 30 years," commented Donald Lamm, M.D., University of Arizona professor, director of BCG oncology and an investigator in the VISTA trial. "Today's standard-of-care for NMIBC provides initial responses in many patients; however, after BCG is no longer effective, there are no meaningful FDA-approved options except surgical removal of the bladder in high-risk patients. I am encouraged by the data demonstrated with Vicinium in prior trials and its potential to offer my patients an alternative to radical cystectomy."

> 10 Hidden Symptoms Of #BladderCancer (https://twitter.com/hashtag/BladderCancer?src=hash&ref_src=twsrc%5Etfw) That Every Woman Needs To Know https://t.co/QuLl8FoQ9n (https://t.co/QuLl8FoQ9n) pic.twitter.com/xASSPZRRXF (https://t.co/xASSPZRRXF)
>
> — BladderCancerCanada (@BladderCancerCA) March 12, 2018 (https://twitter.com/BladderCancerCA/status/973261373303123968?ref_src=twsrc%5Etfw)

Enrollment expanding in ongoing Ph II SHERLOC study of MM-121 in heregulin-positive NSCLC patients progressed after a platinum-containing regimen (http://investors.merrimack.com/news-releases/news-release-details/merrimack-strengthens-sherloc-study-mm-121-non-small-cell-lung)

"We are encouraged by the tremendous interest in the SHERLOC study over the past year, which has been enrolling far faster than we had projected, reflecting what we believe is the significant unmet medical need among this patient population," said Sergio Santillana, M.D., MSc, Chief Medical Officer of Merrimack. "This expansion enables us to maximize this opportunity to gain meaningful insight, by strengthening the statistical design of the study, and emerge with a clear path forward."

With the expanded patient pool and accelerated enrollment, Merrimack continues to anticipate top-line data from the SHERLOC study in the second half of 2018.

> We are expanding enrollment in our ongoing randomized Phase 2 SHERLOC study of our product candidate MM-121 in patients with heregulin-positive non-small cell lung cancer. Find out more: https://t.co/N9VEGcorxY (https://t.co/N9VEGcorxY) pic.twitter.com/asoTbTy9Ud (https://t.co/asoTbTy9Ud)
>
> — Merrimack (@MerrimackPharma) March 13, 2018 (https://twitter.com/MerrimackPharma/status/973560599320854532?ref_src=twsrc%5Etfw)

First patient dosed in TAR-200 trial in non-metastatic muscle-invasive bladder cancer patients (http://www.tarisbiomedical.com/docs/2018%2003%2014%20TARIS%20TAR-200-103%20Study%20Start%20FINAL.pdf)

"This trial seeks to explore the utility of TAR-200 in patients who currently have few viable treatment options. Frail and elderly patients, who are diagnosed with MIBC and are unfit for curative intent therapy, often suffer from significant symptom burden and typically succumb to their disease. This innovative trial affords an opportunity to potentially address this devastating cancer and the challenging symptoms caused by this malignancy," said Kirk A. Keegan, MD, MPH, Assistant Professor of Urologic Surgery at Vanderbilt University and the primary investigator for this trial.

"At TARIS, we are passionate about developing therapies for severely underserved patient populations. MIBC patients who are unfit for curative therapy suffer a significant deterioration in their health and rapidly progress to death. TARIS believes that TAR-200 may offer an entirely new approach to treating MIBC, without the serious morbidity that renders current therapies untenable for so many," said Christopher Cutie, MD, Chief Medical Officer at TARIS. "In addition to initiating this important study, TARIS today also announced a research collaboration with Sweden's Uppsala Clinical Research Center and Professor PerUno Malmström. This collaboration seeks to illuminate the natural history of MIBC, and to better understand the outcomes associated with an inability to receive potentially curative treatment."

> TARIS® Initiates Dosing of TAR-200 (GemRIS™) in Muscle-Invasive #BladderCancer (https://twitter.com/hashtag/BladderCancer?src=hash&ref_src=twsrc%5Etfw) Patients Unfit for Curative Intent Therapy | Business Wire https://t.co/lIqvjbLdHS (https://t.co/lIqvjbLdHS)
>
> — BladderCancer.Me (@BladderCancerMe) March 15, 2018 (https://twitter.com/BladderCancerMe/status/974367679279644672?ref_src=twsrc%5Etfw)

Chi-Med Initiates a Ph Ib/II POC Trial of EGFR inhibitor Epitinib in GBM in China (http://www.chi-med.com/initiates-poc-epitinib-gbm-china/)

Epitinib is a potent and highly selective oral EGFR inhibitor that has demonstrated penetration of the blood-brain barrier and encouraging efficacy in clinical studies in other indications.

This proof-of-concept study is a multi-center, single-arm, open-label study to evaluate the efficacy and safety of epitinib as a monotherapy in patients with EGFR gene amplified, histologically confirmed glioblastoma. The primary endpoint is objective response rate ("ORR"). Additional details about this study may be found at clinicaltrials.gov, using identifier NCT03231501 (https://clinicaltrials.gov/ct2/show/NCT03231501).

Chi-Med Initiates a Phase Ib/II Proof-of-Concept Trial of Epitinib in Glioblastoma in China #btsm (https://twitter.com/hashtag/btsm?src=hash&ref_src=twsrc%5Etfw) https://t.co/aUfvNqqHWF (https://t.co/aUfvNqqHWF)

— IBTA (@theIBTA) March 6, 2018 (https://twitter.com/theIBTA/status/970982336820056064?ref_src=twsrc%5Etfw)

CLINICAL HOLD

(https://io.wp.com/sciwri.club/wp-content/uploads/2018/03/michael-mroczek-199379-unsplash.jpg?ssl=1)

Photo by Michael Mroczek (https://unsplash.com/photos/iC2imdhnPac?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText) on Unsplash (https://unsplash.com/search/photos/stopped?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText)

Ph II trial of Axalimogene filolisbac + Durvalumab in HPV-associated cervical and head and neck cancer patients placed on hold after patient death (http://www.pharmatimes.com/news/cancer_drug_study_placed_on_hold_after_patient_death_1227146)

The regulator suspended the trial on the back of a safety report on the death, which is referred to as a Grade 5 Serious Adverse Event and occurred following the sixth combination cycle in the trial.

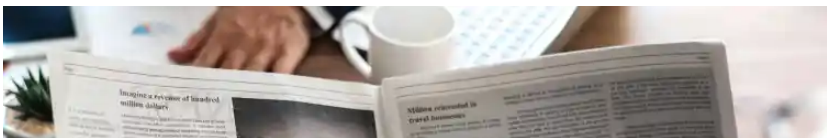
As such, enrollment and further dosing are on hold in this trial while the company, its partner and the FDA work closely with the site investigator to review this event in detail and to resolve this clinical hold.

However, Anthony Lombardo, Advaxis' interim chief executive, said the firm remains "confident in the safety and efficacy profile of axalimogene filolisbac, to date, based on our experience in over 250 patients and over 700 doses across multiple trials in HPV-associated cancers."

FDA hits Advaxis with clinical hold after death in AstraZeneca combination trial https://t.co/BqDKb16EpL (https://t.co/BqDKb16EpL) #enovamed (https://twitter.com/hashtag/enovamed?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/mBgnLBlgHj (https://t.co/mBgnLBlgHj)

— EnovaMed (@enova_med) March 13, 2018 (https://twitter.com/enova_med/status/973545007704522754?ref_src=twsrc%5Etfw)

PROGRAM UPDATE



(https://io.wp.com/sciwri.club/wp-content/uploads/2018/03/rawpixel-com-585630-unsplash.jpg?ssl=1)

Photo by rawpixel.com (https://unsplash.com/photos/UrAoVtUAgmo?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText) on Unsplash (https://unsplash.com/search/photos/news?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText)

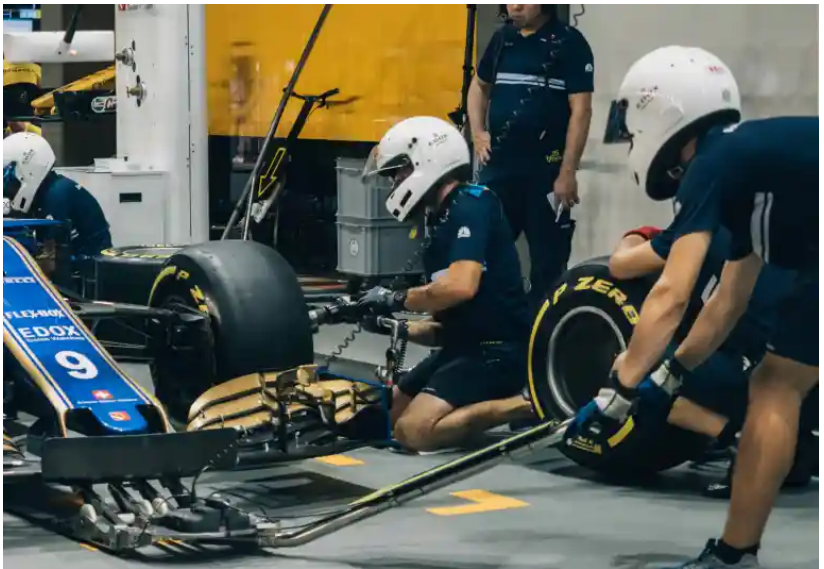
Immune Design reports improvement in survival for CMB305 monotherapy in Sarcoma and increased ORR for G100/pembrolizumab combination in Follicular Lymphoma (http://ir.immunedesign.com/news-releases/news-release-details/immune-design-reports-data-update-lead-immunotherapy-programs)

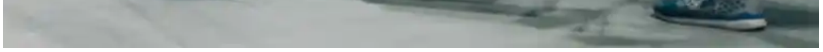
Evidence of clinical benefit continued to mature with both agents, providing not only further support for the advancement of both programs, but also supporting the view that an immunotherapy may provide additional clinical benefit with time.

“These are exciting new data that provide stronger translational and clinical benefit profiles of our CMB305 and G100 therapeutic candidates in important forms of cancer where unmet need persists,” said Carlos Paya, M.D., Chief Executive Officer of Immune Design. “Armed with these findings, we look forward to beginning a Phase 3 pivotal clinical trial midyear 2018 to investigate CMB305 as a maintenance therapy in synovial sarcoma patients – an important step in our goal to provide a new treatment option to this patient population. In addition, these new G100 data give us greater confidence in the promise of this novel therapy in follicular lymphoma, and the potential to expand into other tumors.”

> Immune Design Reports Data Update for Lead Immunotherapy Programs: Improvement in Survival for CMB305 Monotherapy in Sarcoma and Increased Objective Responses for G100/pembrolizumab Combination in Follicular Lymphoma... https://t.co/3IoInA7TF4 (https://t.co/3IoInA7TF4)
>
> — Immune Design (@ImmuneDesign) March 12, 2018 (https://twitter.com/ImmuneDesign/status/973166808126586880?ref_src=twsrc%5Etfw)

COLLABORATION





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UC San Diego Researchers to evaluate anti-ROR1 mAb Cirmtuzumab + BTKi Ibrutinib in several heme malignancies (http://ucsdnews.ucsd.edu/pressrelease/uc_san_diego_researchers_launch_combination_drug_trial_to_eradicate_b_cell)

"This is an important advance," said Thomas Kipps, MD, PhD, Distinguished Professor of Medicine and deputy director of research at UC San Diego Moores Cancer Center, whose lab developed cirmtuzumab. "Although ibrutinib is standard of care for patients with CLL or MCL, it is exceptionally rare for the drug by itself to completely eradicate all leukemia cells or produce long-lasting remissions in CLL without continuous therapy."

"As a result, patients typically need to take ibrutinib indefinitely, or until they develop intolerance or resistance to this drug. Cirmtuzumab targets leukemia and cancer stem cells, which are like the seeds of cancer. They are hard to find and difficult to destroy. By blocking signaling pathways that promote neoplastic-cell growth and survival, cirmtuzumab may have complementary activity with ibrutinib in killing leukemia cells, allowing patients potentially to achieve complete remissions that permit patients to stop therapy altogether."

> Chronic lymphocytic #leukemka (https://twitter.com/hashtag/leukemka?src=hash&ref_src=twsrc%5Etfw) is a common blood #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw). Dr. Choi is treating patients in the @UCSDHealth (https://twitter.com/UCSDHealth?ref_src=twsrc%5Etfw) cirmtuzumab trial. #CIRMSymposium (https://twitter.com/hashtag/CIRMSymposium?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/onuMOuk8rR (https://t.co/onuMOuk8rR)
>
> — CIRM (@CIRMnews) March 23, 2017 (https://twitter.com/CIRMnews/status/844970409132941312?ref_src=twsrc%5Etfw)

IO Biotech and MSD to evaluate IO102 + Pembrolizumab combination in 1L treatment of NSCLC patients (http://www.iobiotech.com/index.php/news/58-clinical-collaboration-merck-msd)

"We believe there is a strong mechanistic rationale to explore the combination of an IDO-derived immune modulating therapy, anti-PD-1 antibody and chemotherapy and are very excited to be able to test this in a first-line treatment setting of patients suffering from metastatic non-small cell lung cancer" said Mai-Britt Zocca, PhD, Chief Executive Officer and founder of IO Biotech. "Through this collaboration, we expect to get a diverse set of clinical data to understand the potential of IO102 to improve durability and response rates in combination with one of the leading treatments within immuno-oncology."

> #merck (https://twitter.com/hashtag/merck?src=hash&ref_src=twsrc%5Etfw) Danish Biotech Collaborates With US Merck on Combination Therapy for Lung Cancer – IO Biotech will test its immune modulator in combination with Mercks checkpoint inhibitor Keytruda known for curing former US President Jimmy Carters cancer. IO ... https://t.co/2GBFAmxeWl (https://t.co/2GBFAmxeWl)
>
> — Merck&Co (@merck_bio) March 14, 2018 (https://twitter.com/merck_bio/status/973718386059415552?ref_src=twsrc%5Etfw)

YEAR-END 2017 FINANCIAL RESULTS

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Photo by Chris Li (https://unsplash.com/photos/6Y6OnwBKk-0?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText) on Unsplash (https://unsplash.com/search/photos/finance?utm_source=unsplash&utm_medium=referral&utm_content=creditCopyText)

Merrimack Provides Business Update and Reports 2017 Financial Results (http://investors.merrimack.com/news-releases/news-release-details/merrimack-provides-business-update-and-reports-2017-financial)

"2017 was a transformative year for Merrimack, in which we reset the company's foundation to focus on our ten wholly owned clinical and preclinical programs, all targeting biomarker-defined cancers. We are very pleased with the advancements we have made across our pipeline, including today's announcement to expand enrollment in the SHERLOC study, a randomized Phase 2 trial evaluating MM-121 in non-small cell lung cancer, and our recent dosing of the first patient in the SHERBOC study, a randomized Phase 2 trial evaluating MM-121 in post-menopausal metastatic breast cancer," said Richard Peters, M.D., Ph.D., President and Chief Executive Officer. "We are well-positioned to carry this momentum forward, with three clinical readouts expected in 2018, including randomized Phase 2 data from MM-141 and MM-121 and Phase 1 data from MM-310."

> #ICYMI (https://twitter.com/hashtag/ICYMI?src=hash&ref_src=twsrc%5Etfw), this morning we released Q4 2017 financial results and a company update. Details here: https://t.co/N9VEGcorxY (https://t.co/N9VEGcorxY) pic.twitter.com/TzGxBSkQjz (https://t.co/TzGxBSkQjz)
>
> — Merrimack (@MerrimackPharma) March 12, 2018 (https://twitter.com/MerrimackPharma/status/973288792927940608?ref_src=twsrc%5Etfw)

NICE's OPINION

Funding for Pembrolizumab for classical Hodgkin lymphoma unlikely, owing to uncertain cost-effectiveness (http://www.pharmatimes.com/news/nice_minded_to_reject_keytruda_for_classical_hodgkin_lymphoma_1226942)

Cost regulators for NHS therapies in England and Wales say they are minded not to recommend funding for MSD's Keytruda as a treatment for classical Hodgkin lymphoma, because its cost-effectiveness is uncertain.

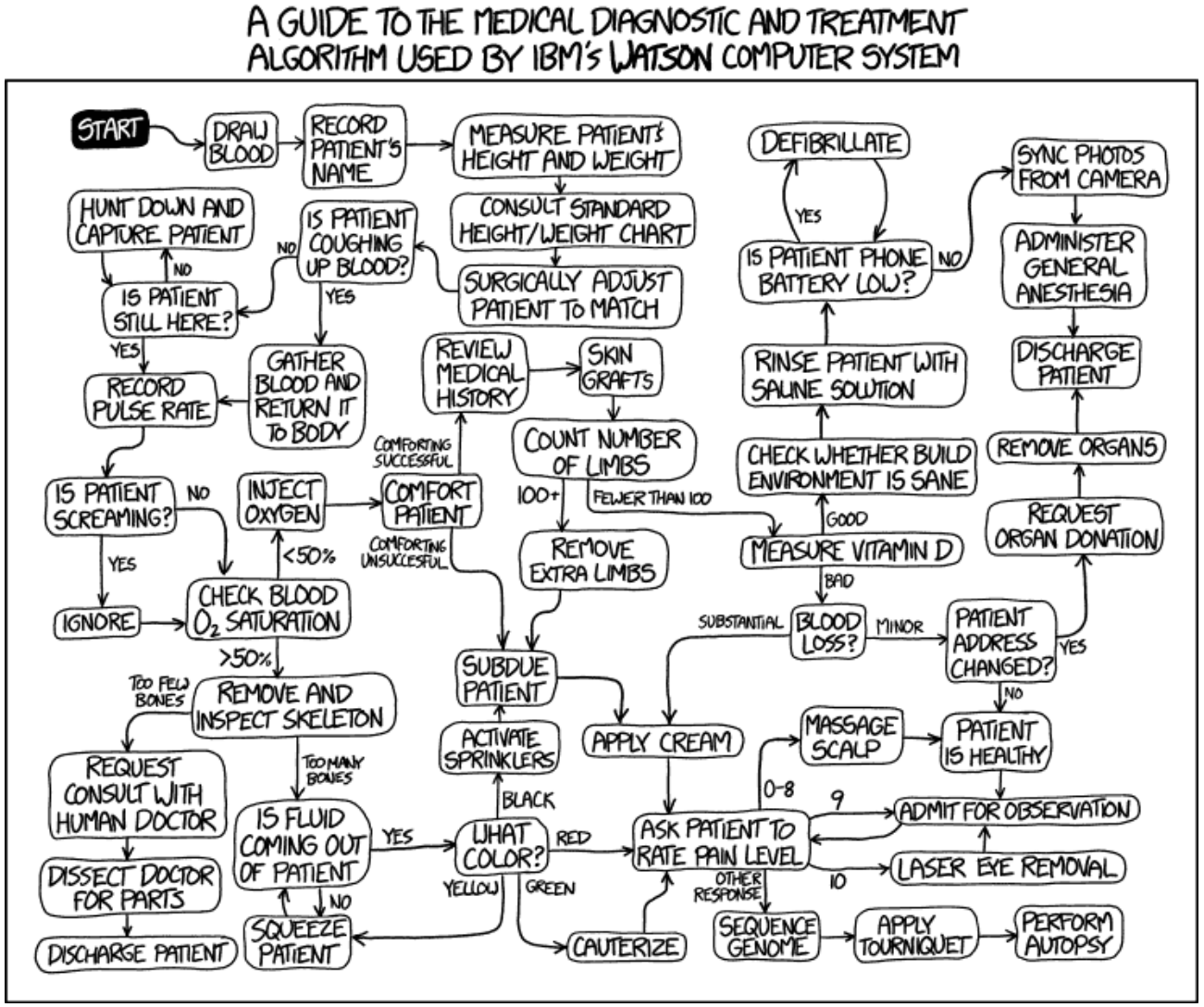
@NICEcomms (https://twitter.com/NICEcomms?ref_src=twsrc%5Etfw) rejects #Keytruda (https://twitter.com/hashtag/Keytruda?src=hash&ref_src=twsrc%5Etfw) for #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw), cites insufficient evidence to prove cost-effectiveness in the long-term. https://t.co/Xouxk4mMM7 (https://t.co/Xouxk4mMM7) pic.twitter.com/qkcEoMzfBX (https://t.co/qkcEoMzfBX)

— AJMC-Oncology (@EBOncology) October 5, 2016 (https://twitter.com/EBOncology/status/783736931406454784?ref_src=twsrc%5Etfw)

The anti-PD-1 therapy won European clearance in the Hodgkin lymphoma setting in May last year, on data from the KEYNOTE-087 and KEYNOTE-013 trials, which included patients regardless of the PD-L1 expression.

KEYNOTE-087 showed an objective response rate of 69 percent in the Keytruda (pembrolizumab) arm with a complete response rate of 22 percent and a partial remission rate of 47 percent, while KEYNOTE-013's data showed 58 percent, 19 percent and 39 percent, respectively.

And now, time to have some fun!



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Source: XKCD-A webcomic of romance, sarcasm, math, and language. (https://xkcd.com/1619/)

About the Author:

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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.

Blog Design: Abhinav Dey (https://www.linkedin.com/in/abhinavdey/)

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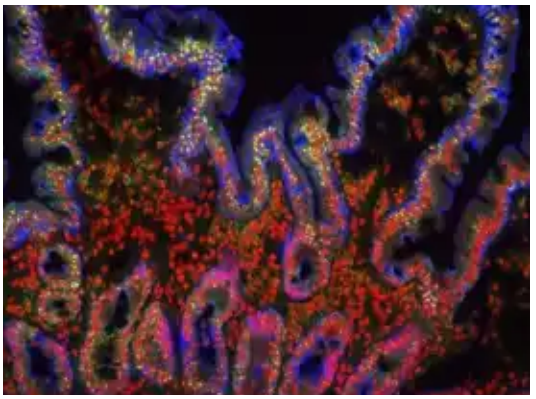

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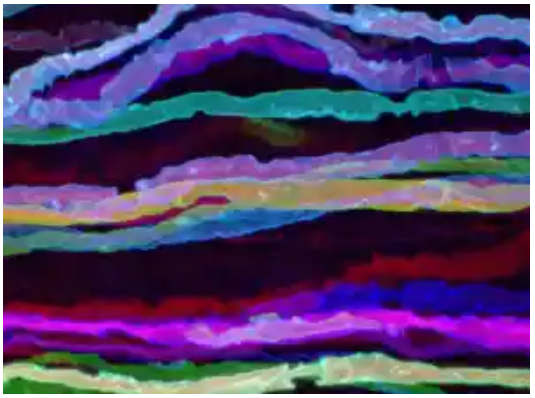

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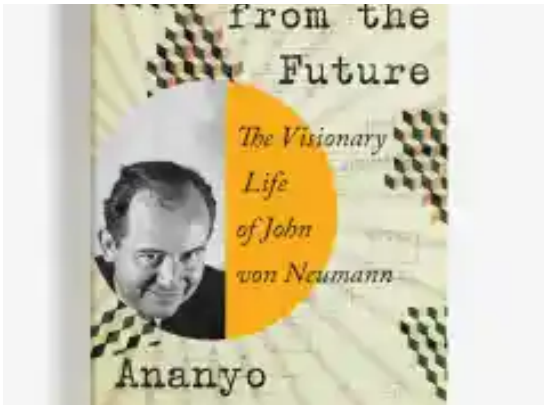

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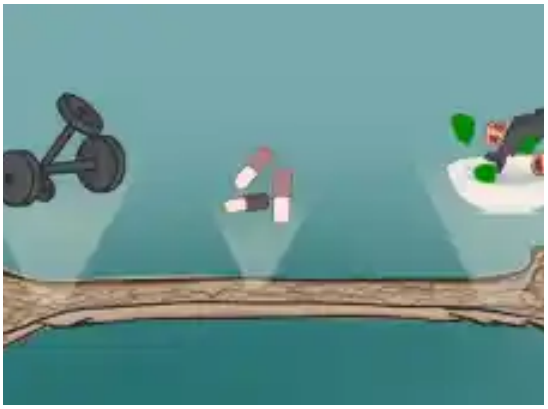

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