

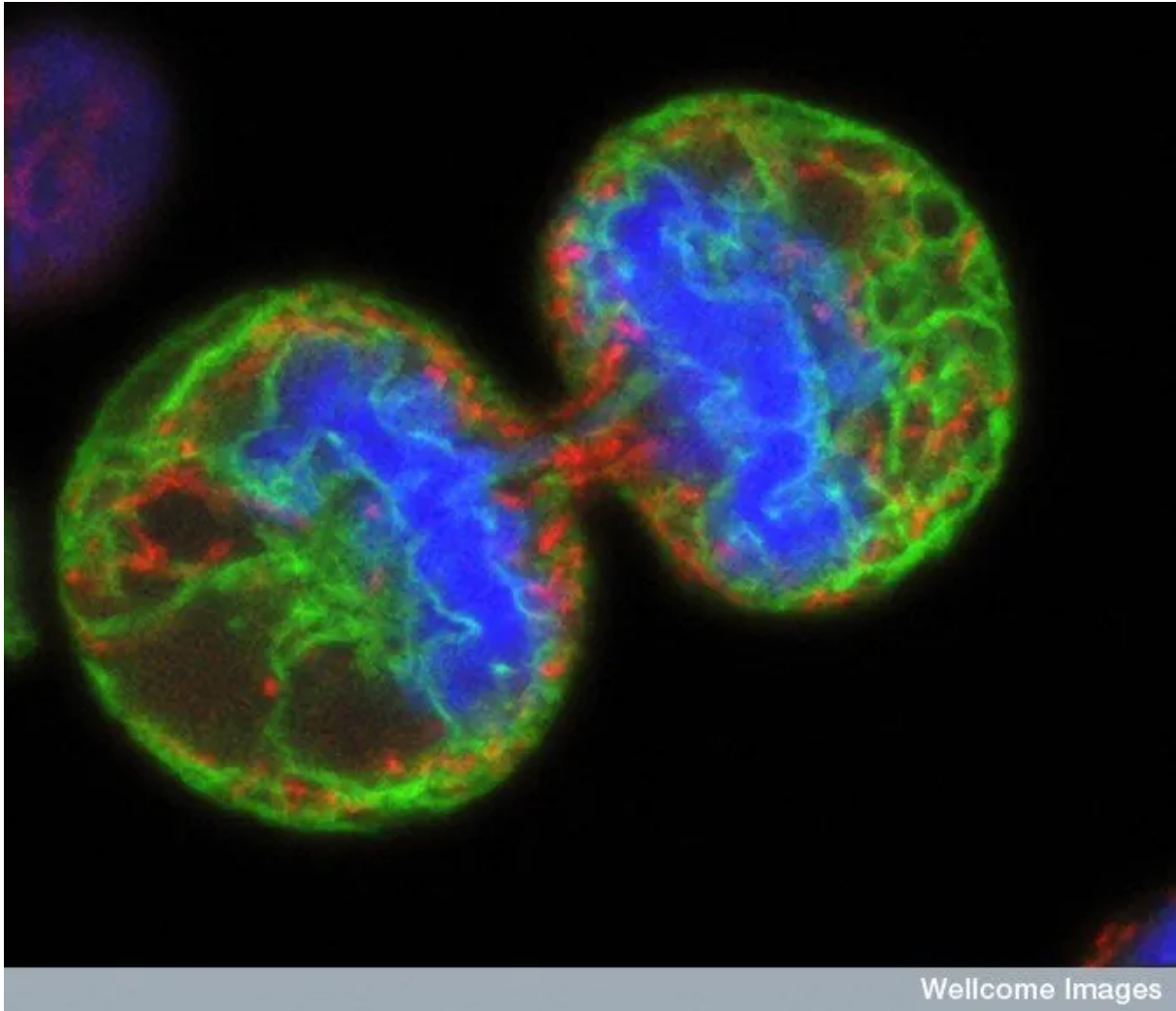


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Onco-this-Week

February 24, 2019(<https://sciwri.club/archives/date/2019/02/24>)



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OTW in a Capsule

HIGHLIGHTS

1. **Priority review to Ivosidenib's sNDA in 1L IDH1m+ unfit AML patients.** Not too earlier, in fact seven months to be precise, Ivosidenib had scored FDA approval in relapsed or refractory IDH1m+ AML patients. And the drug is already set to enter the frontline settings. The best part is that both the trials (R/R settings and 1L setting) are Ph I trials – explaining the grave unmet need in this patient population. The quick timelines, however, can be attributed to FDA's Real-Time Oncology Review pilot program. PDUFA date is June 2019 and it would be great to welcome Ivosidenib in this population!
2. **Priority review to Pembrolizumab in 3L SCLC.** What may come as a great hope to many, Pembrolizumab monotherapy was granted priority review in heavily pre-treated SCLC patients on the basis of data from SCLC cohorts of the Ph II KEYNOTE-158 and Ph Ib KEYNOTE-028 trials. After a series of failures in this patient segment with great unmet need, all the eyes would be Pembrolizumab as the PDUFA date of Jun 2019 gets closer. May it replicate the success of immunotherapies in NSCLC!
3. **Pembrolizumab's failure in HCC.** Not all was rosy for Merck and Pembrolizumab this week though – Ph III pivotal confirmatory KEYNOTE-240 trial of Pembrolizumab failed to meet primary endpoints of OS and PFS improvement. The shocker: the comparator arm was nothing but placebo in these previously-treated HCC patients. How would this negative data readout impact Pembrolizumab's approval in 2L HCC patients and label, is yet to be seen.

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DRUG APPROVALS

FDA approves Pembrolizumab in adjuvant melanoma based on data from Ph III EORTC1325 / KEYNOTE-054 trial (<https://www.mrknewsroom.com/news-release/prescription-medicine-news/fda-approves-mercks-keytruda-pembrolizumab-adjuvant-treatment>)

“In the fight against cancer, progress is made one step at a time, and today we’re pleased to take another important step – making KEYTRUDA available as an adjuvant therapy for patients with stage III melanoma,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. “At Merck, we are committed to transforming the treatment of cancer, as is exemplified by this important advance in the adjuvant treatment of melanoma.”

The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) has approved #Immunotherapy (https://twitter.com/hashtag/Immunotherapy?src=hash&ref_src=twsrc%5Etfw) pembrolizumab for the adjuvant #treatment (https://twitter.com/hashtag/treatment?src=hash&ref_src=twsrc%5Etfw) of #patients (https://twitter.com/hashtag/patients?src=hash&ref_src=twsrc%5Etfw) with #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw) with involvement of lymph node(s) following complete resection. Approval was based on results from EORTC1325/KEYNOTE-054 #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) <https://t.co/npHu6qm4LQ> (<https://t.co/npHu6qm4LQ>) [pic.twitter.com/rWXRn3pH8a](https://t.co/rWXRn3pH8a) (<https://t.co/rWXRn3pH8a>)

— Gil Morgan (@weoncologists) February 20, 2019 (https://twitter.com/weoncologists/status/1098090223676854272?ref_src=twsrc%5Etfw)

REGULATORY NEWS

Priority review granted to Ivosidenib’s sNDA in rL IDH1+ AML patients not eligible for standard therapy; PDUFA: Jun 2019 (<https://agiospharmaceuticalsinc.gcs-web.com/node/12176>)

FDA grants ivosidenib (Tibsovo) priority review for the treatment of patients with newly diagnosed IDH1-mutant acute myeloid leukemia. Read more here: <https://t.co/B8nwJbAu4n> (<https://t.co/B8nwJbAu4n>) #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) [pic.twitter.com/UoirPmLOiT](https://t.co/UoirPmLOiT) (<https://t.co/UoirPmLOiT>)

— AML Global Portal (@AGP_hematology) February 21, 2019 (https://twitter.com/AGP_hematology/status/1098604434022678528?ref_src=twsrc%5Etfw)

“In less than seven months since TIBSOVO’s approval in relapsed or refractory AML, we are pleased to be working with the FDA to expand its labeled indication into the frontline setting,” said Chris Bowden, M.D., chief medical officer of Agios. “Patients with newly diagnosed AML who are not eligible for standard treatments, such as intensive and non-intensive chemotherapy, are currently offered only palliative care. There is tremendous need for new treatment options, and we believe AML patients with IDH1 mutations have the potential to benefit from this targeted therapy.”

Priority review granted to Pembrolizumab monotherapy in 3L SCLC on the basis of SCLC cohorts of the Ph II KEYNOTE-158 and Ph Ib KEYNOTE-028 trials; PDUFA: Jun 2019 (<https://www.mrknewsroom.com/news-release/oncology/fda-grants-priority-review-mercks-supplemental-biologics-license-application-3>)

FDA Grants Pembrolizumab Priority Review for Advanced SCLC <https://t.co/KCzc42zkXW> (<https://t.co/KCzc42zkXW>)

— Jason M. Watts (@mrjasonwatts) February 20, 2019 (https://twitter.com/mrjasonwatts/status/1098248984072765441?ref_src=twsrc%5Etfw)

“There is a significant need for new treatment options for small cell lung cancer, which has a five-year survival rate of only six percent overall,” said Dr. Jonathan Cheng, vice president, oncology clinical research, Merck Research Laboratories. “KEYTRUDA has already been established as an important treatment option for many patients with advanced non-small cell lung cancer and this acceptance provides an opportunity to potentially benefit even more patients.”

Priority Review granted to Entrectinib in NTRKfusion-positive, locally advanced/metastatic solid tumors based on pivotal Ph II STARTRK-2, Ph I STARTRK-1 & ALKA-372-001 trials data; PDUFA: Aug 2019 (<http://hugin.info/174806/R/2235513/880051.pdf>)

FDA Priority Review for Roche’s entrectinib in cancer treatment <https://t.co/5l6b4VrGZx> (<https://t.co/5l6b4VrGZx>) pic.twitter.com/nqlrZo3eyS (<https://t.co/nqlrZo3eyS>)

— David Ledger (@Vedere_Group) February 22, 2019 (https://twitter.com/Vedere_Group/status/1098961879739727872?ref_src=twsrc%5Etfw)

“Entrectinib represents a unique approach to cancer treatment that can potentially target a range of hard-to-treat and rare NTRK fusion-positive tumours regardless of their site of origin, as well as treat ROS1-positive non-small cell lung cancer,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “By combining comprehensive genomic profiling with actionable targeted therapies, like entrectinib, we are advancing our personalised healthcare goal to find the right treatment for each patient. We are working closely with the FDA to make this potential new option available as soon as possible.”

Priority Review granted to CD79b-targeting ADC Polatuzumab vedotin in R/R DLBCL based on Ph Ib/II GO29365 study data; PDUFA: Aug 2019 (<http://hugin.info/174806/R/2235508/880041.pdf>)

Polatuzumab Vedotin Granted Priority Review Designation by FDA for DLBCL:<https://t.co/IFm7ZVoLLZ> (<https://t.co/IFm7ZVoLLZ>) [pic.twitter.com/bYcW4NjxiD](https://t.co/bYcW4NjxiD) (<https://t.co/bYcW4NjxiD>)

— Targeted Oncology (@TargetedOnc) February 19, 2019 (https://twitter.com/TargetedOnc/status/1097917622308560898?ref_src=twsrc%5Etfw)

“Polatuzumab vedotin, a potential first-in-class antibody drug conjugate, in combination with bendamustine and Rituxan, improved clinical outcomes including survival in some people with relapsed or refractory diffuse large B-cell lymphoma compared to bendamustine and Rituxan alone,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “We are working with the FDA to bring this important new option to patients with this aggressive disease as quickly as possible.”

FDA accepts IND application to initiate Ph I trial of Met-targeting PBD ADC, TR1801-ADC (MT-8633), in cMet +ve solid tumors (<http://trlusa.com/tanabe-research-labs-announce-fda-acceptance-of-its-ind-application-for-tr1801-adc-mt-8633-an-adc-targeting-cmet-positive-solid-tumors/>)

Tanabe Research Labs Announce FDA Acceptance of its IND Application for TR1801-ADC (MT-8633), an ADC Targeting cMet <https://t.co/raWHW5zFz5> (<https://t.co/raWHW5zFz5>)

— Crwe World (@CrweWorld) February 14, 2019 (https://twitter.com/CrweWorld/status/1096053733878751232?ref_src=twsrc%5Etfw)

“We are excited to be able to move TR1801-ADC into the clinic,” said Roland Newman, TRL’s Chief Scientific Officer. “TR1801-ADC is an extremely potent ADC that combines a non-agonizing anti-c-Met antibody developed at TRL, with a pyrrolobenzodiazepine dimer (PBD) toxin, and has demonstrated potent dose dependent anti-tumor activity against Met positive tumors in preclinical models.”

Avapritinib receives Ph III clinical trial approval for 3L KIT-driven GIST in China after encouraging Ph I results in 4L+ GIST patients (<https://www.prnewswire.com/news-releases/avapritinib-receives-phase-iii-clinical-trial-approval-for-gist-in-china-300796605.html>)

Avapritinib receives Phase III clinical trial approval for GIST in China: SUZHOU China Feb. 15 2019 PRNewswire CStone Pharmaceuticals "CStone" today announced that the National Medical Products Administration NMPA recently approved a Phase III... <https://t.co/zpBIGeGH5j> (<https://t.co/zpBIGeGH5j>)

— Renal Cell Carcinoma (@Renal_Bio) February 15, 2019 (https://twitter.com/Renal_Bio/status/1096549985842151424?ref_src=twsrc%5Etfw)

Dr. Frank Jiang, chairman and CEO of CStone, commented: “Avapritinib is a first-in-class precision medicine drug that has been awarded Breakthrough Therapy Designation by the U.S. FDA due to its outstanding clinical efficacy. Current available clinical data already demonstrated the drug’s great potential for advanced GIST patients. CStone is delighted to be able to introduce this product to Chinese patients via our partnership with Blueprint Medicines, and we look forward to generating positive clinical data in China.”

TRIAL RESULTS

Ph III pivotal KEYNOTE-240 trial of Pembrolizumab fails to meet primary endpoints of OS and PFS improvement vs placebo in previously-treated HCC patients (<https://investors.merck.com/news/press-release-details/2019/Merck-Provides-Update-on-KEYNOTE-240-a-Phase-3-Study-of-KEYTRUDA-pembrolizumab-in-Previously-Treated-Patients-with-Advanced-Hepatocellular-Carcinoma/default.aspx>)

Phase 3 trial of #pembrolizumab (https://twitter.com/hashtag/pembrolizumab?src=hash&ref_src=twsrc%5Etfw) for advanced hepatocellular carcinoma fails to meet primary endpoints #HCC (https://twitter.com/hashtag/HCC?src=hash&ref_src=twsrc%5Etfw) #livercancer (https://twitter.com/hashtag/livercancer?src=hash&ref_src=twsrc%5Etfw) #Keytruda (https://twitter.com/hashtag/Keytruda?src=hash&ref_src=twsrc%5Etfw) @Merck (https://twitter.com/Merck?ref_src=twsrc%5Etfw) <https://t.co/PEpmmWfYDY> (<https://t.co/PEpmmWfYDY>)

— HemOnc Today (@HemOncToday) February 20, 2019 (https://twitter.com/HemOncToday/status/1098216053417693185?ref_src=twsrc%5Etfw)

“While we are disappointed KEYNOTE-240 did not meet its co-primary endpoints, the results for overall survival, progression-free survival and objective response rate are generally consistent with findings from the Phase 2 study, KEYNOTE-224, which led to the accelerated approval of KEYTRUDA for the treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib,” said Dr. Roy Baynes, senior vice president and head of global clinical development, chief medical officer, Merck Research Laboratories. “We sincerely thank the patients and investigators for their participation in this study and are committed to helping patients diagnosed with this common and difficult-to-treat type of liver cancer.”

TRIAL STATUSES

First patient dosed in Ph Ib trial of B7-H4 inhibitor FPA150 in B7-H4-overexpressing patients with breast, ovarian, and endometrial tumors (<http://investor.fiveprime.com/news-releases/news-release-details/five-prime-therapeutics-doses-first-patient-phase-1b-trial>)

\$FPRX (https://twitter.com/search?q=%24FPRX&src=ctag&ref_src=twsrc%5Etfw) Doses First Patient in Phase Ib Trial of FPA150 immunooncology antibody that targets B7H4 <https://www.businesswire.com/news/home/20190220006026en/PrimeTherapeuticsDosesPatientPhaseIbTrial> \$FPRX (https://twitter.com/search?q=%24FPRX&src=ctag&ref_src=twsrc%5Etfw) Doses First Patient in Phase Ib Trial of FPA150... <https://t.co/lRTJLSdLMg> (<https://t.co/lRTJLSdLMg>)

— Antibody News (@AntibodyNews) February 21, 2019 (https://twitter.com/AntibodyNews/status/1098539713374281728?ref_src=twsrc%5Etfw)

“We are very pleased with the progress of our FPA150 clinical program that began with a dose escalation study in solid tumors and rapidly proceeded to an exploratory basket cohort of tumors that over-express B7-H4,” said Helen Collins, Senior Vice President and Chief Medical Officer. “We have now dosed the first patient in the Phase Ib dose expansion portion of the trial. FPA150 specifically targets B7-H4, which is in the same family of

checkpoint inhibitors as PD-L1 and is over-expressed in breast and gynecological cancers that are not well served by immunotherapy. We are hopeful that a targeted immunotherapy like FPA150 will provide clinical benefit to these patients who have limited treatment options.”

Ph I trial of CD19-targeting PBD ADC, ADCT-402 (loncastuximab tesirine), and Ibrutinib initiated in advanced DLBCL and MCL patients (<https://adctherapeutics.com/>)

Open @RutgersCancer (https://twitter.com/RutgersCancer?ref_src=twsrc%5Etfw): Ph I open-label #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) to evaluate safety & antitumor activity of loncastuximab tesirine and durvalumab in patients with advanced diffuse large B-cell, mantle cell or follicular #lymphomas (https://twitter.com/hashtag/lymphomas?src=hash&ref_src=twsrc%5Etfw). <https://t.co/yZUweT69R2> (<https://t.co/yZUweT69R2>) [pic.twitter.com/MrBptBghZo](https://t.co/MrBptBghZo) (<https://t.co/MrBptBghZo>)

— RutgersCancerInstNJ (@RutgersCancer) January 30, 2019 (https://twitter.com/RutgersCancer/status/1090632401812901888?ref_src=twsrc%5Etfw)

Jay Feingold, MD, PhD, Chief Medical Officer and Senior Vice President of Clinical Development at ADC Therapeutics, said, “At the 60th American Society of Hematology (ASH) Annual Meeting, the data we presented from our 183-patient first-in-human clinical trial of ADCT-402 demonstrated its encouraging safety profile and anti-tumor activity as a single agent against relapsed or refractory diffuse large B-cell lymphoma and mantle cell lymphoma. Now, in our second combination trial of ADCT-402, we look forward to exploring whether ADCT-402 and ibrutinib, both of which target B-cell cancers with different mechanisms of action, may increase the response rate and durability of response compared to the effects of these compounds as single agents.”

Ph II MAGNOLIA trial of BTK inhibitor Zanubrutinib initiated in R/R MZL patients (<http://phx.corporate-ir.net/phoenix.zhtml?c=254246&p=irol-newsArticle&id=2388014>)

BeiGene Initiates Global Phase 2 Trial of Zanubrutinib in Patients with Relapsed or Refractory Marginal Zone Lymphoma | Small Molecules | News Channels – <https://t.co/EPULBfyJ1G> (<https://t.co/EPULBfyJ1G>) <https://t.co/82vC6IEp2G> (<https://t.co/82vC6IEp2G>)

— Follement-bijoux (@Follementbijoux) February 21, 2019 (https://twitter.com/Follementbijoux/status/1098451790398451712?ref_src=twsrc%5Etfw)

“We are excited to initiate this Phase 2 trial following the preliminary results from our Phase I trial of zanubrutinib in patients with relapsed or refractory marginal zone lymphoma, in which seven objective responses in nine patients were reported. More than 1,300 patients worldwide have been treated with zanubrutinib, and we look forward to evaluating its potential in the MAGNOLIA trial for these patients who may find benefit with this novel BTK inhibitor,” commented Jane Huang, M.D., Chief Medical Officer for Hematology at BeiGene.

FDA puts partial clinical hold on Ph I trial of anti-CD123 x anti-CD3 antibody XmAb14045 in R/R AML patients (<https://www.biospace.com/article/fda-places-partial-clinical-hold-on-xencor-clinical-trial-following-two->

patient-deaths/)

After 2 Patient Deaths, FDA Imposes Partial Clinical Hold on Trial of Xencor Blood Cancer Antibody XmAb14045 <https://t.co/1D7GmOuWif> (<https://t.co/1D7GmOuWif>) [pic.twitter.com/nlQKuaUJvW](https://t.co/nlQKuaUJvW) (<https://t.co/nlQKuaUJvW>)

— Thanasis Chalikias (@thanasis232) February 21, 2019 (https://twitter.com/thanasis232/status/1098568583037284352?ref_src=twsrc%5Etfw)

Bassil Dahiyat, president and chief executive officer of Moravia, Calif.-based Xencor, said patient safety is the highest concern of the company. “We are working with the investigators and the FDA and will provide an update when more information about resuming enrollment can be shared. Our ongoing Phase I studies evaluating our other CD3 bispecific antibodies, XmAb13676 and XmAb18087, are not affected,” Dahiyat said in a statement.

Ph I/Ib trial of Deep-Primed T cell product TRQ-1501 initiated in Advanced Solid Tumors or Lymphoma patients (<http://www.torquetx.com/news/press-releases/torque-initiates-phase-i-clinical-trial-of-trq-1501-deep-il-15-primed-t-cells-in-patients-with-advanced-solid-tumors-or-lymphomas/>)

Torque Initiates Phase I Clinical Trial of TRQ-1501 Deep IL-15 Primed T Cells in Patients with Advanced Solid Tumors or Lymphomas <https://t.co/D2UbAKlnkQ> (<https://t.co/D2UbAKlnkQ>)

— Human Immunology (@humanimmuneneews) February 21, 2019 (https://twitter.com/humanimmuneneews/status/109837524955525632?ref_src=twsrc%5Etfw)

“We are grateful to the patients and clinical researchers contributing to Torque’s first Deep-Primed T Cell clinical program,” said Bart Henderson, Chief Executive Officer of Torque. “We developed Deep-Primed T cells to overcome the main challenges limiting cellular immunotherapy—the ability to target heterogeneous tumors, overcome immunosuppression in the tumor microenvironment, and administration as outpatient therapy—and our hope is that this innovative treatment will shift the treatment paradigm, improving patient outcomes in multiple difficult-to-treat solid and hematologic cancers.”

COLLABORATIONS & LICENSING DEALS

Deep IL-15 Primed T Cells (TRQ-1501) to be tested both as a single agent and in combination with Pembrolizumab in Ph I/II study in multiple solid tumor indications (<http://www.torquetx.com/news/press-releases/torque-announces-clinical-trial-collaboration-with-merck/>)

#Torque (https://twitter.com/hashtag/Torque?src=hash&ref_src=twsrc%5Etfw), #Merck (https://twitter.com/hashtag/Merck?src=hash&ref_src=twsrc%5Etfw) to test #Keytruda (https://twitter.com/hashtag/Keytruda?src=hash&ref_src=twsrc%5Etfw) with Deep IL-15 Primed T cells #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #tumor (https://twitter.com/hashtag/tumor?src=hash&ref_src=twsrc%5Etfw) #pharmaceutical (https://twitter.com/hashtag/pharmaceutical?src=hash&ref_src=twsrc%5Etfw) <https://t.co/oYPkXqH2gt> (<https://t.co/oYPkXqH2gt>) [pic.twitter.com/GtX9bm1zil](https://t.co/GtX9bm1zil) (<https://t.co/GtX9bm1zil>)

— insidescratch (@insidescratch) February 20, 2019 (https://twitter.com/insidescratch/status/1098245924147642369?ref_src=twsrc%5Etfw)

“We are very excited about this clinical collaboration with Merck to evaluate the combination of KEYTRUDA with our Deep IL-15 Primed T cells,” said Bart Henderson, Chief Executive Officer of Torque. “Torque’s new class of cellular immunotherapy is designed to harness the full biology of natural T cells for treating multiple solid tumors, and we believe the combination with anti-PD-1 therapy will further enhance the function of these cells by protecting them against immunosuppression in the tumor microenvironment. This combination has the potential to improve treatment outcomes for patients with solid tumors that are relapsed or refractory to currently available treatments and broaden the applications of cellular immunotherapy.”

RESULTS // ASCO GU 2019

4- Today my colleague @DrScottTagawa (https://twitter.com/DrScottTagawa?ref_src=twsrc%5Etfw) presented the full results of the urothelial cancer cohort from the phase I clinical @ASCO (https://twitter.com/ASCO?ref_src=twsrc%5Etfw) #GU19 (https://twitter.com/hashtag/GU19?src=hash&ref_src=twsrc%5Etfw) [pic.twitter.com/vpT9CxoIVj](https://t.co/vpT9CxoIVj) (<https://t.co/vpT9CxoIVj>)

— DrBishoyFaltas (@FaltasLab) February 15, 2019 (https://twitter.com/FaltasLab/status/1096534428367482880?ref_src=twsrc%5Etfw)

1. Results of discontinued Ph Ib/II trial of AKT oligonucleotide inhibitor RX-0201+ Everolimus in mRCC patients presented (<https://www.urotoday.com/conference-highlights/asco-gu-2019/asco-gu-2019-kidney-cancer/110430-asco-gu-2019-results-of-a-phase-ii-study-to-evaluate-the-safety-and-efficacy-of-rx-0201-in-combination-with-everolimus-in-subjects-with-mrcc.html>)
2. Updated interim data from Ph IIa trial of nucleic acid synthesis inhibitor RX-3117 in advanced bladder cancer patients presented (<https://www.rexahn.com/news-media/press-releases/detail/293/rexahn-presents-updated-interim-data-from-phase-2a-trial-of>)
3. Topline data from Ph III TIVO-3 trial of VEGF TKI Tivozanib in R/R RCC patients presented (<https://investor.aveooncology.com/news-releases/news-release-details/aveo-oncology-announces-oral-presentation-tivo-3-trial-topline>)
4. Data from Ph I/II PIVOT-02 trial of CD122-biased agonist NKTR-214 + nivolumab in iL advanced/metastatic urothelial carcinoma patients presented (<https://ir.nektar.com/news-releases/news-release-details/clinical-data-presented-pivot-02-study-bempegaldesleukin-nktr>)
5. Pembrolizumab + Axitinib extended OS and PFS in iL RCC patients in Ph III KEYNOTE-426 trial (<https://www.mrknewsroom.com/news-release/oncology/keytruda-pembrolizumab-combination-inlyta-axitinib-reduced-risk-death-nearly-h>)
6. Updated Ph I data of glutaminase inhibitor Telaglenastat + Cabozantinib in advanced RCC patients presented (http://ir.calithera.com/news-releases/news-release-details/updated-results-phase-i-study-telaglenastat-cb-839-be-presented?field_nir_news_date_value%5bmin%5d=)

7. Subgroup analyses data announced and published from Ph III JAVELIN Renal 101 trial of Avelumab + Axitinib in advanced RCC patients (https://www.merckgroup.com/en/news/asco-i6-02-2019.html?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)
8. Statistically significant improvement in MFS observed in Ph III ARAMIS trial of ARi Darolutamide in nmCRPC patients; mOS not reached (<https://www.bayer.us/en/newsroom/press-releases/article/?id=123278>)
9. Nivolumab + Ipilimumab show response in pre-treated mCRPC patients in Ph II CheckMate-650 trial (<https://news.bms.com/press-release/corporatefinancial-news/opdivo-nivolumab-plus-yervoy-ipilimumab-shows-response-pre-tre>)
10. Promising response rates observed in interim analysis of Ph II GALAHAD trial of Niraparib in mCRPC patients with DRD (<https://www.janssen.com/janssen-announces-preliminary-results-phase-2-galahad-study-adults-metastatic-castration-resistant>)
11. Encouraging SM-88 results observed without typical hormone-related AEs in Ph II trial of patients with biomarker recurrent Prostate Cancer (<https://www.tymeinc.com/investors/news-releases/press-release-details/2019/TYME-Reports-Encouraging-SM-88-Clinical-Results-without-Typical-Hormone-Related-Side-Effects-in-Phase-II-Study-of-Patients-with-Biomarker-Recurrent-Prostate-Cancer/default.aspx>)
12. Safety lead-in data presented from Ph II trial of PLK1 inh Onvansertib + abiraterone acetate/prednisone in mCRPC patients (<http://trovogeneoncology.investorroom.com/2019-02-14-Trovogene-Presents-Update-on-Phase-2-Study-of-Onvansertib-in-Combination-with-Zytiga-in-Patients-with-mCRPC-at-ASCO-GU-Conference>)
13. Trial design of Ph Ib/II trial of tubulin inhibitor VERU-111 in mCRPC patients presented (<https://verupharma.com/investors/press-releases/press-release/?releaseid=2387077>)
14. Immunomedics presented trial design of Ph II TROPHY U-01 and longer follow-up data on TRPO2-targeting SN38 ADC sacituzumab govitecan in mUC patients from Ph I/II trial (<https://www.immunomedics.com/our-company/news-and-events/immunomedics-announces-oral-presentation-at-the-2019-genitourinary-cancers-symposium/>)
15. Merck highlighted clinical updates from KEYNOTE-199, -365, -057, -0426, -427 and PROPEL trials (<https://www.mrknewsroom.com/news-release/oncology/merck-highlights-breadth-immuno-oncology-research-program-genitourinary-cancer>)
16. Data from Ph II CALYPSO trial of c-MET inh Savolitinib + Durvalumab in papillary RCC patients presented (<https://www.chi-med.com/calypso-pres-at-2019-asco-gu-sym/>)
17. LuPSMA treatment provides high response rates in mCRPC patients (<https://www.asco.org/about-asco/press-center/news-releases/phase-ii-trial-shows-novel-radiolabeled-psma-targeted>)
18. Pembrolizumab + Axitinib extended OS and PFS in 1L RCC patients in Ph III KEYNOTE-426 trial (<https://www.asco.org/about-asco/press-center/news-releases/pembrolizumab-plus-axitinib-extended-overall-survival-and>)
19. Ph III ARCHES trial shows enzalutamide significantly improved radiographic PFS in mCSPC patients (<https://newsroom.astellas.us/2019-02-11-Phase-3-ARCHES-Trial-Shows-XTANDI-R-enzalutamide-Significantly-Improved-Radiographic-Progression-Free-Survival-in-Men-with-Metastatic-Hormone-Sensitive-Prostate-Cancer>)
20. Results from Ph II trial of FGFR3 inh Vofatamab in FGFR3 mutation positive patients with locally advanced or metastatic bladder cancer presented (https://www.rainierrx.com/wp-content/uploads/2019/02/Final-2.15.19-ASCO_GU-data-Release-Rainier.pdf)

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(<https://io.wp.com/www.sciwri.club/wp-content/uploads/2018/03/RT.jpg>)

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Image Sources: Wikipedia and Twitter

Cover image: “Human melanoma cell undergoing cell division. The chromosomes (blue) have separated and the two daughter cells have almost split apart – only a small bridge of cytoplasm remains. The green staining labels the endoplasmic reticulum and the red labels the mitochondria. The image was produced on a confocal microscope; the ER and mitochondria are from a single optical section but the chromosomes are a 3D reconstruction from a series of sections.” Source (<http://www.cellimagelibrary.org/images/38978>)

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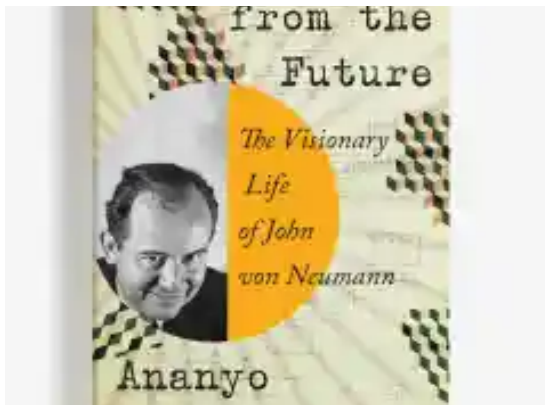
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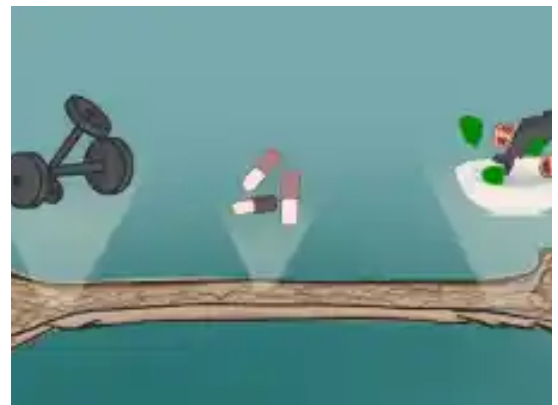
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