Onco-this-Week: Top Tens of 2018

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In The Final Edition Of 2018, Onco-This-Week Covers The Most Impactful Oncology News Of The Year 2018. We Showcase The Top Ten Newsmakers In Most Impactful Approvals, Failures, Promising Trials, Biosimilars, And Financial Deals Along With Selected Novel Oncology Drug Approvals From FDA. We Wish You A Happy And Prosperous New Year 2019!

This Edition Of Onco-This-Week Is Sponsored By

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Most Impactful Approvals

1. **Larotrectinib (https://ir.loxooncology.com/press-releases/2378241-Fda-approves-vitrakvi-larotrectinib-the-first-ever-trk-inhibitor-for-patients-with-advanced-solid-tumors-harboring-an-ntrk-gene-fusion12): FDA approves Larotrectinib, the first ever TRK inhibitor, as first treatment with a tumor-agnostic indication for NTRK+ patients**

> "When we went back to MSK, they were even more shocked. They were like 'Whoa, we've never seen this process go fast. We've seen it in months, but so fast, within a week?'" More on #Larotrectinib (https://twitter.com/hashtag/Larotrectinib?src=hash&ref_src=twsrc%5Etfw)'s landmark approval via @NBCNews (https://twitter.com/NBCNews?ref_src=twsrc%5Etfw) https://t.co/EkXrPjHqFo (https://t.co/EkXrPjHqFo)
>
> — Memorial Sloan Kettering Cancer Center (@sloan_kettering) November 27, 2018 (https://twitter.com/sloan_kettering/status/1067510133176045568?ref_src=twsrc%5Etfw)

2. **Venetoclax (https://www.roche.com/media/releases/med-cor-2018-11-21.htm) and Glasdegib (https://www.pfizer.com/news/press-release/press-release-detail/u_s_fda_approves_daurismo_glasdegib_for_adult_patients_with_newly_diagnosed_acute_myeloid_leukemia_aml_for_whom_intensive_che FDA grants not one but two approvals in 1L elderly or unfit AML patients in the same week – Venclexta's accelerated approval based on results from the M14-358 study and the M14-387 study and Glasdegib's approval on the basis of Ph II BRIGHT 1003 trial**

> This newly updated #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) reference resource reflects @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) approval of glasdegib and venetoclax https://t.co/D8jAu83CkS (https://t.co/D8jAu83CkS) #MedUpdate (https://twitter.com/hashtag/MedUpdate?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/2Bum5YTKEh (https://t.co/2Bum5YTKEh)
>
> — Medscape (@Medscape) December 20, 2018 (https://twitter.com/Medscape/status/1075724499000221696?ref_src=twsrc%5Etfw)

3. **Kymriah® (tisagenlecleucel) (https://www.novartis.com/news/media-releases/kymriahr-tisagenlecleucel-first-class-car-t-therapy-from-novartis-receives-second-fda-approval-treat-appropriate-rr-patients-large-b-cell-lymphoma) and Yescarta (axicabtagene ciloleucel) (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm581216.htm): Kymriah gets EU and FDA approvals in R/R B-ALL and DLBCL patients; and Yescarta in R/R DLBCL and PMBCL patients also making them the costliest therapies ever**

> ICER's evidence ratings of #CART (https://twitter.com/hashtag/CART?src=hash&ref_src=twsrc%5Etfw) therapies #Kymriah (https://twitter.com/hashtag/Kymriah?src=hash&ref_src=twsrc%5Etfw) and #Yescarta (https://twitter.com/hashtag/Yescarta?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/nTCAURhCRl (https://t.co/nTCAURhCRl)
>
> — ICER (@icer_review) March 2, 2018 (https://twitter.com/icer_review/status/969647970797879296?ref_src=twsrc%5Etfw)

4. **Tagraxofusp-erzs (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm629020.htm): FDA approves tagraxofusp-erzs (SL-401) as first treatment in 1L adult and pediatric BPDCN patients**

> #Elzonris (https://twitter.com/hashtag/Elzonris?src=hash&ref_src=twsrc%5Etfw) (tagraxofusp-erzs) infusion was granted the first approval for the treatment of #blastic (https://twitter.com/hashtag/blastic?src=hash&ref_src=twsrc%5Etfw) #plasmacytoid (https://twitter.com/hashtag/plasmacytoid?src=hash&ref_src=twsrc%5Etfw) #dendritic (https://twitter.com/hashtag/dendritic?src=hash&ref_src=twsrc%5Etfw) cell #neoplasm (https://twitter.com/hashtag/neoplasm?src=hash&ref_src=twsrc%5Etfw) (#BPDCN (https://twitter.com/hashtag/BPDCN?src=hash&ref_src=twsrc%5Etfw)) https://t.co/xSTNzxVoZj (https://t.co/xSTNzxVoZj) di @debugliesnews (https://twitter.com/debugliesnews?ref_src=twsrc%5Etfw) pic.twitter.com/D8p7cGtenH (https://t.co/D8p7cGtenH)
>
> — debuglies (@debugliesnews) December 25, 2018 (https://twitter.com/debugliesnews/status/1077594606143983617?ref_src=twsrc%5Etfw)

5. **Olaparib (https://www.astrazeneca.com/media-centre/press-releases/2018/lynparza-approved-by-us-fda-for-1st-line-maintenance-therapy-in-brca-mutated-advanced-ovarian-cancer19122018.html): FDA approves Olaparib as first PARP inhibitor for 1L maintenance in BRCAm advanced ovarian cancer patients based on Ph III SOLO-1 trial results**

> Olaparib Gets First-Line Ovarian Cancer Maintenance Indication https://t.co/s9xoW1EfcK (https://t.co/s9xoW1EfcK) pic.twitter.com/8X8IkfbEDc (https://t.co/8X8IkfbEDc)
>
> — Med. Tech. Network (@MedTechNetwork) December 23, 2018 (https://twitter.com/MedTechNetwork/status/1076871192651288579?ref_src=twsrc%5Etfw)

6. **Brentuximab vedotin (http://investor.seattlegenetics.com/news-releases/news-release-details/seattle-genetics-announces-fda-approval-adcetrisr-brentuximab-1): FDA approves CD30-targeting MMAE ADC, Brentuximab vedotin, in 1L PTCL patients based on Ph III ECHELON-2 data as first option to come in decades after chemotherapy as standard of care**

Our Anaplastic Large Cell Lymphoma reference resource has been updated with approval of brentuximab vedotin by @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) for treatment of certain patients #MedUpdate (https://twitter.com/hashtag/MedUpdate?src=hash&ref_src=twsrc%5Etfw) #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/teIWHWakSz (https://t.co/teIWHWakSz) pic.twitter.com/sUy1VoWJ4X (https://t.co/sUy1VoWJ4X)

— Medscape (@Medscape) December 22, 2018 (https://twitter.com/Medscape/status/1076437697516982272?ref_src=twsrc%5Etfw)

7. **Cemiplimab (http://hugin.info/152918/R/2217053/867105.pdf): FDA approves PD-1 inhibitor Cemiplimab as first and only treatment specifically approved for advanced CSCC patients based on data from Ph II EMPOWER-CSCC-1 and the two advanced CSCC expansion cohorts from a Ph I trial**

The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) approved the #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) drug cemiplimab (Libtayo) for an advanced form of cutaneous squamous cell carcinoma (SCC), a common type of #SkinCancer (https://twitter.com/hashtag/SkinCancer?src=hash&ref_src=twsrc%5Etfw). It is the first agent to be approved specifically for advanced SCC.#PrecisionMedicine (https://twitter.com/hashtag/PrecisionMedicine?src=hash&ref_src=twsrc%5Etfw) #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw)https://t.co/9tVsKYKHMe (https://t.co/9tVsKYKHMe) pic.twitter.com/LKhT5HseXM (https://t.co/LKhT5HseXM)

— MyOncoPath (@MyOncoPath) October 26, 2018 (https://twitter.com/MyOncoPath/status/1055914483812630532?ref_src=twsrc%5Etfw)

8. **Durvalumab (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm597217.htm): FDA and EU approves Durvalumab as adjuvant maintenance therapy for unresectable stage III PD-L1+ NSCLC patients based on Ph III PACIFIC trial data, making it the first immunotherapy to demonstrate significant OS benefit**

#FDAapproves (https://twitter.com/hashtag/FDAapproves?src=hash&ref_src=twsrc%5Etfw) new indication for Imfinzi (durvalumab): https://t.co/hVgcgfjBH5 (https://t.co/hVgcgfjBH5). pic.twitter.com/WeDjINCEb4 (https://t.co/WeDjINCEb4)

— FDA Drug Information (@FDA_Drug_Info) February 16, 2018 (https://twitter.com/FDA_Drug_Info/status/964622305426116608?ref_src=twsrc%5Etfw)

9. **Talazoparib (https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm623540.htm): Talazoparib's FDA approval in gBRCA+ HER2 neg breast cancer patients (including 44% TNBC patients) based on results from Ph III EMBRACA Study (NCT01945775)**

Clinical success of PARP inhibitors appears related to trapping PARP to DNA, not catalytic inhibition. Although Ki's of five PARPi's are ~equal, they vary in PARP-DNA binding potential: Talazoparib $PFZ (https://twitter.com/search?q=%24PFZ&src=ctag&ref_src=twsrc%5Etfw) > Olaparib $AZD (https://twitter.com/search?q=%24AZD&src=ctag&ref_src=twsrc%5Etfw) > $TSRO (https://twitter.com/search?q=%24TSRO&src=ctag&ref_src=twsrc%5Etfw) / $CLVS (https://twitter.com/search?q=%24CLVS&src=ctag&ref_src=twsrc%5Etfw) > Veliparib $ABBV (https://twitter.com/search?q=%24ABBV&src=ctag&ref_src=twsrc%5Etfw) . https://t.co/tkK2JDdGRV (https://t.co/tkK2JDdGRV) pic.twitter.com/PfFZ4lStSN (https://t.co/PfFZ4lStSN)

— Biotech Junto (@BiotechJunto) July 9, 2018 (https://twitter.com/BiotechJunto/status/1016401533829861382?ref_src=twsrc%5Etfw)

10. **Iobenguane I-131 (https://progenicsgc.gcs-web.com/news-releases/news-release-details/progenics-pharmaceuticals-announces-fda-approval-azedrar): FDA approves Iobenguane I-131 as the first and only approved therapy for rare NETs (pheochromocytoma or paraganglioma)**

FDA has approved Azedra (iobenguane I 131), the first drug approved for the treatment of pheochromocytoma or paraganglioma (rare tumors of the adrenal gland) that cannot be surgically removed in adolescents ≥12 y/o and adults. https://t.co/wscDfSDxeR (https://t.co/wscDfSDxeR) pic.twitter.com/j8Xn9nBksX (https://t.co/j8Xn9nBksX)

— Stephen R Saklad (@pharmacopsych) July 31, 2018 (https://twitter.com/pharmacopsych/status/1024408609487241216?ref_src=twsrc%5Etfw)

2018 saw 32 #FDAapprovals (https://twitter.com/hashtag/FDAapprovals?src=hash&ref_src=twsrc%5Etfw) in #hematology (https://twitter.com/hashtag/hematology?src=hash&ref_src=twsrc%5Etfw) including 12 NMEs & 5 #biosimilars (https://twitter.com/hashtag/biosimilars?src=hash&ref_src=twsrc%5Etfw). 8 had pediatric indications. 6 were for 1st-line indications. We used the Real-Time Oncology Review to approve brentuximab vedotin 2 wks after receiving the company's completed application. #ASH18 (https://twitter.com/hashtag/ASH18?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/DwCZfVnSdE (https://t.co/DwCZfVnSdE)

— FDA Oncology (@FDAOncology) December 3, 2018 (https://twitter.com/FDAOncology/status/1069683685283282944?ref_src=twsrc%5Etfw)

Most Significant Failures

1. **Ph III JAVELIN Ovarian 100 study (https://www.merckgroup.com/en/news/javelin-ovarian-100-21-12-2018.html?utm_source=press-release&utm_medium=email&utm_campaign=press-**

mailer&utm_content=en): Ph III JAVELIN Ovarian 100 trial of Avelumab didn't support initial hypothesis of PFS improvement in interim analysis in previously untreated ovarian cancer patients

> Merck and Pfizer Reports Results of Avelumab in P-III JAVELIN Ovarian 100 study for Previously Untreated Advanced Ovarian Cancer @Merck_lifesci (https://twitter.com/Merck_lifesci?ref_src=twsrc%5Etfw) @pfizer (https://twitter.com/pfizer?ref_src=twsrc%5Etfw) https://t.co/3iiOlTptd4 (https://t.co/3iiOlTptd4) pic.twitter.com/sdwXWfoGdQ (https://t.co/sdwXWfoGdQ)
>
> — PharmaShots (@Pharmashot) December 28, 2018 (https://twitter.com/Pharmashot/status/1078557887964823553?ref_src=twsrc%5Etfw)

2. **Ph III TAHOE trial (https://news.abbvie.com/news/press-releases/phase-3-trial-rova-t-as-second-line-therapy-for-advanced-small-cell-lung-cancer-tahoe-study-halted.htm): Ph III TAHOE trial of Rova-T as 2L therapy for advanced SCLC halted due to shorter OS with Rova-T arm compared with the topotecan**

> Unfortunately for Abbvie & for patients, Abbvie terminates TAHOE Phase III trial for Rova-T as second-line therapy fr advanced small-cell #LungCancer (https://twitter.com/hashtag/LungCancer?src=hash&ref_src=twsrc%5Etfw). As we reflect on the $5.6bn acquisition drowning, its a stark reminder of binary risk in drug development https://t.co/Z9NCCZOyKP (https://t.co/Z9NCCZOyKP) pic.twitter.com/EECvill5Hz (https://t.co/EECvill5Hz)
>
> — Pushpa Vijayaraghavan (@pushpa_sathguru) December 6, 2018 (https://twitter.com/pushpa_sathguru/status/1070568537863962624?ref_src=twsrc%5Etfw)

3. **Ph III EAGLE trial (https://www.astrazeneca.com/media-centre/press-releases/2018/update-on-the-phase-iii-eagle-trial-of-imfinzi-and-tremelimumab-in-advanced-head-and-neck-cancer-07122018.html): No survival benefit seen with Durvalumab + tremelimumab in SCCHN patients progressing following platinums, regardless of PD-L1 tumor status.**

> AstraZeneca Reports Imfinzi (durvalumab) & tremelimumab Results in P-III EAGLE trial for Advanced Head and Neck Cancer @AstraZeneca (https://twitter.com/AstraZeneca?ref_src=twsrc%5Etfw) https://t.co/cargbWBQZv (https://t.co/cargbWBQZv) pic.twitter.com/i7uZCHEg4R (https://t.co/i7uZCHEg4R)
>
> — PharmaShots (@Pharmashot) December 10, 2018 (https://twitter.com/Pharmashot/status/1072150739567312897?ref_src=twsrc%5Etfw)

4. **Ph III CheckMate-331 trial (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-announces-phase-3-checkmate-331-study-doe): Nivolumab failed to improve OS compared with the standard chemotherapy of topotecan or amrubicin in 2L+ SCLC patients**

> #Opdivo (https://twitter.com/hashtag/Opdivo?src=hash&ref_src=twsrc%5Etfw) failed to increase overall survival compared to #chemotherapy (https://twitter.com/hashtag/chemotherapy?src=hash&ref_src=twsrc%5Etfw) in the phase 3 CheckMate-331 trial of patients with small cell #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw)https://t.co/bbnnrSitxS (https://t.co/bbnnrSitxS) pic.twitter.com/VNg9P6f8fr (https://t.co/VNg9P6f8fr)
>
> — AJMC (@AJMC_Journal) October 21, 2018 (https://twitter.com/AJMC_Journal/status/1053918815657099265?ref_src=twsrc%5Etfw)

5. **Ph III ARCTIC trial (https://www.astrazeneca.com/content/astraz/media-centre/press-releases/2018/astrazeneca-reports-results-from-the-arctic-trial-in-third-line-non-small-cell-lung-cancer-24042018.html): Durvalumab + Tremelimumab combo fails to meet primary endpoint of PFS and OS improvement in PD-L1 low/neg 3L NSCLC patients**

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

6. **Ph III KEYNOTE-061 study (http://www.ascopost.com/News/59007): Pembrolizumab fails to show survival benefit in PD-L1 ≥1 Gastric/GEJ cancers progressing on platinum-fluoropyrimidine treatment**

> Unfortunately, KEYNOTE-061 study did not significantly improve overall survival or progression-free survival: https://t.co/MrHGZ68QIV (https://t.co/MrHGZ68QIV) Dr. Shitara shared his insights on the trial.#GastricCancer (https://twitter.com/hashtag/GastricCancer?src=hash&ref_src=twsrc%5Etfw) #ClinicalTrial (https://twitter.com/hashtag/ClinicalTrial?src=hash&ref_src=twsrc%5Etfw) #Oncology (https://twitter.com/hashtag/Oncology?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/Bx2HZO6nNu (https://t.co/Bx2HZO6nNu)
>
> — Targeted Oncology (@TargetedOnc) July 12, 2018 (https://twitter.com/TargetedOnc/status/1017378202203971584?ref_src=twsrc%5Etfw)

7. **Ph III PRODIGE9 trial (http://ascopubs.org/doi/full/10.1200/JCO.2017.75.2931): Bevacizumab maintenance after frontline induction therapy reveals no survival benefit (progression-free or overall) in CRC patients**

> Now this is what I call #practicechanger (https://twitter.com/hashtag/practicechanger?src=hash&ref_src=twsrc%5Etfw) and #clinicallyrelevant (https://twitter.com/hashtag/clinicallyrelevant?src=hash&ref_src=twsrc%5Etfw) trial. #PRODIGE9 (https://twitter.com/hashtag/PRODIGE9?src=hash&ref_src=twsrc%5Etfw) @JCO_ASCO (https://twitter.com/JCO_ASCO?ref_src=twsrc%5Etfw) answers a very important clinical question. https://t.co/W4ay3ySRbe (https://t.co/W4ay3ySRbe) pic.twitter.com/BJWaX484Dx (https://t.co/BJWaX484Dx)
>
> — Bishal Gyawali (@oncology_bg) January 19, 2018 (https://twitter.com/oncology_bg/status/954276155015667712?ref_src=twsrc%5Etfw)

8. **Ph IIb METRIC trial (https://ir.celldex.com/news-releases/news-release-details/celldexs-metric-study-metastatic-triple-negative-breast-cancer-0): CellDex discontinues Glembatumumab development after the first-in-class GPNMB inhibitor fails in gpNMB-overexpressing TNBC**

> The METRIC trial completed enrollment in 2017 for investigating safety and efficacy of the glycoprotein NMB-targeting antibody-drug conjugate glembatumumab vedotin #TNBCDay (https://twitter.com/hashtag/TNBCDay?src=hash&ref_src=twsrc%5Etfw) #TNBC (https://twitter.com/hashtag/TNBC?src=hash&ref_src=twsrc%5Etfw)https://t.co/6aUWGvxCmz (https://t.co/6aUWGvxCmz) pic.twitter.com/1LoAWq0RFA (https://t.co/1LoAWq0RFA)
>
> — Targeted Oncology (@TargetedOnc) March 4, 2018 (https://twitter.com/TargetedOnc/status/970146861561597953?ref_src=twsrc%5Etfw)

9. **Ph III LUME-Meso trial (https://www.boehringer-ingelheim.com/press-release/lume-meso-phase-iii-results?): Nintedanib failed to improve PFS in unresectable, epithelioid malignant pleural mesothelioma patients**

> Dr. @giorgioscaglio3 (https://twitter.com/giorgioscaglio3?ref_src=twsrc%5Etfw) demonstrates for Epithelioid Meso the LUME-Meso trial no increase in PFS and/or OS with Nintedanib + Platinum + Pem. Rare cancer and its unmet needs still on the need for shining lights #WCLC2018 (https://twitter.com/hashtag/WCLC2018?src=hash&ref_src=twsrc%5Etfw) #LCSM (https://twitter.com/hashtag/LCSM?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/IFZDTmcUlu (https://t.co/IFZDTmcUlu)
>
> — Marcelo Corassa (@MarceloCorassa) September 25, 2018 (https://twitter.com/MarceloCorassa/status/1044581841146183681?ref_src=twsrc%5Etfw)

10. **Ph III ECHO-301/KEYNOTE-252 (http://www.incyte.com/ir/press-releases.aspx): Ph III trial with combination of epacadostat and pembrolizumab failed to demonstrate a statistically valid PFS improvement in unresectable/metastatic melanoma patients**

> #ASCO18 (https://twitter.com/hashtag/ASCO18?src=hash&ref_src=twsrc%5Etfw) Who says +ve trials get all the attention? Packed to the rafters for the $INCY (https://twitter.com/search?q=%24INCY&src=ctag&ref_src=twsrc%5Etfw) $MRK (https://twitter.com/search?q=%24MRK&src=ctag&ref_src=twsrc%5Etfw) ECHO-301/KEYNOTE-252 trial of Keytruda ± epacadostat. Initial Ph2 55% ORR didn't happen in any Ph3 subgroup (34%) and KMs identical #DRGOncology (https://twitter.com/hashtag/DRGOncology?src=hash&ref_src=twsrc%5Etfw) #Melanoma (https://twitter.com/hashtag/Melanoma?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/tlHW6Rx43I (https://t.co/tlHW6Rx43I)
>
> — Joshua Dawkins (@JBNDawkins) June 3, 2018 (https://twitter.com/JBNDawkins/status/1003309236959567878?ref_src=twsrc%5Etfw)

Most Promising Trials

1. **Ph III IMpassion130 trial (http://hugin.info/174806/R/2225295/872846.pdf): FDA grants priority review to Atezolizumab + Abraxane in 1L PD-L1-positive mTNBC patients based on significant reduction in PFS, risk of disease worsening or death; PDUFA: Mar 2019**

> LIVE EVENT BROADCAST from the Canadian Immuno-Oncology Summit 2018 in Toronto. Dr. Sunil Verma from Tom Baker Cancer Centre, Calgary, presenting on Immuno-Therapies in Practice in Breast Cancer. Highlights include recently published IMpassion130 trial #CANIO2018 (https://twitter.com/hashtag/CANIO2018?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/FP5wVA1qVo (https://t.co/FP5wVA1qVo)
>
> — OncologyEducation (@OncEd) November 1, 2018 (https://twitter.com/OncEd/status/1058015982453751808?ref_src=twsrc%5Etfw)

2. **Ph IIb STORM trial (http://investors.karyopharm.com/news-releases/news-release-details/us-food-and-drug-administration-accepts-karyopharms-new-drug): FDA grants priority review to Selinexor for penta-refractory multiple myeloma patients refractory to glucocorticoids, at least one PI, at least one IMiD, Daratumumab and their most recent therapy; PDUFA: Apr 2019**

#selinexor (https://twitter.com/hashtag/selinexor?src=hash&ref_src=twsrc%5Etfw) #STORM (https://twitter.com/hashtag/STORM?src=hash&ref_src=twsrc%5Etfw) trial update, look at continuous dosing for #pentarefractory (https://twitter.com/hashtag/pentarefractory?src=hash&ref_src=twsrc%5Etfw) #ASH18 (https://twitter.com/hashtag/ASH18?src=hash&ref_src=twsrc%5Etfw) #mmsm (https://twitter.com/hashtag/mmsm?src=hash&ref_src=twsrc%5Etfw) #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/8Qv8mhLdiY (https://t.co/8Qv8mhLdiY)

— Teresa Miceli (@IMFnurseMyeloma) December 3, 2018 (https://twitter.com/IMFnurseMyeloma/status/1069618601898860545?ref_src=twsrc%5Etfw)

3. **Ph III QuANTUM-R trial (https://www.prnewswire.com/news-releases/fda-grants-priority-review-for-daiichi-sankyos-new-drug-application-for-flt3-inhibitor-quizartinib-for-treatment-of-patients-with-relapsedrefractory-flt3-itd-aml-300754221.html): FDA grants priority review for FLT3 inhibitor Quizartinib for treatment of patients with R/R FLT3-ITD AML, making it the first FLT3 inhibitor to demonstrate a survival benefit in a randomized Ph III trial; PDUFA: May 25, 2019**

Jorge Cortes, MD, of @LeukemiaMDA (https://twitter.com/LeukemiaMDA?ref_src=twsrc%5Etfw) told @RareDR (https://twitter.com/RareDR?ref_src=twsrc%5Etfw) at #ASH18 (https://twitter.com/hashtag/ASH18?src=hash&ref_src=twsrc%5Etfw) that the phase 3 QuANTUM-R trial evaluating quizartinib is the first study ever that has demonstrated a survival benefit in the context of salvage treatment for acute myeloid #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw)

READ: https://t.co/O2BQskLWJX (https://t.co/O2BQskLWJX) pic.twitter.com/MAlopL5p1f (https://t.co/MAlopL5p1f)

— Rare Disease Report (@RareDR) December 6, 2018 (https://twitter.com/RareDR/status/1070709701719945216?ref_src=twsrc%5Etfw)

4. **Ph III TAGS (*TA*S-102 *G*astric *S*tudy) trial (https://www.taiho.co.jp/en/release/2018/20181026.html): FDA grants priority review to TAS-102 for previously treated gastric/GEJ cancer; PDUFA: Feb 2019**

Josep Tabernero, MD, PhD, ESMO president, summarizes the overall survival results from the TAGS study of trifluridine/tipiracil vs placebo in patients with metastatic gastric cancer refractory to standard therapies. Watch here: https://t.co/zQzj21NrME (https://t.co/zQzj21NrME) pic.twitter.com/wajaAtttyl (https://t.co/wajaAtttyl)

— World GI (@WCGIC) October 30, 2018 (https://twitter.com/WCGIC/status/1057346401217081344?ref_src=twsrc%5Etfw)

5. **Ph III KEYNOTE-181 trial (https://www.mrknewsroom.com/news-release/oncology/mercks-keytruda-pembrolizumab-significantly-improved-overall-survival-os-compa): Pembrolizumab significantly improved OS in PD-L1+ advanced esophageal or EGJ carcinoma patients in Ph III KEYNOTE-181 trial – becomes the first PD-1 inhibitor to demonstrate a survival benefit for these patients**

Merck Reports Improved Overall Survival Results of Keytruda (pembrolizumab) vs Chemotherapy in KEYNOTE-181 Study @Merck (https://twitter.com/Merck?ref_src=twsrc%5Etfw) https://t.co/OfrUCohqeb (https://t.co/OfrUCohqeb) pic.twitter.com/TGONAoLooD (https://t.co/TGONAoLooD)

— PharmaShots (@Pharmashot) November 15, 2018 (https://twitter.com/Pharmashot/status/1062953605639086081?ref_src=twsrc%5Etfw)

6. **Ph II STELLAR trial (https://www.novocure.com/data-from-stellar-registration-trial-of-tumor-treating-fields-in-mesothelioma-to-be-presented-at-the-iaslc-19th-world-conference-on-lung-cancer/): TTFs + SoC chemotherapy significantly extends mOS by 6.1 months in STELLAR Ph II registration trial in Mesothelioma, pitching it as first indication outside of the brain where TTFs show exemplary performance**

Today at 12:30, we'll be hosting an analyst and investor briefing featuring the final STELLAR trial results in #mesothelioma (https://twitter.com/hashtag/mesothelioma?src=hash&ref_src=twsrc%5Etfw) being presented at #WCLC2018 (https://twitter.com/hashtag/WCLC2018?src=hash&ref_src=twsrc%5Etfw). Tune in here: https://t.co/Lqu8canGnQ (https://t.co/Lqu8canGnQ) pic.twitter.com/4YaZACNKgW (https://t.co/4YaZACNKgW)

— Novocure (@Novocure) September 25, 2018 (https://twitter.com/Novocure/status/1044574825040236544?ref_src=twsrc%5Etfw)

7. **Ph I/II LIBRETTO-001 trial (https://ir.loxooncology.com/press-releases/2371557-Loxo-oncology-announces-receipt-of-breakthrough-therapy-designation-from-u.s.-food-and-drug-administration-for-loxo-292-for-the-treatment-of-ret-fusion-positive-thyroid-cancer): LOXO-292 gets breakthrough therapy designation for the treatment of RET fusion-positive Thyroid Cancer based on 45% ORR in RET-mutated MTC patients**

> An expert at @sloan_kettering (https://twitter.com/sloan_kettering?ref_src=twsrc%5Etfw) discussed the promising efficacy results of LOXO-292 for RET altered cancers: https://t.co/jqkfSdYocy (https://t.co/jqkfSdYocy) The LIBRETTO-001 trial was presented at #ASCO18 (https://twitter.com/hashtag/ASCO18?src=hash&ref_src=twsrc%5Etfw).#LOXO292 (https://twitter.com/hashtag/LOXO292?src=hash&ref_src=twsrc%5Etfw) #ClinicalTrial (https://twitter.com/hashtag/ClinicalTrial?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/bLUBGuPSaC (https://t.co/bLUBGuPSaC)
>
> — Targeted Oncology (@TargetedOnc) June 27, 2018 (https://twitter.com/TargetedOnc/status/1011972542221946881?ref_src=twsrc%5Etfw)

8. **Ph III CheckMate-227 study (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-provides-update-ongoing-regulatory-review): Nivolumab + Ipilimumab demonstrated a statistically significant HR of 0.58 (97.5% CI: 0.41 to 0.81; p=0.0002) versus chemotherapy in patients with TMB ≥10 mut/Mb. A descriptive analysis showed a positive trend for OS, which is secondary endpoint**

> Dr. Hellmann on Checkmate-227: “The results of this study highlight the importance of molecular profiling to identify the best treatment for each patient. We’re routinely doing this type of testing for people with lung cancer, for example, with MSK-IMPACT.” #AACR18 (https://twitter.com/hashtag/AACR18?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/uHuYQGJ66Y (https://t.co/uHuYQGJ66Y)
>
> — Memorial Sloan Kettering Cancer Center (@sloan_kettering) April 16, 2018 (https://twitter.com/sloan_kettering/status/985881313407307776?ref_src=twsrc%5Etfw)

9. **Ph II Tipifarnib registrational trial (http://ir.kuraoncology.com/news-releases/news-release-details/kura-oncology-initiates-registration-directed-trial-tipifarnib): Registrational AIM-HN trial of Tipifarnib was initiated in HRAS m+ SCCHN patients after announcement of preliminary results from its Ph II open-label trial where four out of six evaluable HRAS mutant HNSCC achieved a confirmed PR**

> ICYMI: Updated data at #ESMO18 (https://twitter.com/hashtag/ESMO18?src=hash&ref_src=twsrc%5Etfw) from Kura’s ongoing Phase 2 trial of tipifarnib in patients with hard-to-treat HRAS mutant cancers: HNSCC and SCC. Read the full summary: https://t.co/fxI1biMVdN (https://t.co/fxI1biMVdN) #PrecisionMedicine (https://twitter.com/hashtag/PrecisionMedicine?src=hash&ref_src=twsrc%5Etfw) @myESMO (https://twitter.com/myESMO?ref_src=twsrc%5Etfw) pic.twitter.com/9IDGbTBwfk (https://t.co/9IDGbTBwfk)
>
> — Kura Oncology (@kuraoncology) October 22, 2018 (https://twitter.com/kuraoncology/status/1054405008706306048?ref_src=twsrc%5Etfw)

10. **Ph II STARTRK-2, Ph I STARTRK-1 and Ph I ALKA-372-001 trials (http://hugin.info/174806/R/2221294/869467.pdf): Entrectinib shrank tumours in people with NTRK fusion-positive ten different solid tumours irrespective of tumour type or CNS spread. Entrectinib has been granted Breakthrough Therapy Designation (BTD) by FDA; PRIME designation by the EMA; and Sakigake designation by the Japanese health authorities for the treatment of NTRK fusion-positive tumors**

> $RHHBY (https://twitter.com/search?q=%24RHHBY&src=ctag&ref_src=twsrc%5Etfw) / IGNYTA – #JPM18 (https://twitter.com/hashtag/JPM18?src=hash&ref_src=twsrc%5Etfw)
> STARTRK-2, Ph2 study
> Entrectinib targeting ROS1 and TRK. For ROS1, 90% of pts had NSCLC.
> For TRK, just 16% had NSCLC. pic.twitter.com/hhByxSCLGN (https://t.co/hhByxSCLGN)
>
> — Bursatil Biotech (@BursatilBiotech) January 9, 2018 (https://twitter.com/BursatilBiotech/status/950785889633959942?ref_src=twsrc%5Etfw)

Novel Oncology Drug Approvals for 2018

(covering those not already mentioned above)

1. **Calaspargase pegol-mknl (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=761102%20) (12/20/2018): To treat acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years**

> #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) grants approval for a new enzyme product, calaspargase pegol-mknl, for use in ALL. https://t.co/LqYF6lh8G5 (https://t.co/LqYF6lh8G5) pic.twitter.com/6ijjA5bQR6 (https://t.co/6ijjA5bQR6)
>
> — Medscape Pharmacists (@MedscapePharm) December 27, 2018 (https://twitter.com/MedscapePharm/status/1078101661111988225?ref_src=twsrc%5Etfw)

2. **Gilteritinib (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm627072.htm) (11/28/2018): To treat patients who have relapsed or refractory acute myeloid leukemia (AML)**

> FDA grants approval to gilteritinib (Xospata®) for the treatment of relapsed or refractory acute myeloid leukemia with FLT3 mutation https://t.co/F4QsNwi4n9 (https://t.co/F4QsNwi4n9) #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) pic.twitter.com/SuW5rIxFiz (https://t.co/SuW5rIxFiz)
>
> — AML Global Portal (@AGP_hematology) December 7, 2018 (https://twitter.com/AGP_hematology/status/1071165964547440640?ref_src=twsrc%5Etfw)

3. **Lorlatinib (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=210868%20) (11/2/2018): To treat patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer**

> The FDA has granted accelerated approval to lorlatinib for the treatment of patients with NSCLC that is ALK mutation positive: https://t.co/SrlrvFo1EX (https://t.co/SrlrvFo1EX) pic.twitter.com/NDJSG8UYLs (https://t.co/NDJSG8UYLs)
>
> — Perspectives in Thoracic Oncology (@ThoracicOnc) December 19, 2018 (https://twitter.com/ThoracicOnc/status/1075423008767008768?ref_src=twsrc%5Etfw)

4. **Dacomitinib (httphttp://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=211288%20) (9/27/2018): To treat metastatic non-small-cell lung cancer**

> Latest @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) approval of dacomitinib, based on ARCHER 1050 trial, puts a new kinase inhibitor in the frontline for #lungcancer (https://twitter.com/hashtag/lungcancer?src=hash&ref_src=twsrc%5Etfw) patients with EGFR mutated disease.
>
> Read more >>> https://t.co/v3unG7v4xV (https://t.co/v3unG7v4xV) pic.twitter.com/EdhS91Jn9k (https://t.co/EdhS91Jn9k)
>
> — ecancer (@ecancer) September 28, 2018 (https://twitter.com/ecancer/status/1045732426415263744?ref_src=twsrc%5Etfw)

5. **Duvelisib (http://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&varApplNo=211155%20) (9/24/2018): To treat relapsed or refractory chronic lymphocytic leukemia, small lymphocytic lymphoma and follicular lymphoma**

> Time for my first tattoo? Today the FDA approved duvelisib (COPIKTRA)! Initially in our lab @UCSF (https://twitter.com/UCSF?ref_src=twsrc%5Etfw) ➡️ Intellikine ➡️ @INFIPharma (https://twitter.com/INFIPharma?ref_src=twsrc%5Etfw) ➡️ @VerastemOncolog (https://twitter.com/VerastemOncolog?ref_src=twsrc%5Etfw). PIK-294 was our lab's "lead" that started our journey. @HHMINEWS (https://twitter.com/HHMINEWS?ref_src=twsrc%5Etfw) @UCSFCancer (https://twitter.com/UCSFCancer?ref_src=twsrc%5Etfw) https://t.co/lKUAitd1nv (https://t.co/lKUAitd1nv) pic.twitter.com/h4ek50fHc9 (https://t.co/h4ek50fHc9)
>
> — Kevan Shokat (@kevansf) September 25, 2018 (https://twitter.com/kevansf/status/1044387426842533888?ref_src=twsrc%5Etfw)

6. **Moxetumomab pasudotox-tdfk (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620448.htm) (9/13/2018): To treat hairy cell leukemia**

> The @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) has approved moxetumomab pasudotox-tdfk, an antiCD22 recombinant #immunotoxin (https://twitter.com/hashtag/immunotoxin?src=hash&ref_src=twsrc%5Etfw), for treatment of hairy cell #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw). The drug delivers a toxin to the leukemic cell that triggers apoptotic cell death. https://t.co/K1GoZWA2Oy (https://t.co/K1GoZWA2Oy) pic.twitter.com/oTxDrLmjRf (https://t.co/oTxDrLmjRf)
>
> — JAMA (@JAMA_current) October 17, 2018 (https://twitter.com/JAMA_current/status/1052574961716609026?ref_src=twsrc%5Etfw)

7. **Mogamulizumab-kpkc (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm620448.htm) (8/8/2018): To treat two rare types of non-Hodgkin lymphoma**

> Last week, a new treatment option for two rare types of #lymphoma (https://twitter.com/hashtag/lymphoma?src=hash&ref_src=twsrc%5Etfw) was approved by the #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw). The medicine is called Poteligeo® (mogamulizumab-kpkc). If you have any questions, please contact us at hello@aposave.com.
>
> Read more about the new approval here: https://t.co/tlWxiWTpcj (https://t.co/tlWxiWTpcj) pic.twitter.com/ETRV2JrmOn (https://t.co/ETRV2JrmOn)
>
> — Aposave (@AposavePharmacy) August 17, 2018 (https://twitter.com/AposavePharmacy/status/1030424067533414400?ref_src=twsrc%5Etfw)

8. **Ivosidenib (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm614115.htm) (7/20/2018): To treat patients with relapsed or refractory acute myeloid leukemia**

> The FDA approves ivosidenib for relapsed or refractory acute myeloid leukaemia
> Read the full story here >> https://t.co/L6MTIva2qW (https://t.co/L6MTIva2qW)#leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) #leukaemia (https://twitter.com/hashtag/leukaemia?src=hash&ref_src=twsrc%5Etfw) #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/pdcg37RKx5 (https://t.co/pdcg37RKx5)
>
> — ecancer (@ecancer) July 23, 2018 (https://twitter.com/ecancer/status/1021319861937627136?ref_src=twsrc%5Etfw)

9. **Encorafenib (https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm611981.htm) (6/27/2018): To treat unresectable or metastatic melanoma**

> Combination therapy with encorafenib plus binimetinib significantly improved OS compared with vemurafenib or encorafenib alone for patients with advanced BRAF-mutated #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw), according to phase 3 results from the COLUMBUS trial presented at #ASCO18 (https://twitter.com/hashtag/ASCO18?src=hash&ref_src=twsrc%5Etfw) https://t.co/ER87bvfzj5 (https://t.co/ER87bvfzj5) pic.twitter.com/g3bFd4edrb (https://t.co/g3bFd4edrb)
>
> — AIM at Melanoma (@AIMatMelanoma) June 7, 2018 (https://twitter.com/AIMatMelanoma/status/1004758742980857856?ref_src=twsrc%5Etfw)

10. **Binimetinib (https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm611981.htm) (6/27/2018): To treat unresectable or metastatic melanoma**

11. **Apalutamide (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm596768.htm) (2/14/2018): To treat a certain type of prostate cancer using novel clinical trial endpoint**

> The @FDA (https://twitter.com/FdA?ref_src=twsrc%5Etfw) approved apalutamide for castration-resistant prostate cancer. Here's what you need to know, from our latest New Drug Review. https://t.co/ValgU1fBbO (https://t.co/ValgU1fBbO) pic.twitter.com/FoGQGSQxXp (https://t.co/FoGQGSQxXp)
>
> — Drug Topics (@Drug_Topics) April 8, 2018 (https://twitter.com/Drug_Topics/status/983024678137729024?ref_src=twsrc%5Etfw)

12. **Lutetium Lu 177 dotatate (https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm594043.htm) (1/26/2018): To treat a type of cancer that affects the pancreas or gastrointestinal tract called gastroenteropancreatic neuroendocrine tumors (GEP-NETs)**

> The U.S. Food and Drug Administration approved Lutathera (lutetium Lu 177 dotatate) for the treatment of a type of #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) that affects the #pancreas (https://twitter.com/hashtag/pancreas?src=hash&ref_src=twsrc%5Etfw) or gastrointestinal tract called gastroenteropancreatic neuroendocrine #tumors (https://twitter.com/hashtag/tumors?src=hash&ref_src=twsrc%5Etfw) (GEP-NETs).https://t.co/opWBZlorsz (https://t.co/opWBZlorsz) pic.twitter.com/nbbn2WRc7G (https://t.co/nbbn2WRc7G)
>
> — Massive Bio (@MassiveBio) March 10, 2018 (https://twitter.com/MassiveBio/status/972569331639910400?ref_src=twsrc%5Etfw)

Biosimilar News

1. **Ogivri (trastuzumab-dkst) (https://www.biocon.com/191218_Biocon_Company_Statement_SE.asp?rel=0), Trastuzumab biosimilar: Approved in EU for HER2+ breast or metastatic stomach cancer (gastric or GEJ adenocarcinoma) patients**

> The biosimilar, to be sold under the brand name Ogivri, brings Biocon a step closer to building a truly original bio-drug, or 'novel biologic' as it's called, for various markets.
> Read More: https://t.co/WR3Zr3tZGx (https://t.co/WR3Zr3tZGx) pic.twitter.com/NL1wrGLjIp (https://t.co/NL1wrGLjIp)
>
> — VeedaCRO (Official) (@veedacr) January 30, 2018 (https://twitter.com/veedacr/status/958228156338487296?ref_src=twsrc%5Etfw)

2. **Bevacizumab-biosimilar Zirabev (https://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_positive_chmp_opinion_for_oncology_biosimilar_zirabev_bevacizumab): Positive CHMP opinion for treatment of mCRC, metastatic breast cancer, unresectable advanced, mNSCLC, advanced and/or metastatic RCC and persistent, recurrent or metastatic carcinoma of the cervix**

> Pfizer receives positive CHMP opinion for bevacizumab biosimilar, Zirabev pic.twitter.com/Af206SdppQ (https://t.co/Af206SdppQ)
>
> — biosimilars (@biosims) December 20, 2018 (https://twitter.com/biosims/status/1075777995686563845?ref_src=twsrc%5Etfw)

3. **HERZUMA (trastuzumab-pkrb) (http://www.celltrion.com/en/pr/reportDetail.do?seq=534): FDA approval in HER2 overexpressing adjuvant and metastatic 1L/2L+ breast cancer patients**

> Celltrion's another biosimilar Herzuma, its version of Roche's breast cancer treatment Herceptin, is also awaiting FDA approval this month. Very soon. pic.twitter.com/HJQMjxKaQ1 (https://t.co/HJQMjxKaQ1)
>
> — betterthanK (@betterthank) December 1, 2018 (https://twitter.com/betterthank/status/1068699634065825793?ref_src=twsrc%5Etfw)

4. **HERZUMA (https://www.businesswire.com/news/home/20180213006724/en/Celltrion-Receives-EU-Approval-Trastuzumab-Biosimilar): Celltrion Receives EU Approval for Trastuzumab Biosimilar for early breast cancer, metastatic breast cancer, and metastatic gastric cancer**

Celltrion's Herzuma, a biosimilar of Herceptin, was recommended for approval by CHMP, EMA(European Medicines Agency) pic.twitter.com/BQodQSzy87 (https://t.co/BQodQSzy87)

— betterthanK (@betterthank) December 15, 2017 (https://twitter.com/betterthank/status/941647054270382081?ref_src=twsrc%5Etfw)

5. **Truxima (rituximab-abbs) (https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm627035.htm): FDA approval as the first biosimilar to Rituxan for CD20+ B-NHL patients as monotherapy or in combination with chemotherapy**

FDA approves Truxima (rituximab-abbs), the first #biosimilar (https://twitter.com/hashtag/biosimilar?src=hash&ref_src=twsrc%5Etfw) to Rituxan (rituximab) for the treatment of adult patients with CD20-positive, B-cell non-Hodgkin's #lymphoma (https://twitter.com/hashtag/lymphoma?src=hash&ref_src=twsrc%5Etfw) (NHL) https://t.co/GxzFfU3QoP (https://t.co/GxzFfU3QoP) #NonHodgkinsLymphoma (https://twitter.com/hashtag/NonHodgkinsLymphoma?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/2JBJeFosCA (https://t.co/2JBJeFosCA)

— The Medical Letter (@MedicalLetter) November 28, 2018 (https://twitter.com/MedicalLetter/status/1067856948983410689?ref_src=twsrc%5Etfw)

6. **Hyrimoz(TM) (adalimumab-adaz) (https://www.novartis.com/news/media-releases/sandoz-receives-us-fda-approval-biosimilar-hyrimoztm-adalimumab-adaz): Sandoz receives US FDA approval for biosimilar Hyrimoz(TM) (adalimumab-adaz) for all indications of reference medicine not protected by orphan exclusivity**

FDA Approves Sandoz's Hyrimoz, for treatment of #RA (https://twitter.com/hashtag/RA?src=hash&ref_src=twsrc%5Etfw), juvenile idiopathic arthritis #JIA (https://twitter.com/hashtag/JIA?src=hash&ref_src=twsrc%5Etfw), psoriatic arthritis #PsA (https://twitter.com/hashtag/PsA?src=hash&ref_src=twsrc%5Etfw), ankylosing spondylitis #AS (https://twitter.com/hashtag/AS?src=hash&ref_src=twsrc%5Etfw), adult Crohn's disease #CD (https://twitter.com/hashtag/CD?src=hash&ref_src=twsrc%5Etfw), ulcerative colitis #UC (https://twitter.com/hashtag/UC?src=hash&ref_src=twsrc%5Etfw) and plaque psoriasis #Ps (https://twitter.com/hashtag/Ps?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/4dtoeWbCXd (https://t.co/4dtoeWbCXd)

— Autoimmune List (@AutoimmuneList) November 10, 2018 (https://twitter.com/AutoimmuneList/status/1061302222456266753?ref_src=twsrc%5Etfw)

7. **MVASI (http://www.amgen.com/media/news-releases/2018/01/european-commission-approves-amgen-and-allergans-mvasi-biosimilar-bevacizumab-for-the-treatment-of-certain-types-of-cancer/): Post FDA approval and positive CHMP opinion, Bevacizumab biosimilar MVASI gets approved in 5 eligible indications**

FDA approves #Mvasi (https://twitter.com/hashtag/Mvasi?src=hash&ref_src=twsrc%5Etfw) (#bevacizumab (https://twitter.com/hashtag/bevacizumab?src=hash&ref_src=twsrc%5Etfw)-awwb) 1st #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #biosimilar (https://twitter.com/hashtag/biosimilar?src=hash&ref_src=twsrc%5Etfw) to $3B #Avastin (https://twitter.com/hashtag/Avastin?src=hash&ref_src=twsrc%5Etfw) @AmgenBiosim (https://twitter.com/AmgenBiosim?ref_src=twsrc%5Etfw) @biosimfacts (https://twitter.com/biosimfacts?ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) https://t.co/3UoheN6xLA (https://t.co/3UoheN6xLA) pic.twitter.com/g5BKCxiYeY (https://t.co/g5BKCxiYeY)

— Dr. Ryan L Cotten (@medicalmomentum) September 15, 2017 (https://twitter.com/medicalmomentum/status/908526777521266688?ref_src=twsrc%5Etfw)

8. **TRAZIMERA (https://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_european_approval_for_oncology_biosimilar_trazimera_trastuzumab): TRASTUZUMAB biosimilar receives EU approval in HER2 overexpressing breast cancer and metastatic gastric or gastroesophageal junction Adenocarcinoma**

European Commission approves @Pfizer (https://twitter.com/pfizer?ref_src=twsrc%5Etfw)'s #Herceptin (https://twitter.com/hashtag/Herceptin?src=hash&ref_src=twsrc%5Etfw) #biosimilar (https://twitter.com/hashtag/biosimilar?src=hash&ref_src=twsrc%5Etfw) in the #EU (https://twitter.com/hashtag/EU?src=hash&ref_src=twsrc%5Etfw) – https://t.co/s7z5tPML76 (https://t.co/s7z5tPML76) – #pharma (https://twitter.com/hashtag/pharma?src=hash&ref_src=twsrc%5Etfw) @EU_Commission (https://twitter.com/EU_Commission?ref_src=twsrc%5Etfw) #Trazimera (https://twitter.com/hashtag/Trazimera?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/oWG1doJTzn (https://t.co/oWG1doJTzn)

— pharmaphorum (@pharmaphorum) August 1, 2018 (https://twitter.com/pharmaphorum/status/1024716610387537926?ref_src=twsrc%5Etfw)

9. **ABP 980 (http://www.amgen.com/media/news-releases/2018/03/amgen-and-allergan-receive-positive-chmp-opinion-for-abp-980-biosimilar-herceptin-for-the-treatment-of-three-types-of-cancer/): ABP 980 (Biosimilar Herceptin®) receives positive CHMP opinion for the treatment of three types of cancer**

> Herceptin #biosimliar (https://twitter.com/hashtag/biosimliar?src=hash&ref_src=twsrc%5Etfw), ABP 980, receives positive #CHMP (https://twitter.com/hashtag/CHMP?src=hash&ref_src=twsrc%5Etfw) opinion https://t.co/fLt05PAwEH (https://t.co/fLt05PAwEH) @Amgen (https://twitter.com/Amgen?ref_src=twsrc%5Etfw) @Allergan (https://twitter.com/Allergan?ref_src=twsrc%5Etfw) @EPM_Magazine (https://twitter.com/EPM_Magazine?ref_src=twsrc%5Etfw) #ABP980 (https://twitter.com/hashtag/ABP980?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/VeO1vTSlMM (https://t.co/VeO1vTSlMM)
>
> — Euro Pharma Mag (@EPM_Magazine) April 1, 2018 (https://twitter.com/EPM_Magazine/status/980427097712807936?ref_src=twsrc%5Etfw)

10. **PF-05280586 (https://www.businesswire.com/news/home/20181202005033/en/Pfizer-Presents-Positive-26-Week-Data-PF-05280586-Potential): Ongoing REFLECTIONS B328-06 trial met its primary endpoint of comparable safety and efficacy for FL patients as per 26-week data**

> Efficacy, safety, immunogenicity, pharmacokinetics, and pharmacodynamics of PF-05280586 and reference rituximab were similar at week 26 in patients with follicular lymphoma, researchers will report at #ASH18 (https://twitter.com/hashtag/ASH18?src=hash&ref_src=twsrc%5Etfw). pic.twitter.com/s102hSkfh4 (https://t.co/s102hSkfh4)
>
> — CenterForBiosimilars (@BiosimCenter) December 1, 2018 (https://twitter.com/BiosimCenter/status/1068868622263730181?ref_src=twsrc%5Etfw)

Major Financial Deals

1. **Novartis (https://www.novartis.com/news/media-releases/novartis-successfully-completes-acquisition-endocyte) completes acquisition of Endocyte and adds 177Lu-PSMA-617, a potential first-in-class radioligand therapy in Phase III development for mCRPC to expand expertise in radiopharmaceuticals**

> Novartis to Buy Prostate Cancer Therapy Firm Endocyte for $2.1 Billion – Fortune https://t.co/V5pP9tskaZ (https://t.co/V5pP9tskaZ) pic.twitter.com/u0MXMejahv (https://t.co/u0MXMejahv)
>
> — Swallow This – The War On Cancer! (@miracle_cures) December 29, 2018 (https://twitter.com/miracle_cures/status/1079155372458266624?ref_src=twsrc%5Etfw)

2. **Cilag GmbH International (https://www.argenx.com/en-GB/news-internal/argenx-enters-exclusive-global-collaboration-and-license-agreement-with-cilag-gmbh-international-an-affiliate-of-janssen-for-cusatuzumab-argx-110/30209/), an affiliate of Janssen, gets license for anti-CD70 SIMPLE Antibody cusatuzumab (ARGX-110) Rights to PI3Ki ME-401 and EGFRi Lazertinib secured by MEI Pharma (https://xconomy.com/san-diego/2018/11/05/mei-pharma-inks-cancer-drug-deal-with-japans-kyowa-hakko-kirin/) and J&J (https://pharmaphorum.com/news/jj-buys-novel-lung-cancer-drug-from-south-koreas-yuhan/), respectively**

> Janssen Pharma's subsidiary Cilag GmbH International reached an agreement with Argenx obtained the authorization of its antibody drug cusatuzumab (ARGX-110). Cusatuzumab is a CD70 antibody for blood cancer, some solid tumors, and autoimmune diseases. https://t.co/xLKf7jbyjX (https://t.co/xLKf7jbyjX) pic.twitter.com/c7WKKKIflB (https://t.co/c7WKKKIflB)
>
> — Sinoway Industrial (@sinowaychem) December 14, 2018 (https://twitter.com/sinowaychem/status/1073555734992846848?ref_src=twsrc%5Etfw)

3. **AstraZeneca (https://www.astrazeneca.com/media-centre/press-releases/2018/astrazeneca-strengthens-and-expands-oncology-development-and-commercialisation-collaboration-with-innate-pharma23102018.html) strengthens and expands oncology development and commercialisation collaboration with Innate Pharma; obtains full rights to anti-NKG2A antibody monalizumab**

> With Money and Equity Changing Hands, Innate Pharma and AstraZeneca Move Deeper into an Immuno-oncology Pact https://t.co/9Z8Rz2qNY3 (https://t.co/9Z8Rz2qNY3) pic.twitter.com/uRa5fVQdMM (https://t.co/uRa5fVQdMM)
>
> — Carnivores VC (@CarnivoresVC) November 3, 2018 (https://twitter.com/CarnivoresVC/status/1058564430483636224?ref_src=twsrc%5Etfw)

4. **Geron (http://ir.geron.com/news-releases/news-release-details/geron-announces-discontinuation-imetelstat-collaboration-janssen) regains the global rights of first-in-class telomerase inhibitor Imetelstat; collaboration with Janssen discontinued**

> A Closer Look At The Geron Janssen Collaboration Agreement https://t.co/wffoNHfAwy (https://t.co/wffoNHfAwy) pic.twitter.com/CWIs7xIlpt (https://t.co/CWIs7xIlpt)
>
> — Dividend Digest (@DividendDigest) June 29, 2018 (https://twitter.com/DividendDigest/status/1012688850152448000?ref_src=twsrc%5Etfw)

5. **Sierra Oncology (http://investor.sierraoncology.com/2018-08-22-Sierra-Oncology-Acquires-Momelotinib-an-Investigational-Janus-Kinase-JAK-1-2-and-Activin-Receptor-Type-1-ACVR1-Inhibitor-for-Myelofibrosis-from-Gilead-Sciences) acquires Momelotinib, an investigational JAK1/2 and ACVR1 Inhibitor for Myelofibrosis, from Gilead Sciences**

> Sierra Oncology Acquires Gilead's Stalled Myelofibrosis Drug – Xconomy: Xconomy Sierra Oncology Acquires Gilead's Stalled Myelofibrosis Drug Xconomy Xconomy Seattle —. An experimental myelofibrosis drug that fell short of expectations for Gilead Sciences... https://t.co/88KKNN3XuC (https://t.co/88KKNN3XuC) pic.twitter.com/OqrpRgGPz7 (https://t.co/OqrpRgGPz7)
>
> — Oncology Board (@mb_Oncology) August 22, 2018 (https://twitter.com/mb_Oncology/status/1032401818507038720?ref_src=twsrc%5Etfw)

6. **Adlai Nortye (http://www.adlainortye.com/en_newsdetail.php?cid=69&id=90) Announce Global License Agreement for Buparlisib (BKM120) and acquires development and marketing rights of its PGE2 receptor antagonist E7046 from Eisai (http://www.eisai.com/news/enews201805pdf.pdf)**

> Adlai Nortye Enters into Global Licensing Agreement with Eisai for EP4 Antagonist. #healthnews (https://twitter.com/hashtag/healthnews?src=hash&ref_src=twsrc%5Etfw) #Medical (https://twitter.com/hashtag/Medical?src=hash&ref_src=twsrc%5Etfw) #biopharma (https://twitter.com/hashtag/biopharma?src=hash&ref_src=twsrc%5Etfw) #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/vzUFzxJFKb (https://t.co/vzUFzxJFKb) pic.twitter.com/MATpGQL4BT (https://t.co/MATpGQL4BT)
>
> — Drugdu.com (@Drugdu) January 22, 2018 (https://twitter.com/Drugdu/status/955375773233373184?ref_src=twsrc%5Etfw)

7. **GSK (http://ir.adaptimmune.com/phoenix.zhtml?c=253991&p=irol-newsArticle&ID=2359593) to develop and commercialize NY-ESO SPEAR T-cell therapy program**

> True and still $ADAP (https://twitter.com/search?q=%24ADAP&src=ctag&ref_src=twsrc%5Etfw) TCR T-cells don't have 2b shy 4 comparisons with CAR-T as the now sold to $GSK (https://twitter.com/search?q=%24GSK&src=ctag&ref_src=twsrc%5Etfw) NY-ESO SPEAR T-cells demonstrated in #MM (https://twitter.com/hashtag/MM?src=hash&ref_src=twsrc%5Etfw) as a blood cancer (now being tested in combination with $MRK (https://twitter.com/search?q=%24MRK&src=ctag&ref_src=twsrc%5Etfw) Keytruda) pic.twitter.com/1CBbidx4Ns (https://t.co/1CBbidx4Ns)
>
> — Dieter Hovekamp (@dhovekamp42) October 24, 2018 (https://twitter.com/dhovekamp42/status/1055189148703879168?ref_src=twsrc%5Etfw)

8. **MabVax Therapeutics (https://www.mabvax.com/news-media/press-releases/detail/132/mabvax-therapeutics-and-boehringer-ingelheim-sign-asset) licenses its antibody development program targeting multiple solid tumor cancers to Boehringer Ingelheim**

> MabVax Secures $11 Million from Boehringer Ingelheim for Antibody Development Program https://t.co/TQ695Pqox6 (https://t.co/TQ695Pqox6) pic.twitter.com/nF6tAR6JlD (https://t.co/nF6tAR6JlD)
>
> — Biotechnology (@Biotechnology) July 9, 2018 (https://twitter.com/Biotechnology/status/1016357809607196673?ref_src=twsrc%5Etfw)

9. **Celgene (https://www.celgene.com/newsroom/cellular-immunotherapies/celgene-corporation-to-acquire-juno-therapeutics-inc/) acquires Juno Oncology to add CAR-Ts and TCRs to its portfolio**

> Great graphic depicting #Celgene (https://twitter.com/hashtag/Celgene?src=hash&ref_src=twsrc%5Etfw)'s partnerships. $CELG (https://twitter.com/search?q=%24CELG&src=ctag&ref_src=twsrc%5Etfw) $BLUE (https://twitter.com/search?q=%24BLUE&src=ctag&ref_src=twsrc%5Etfw) $EPZM (https://twitter.com/search?q=%24EPZM&src=ctag&ref_src=twsrc%5Etfw) $AGIO (https://twitter.com/search?q=%24AGIO&src=ctag&ref_src=twsrc%5Etfw) $AZN (https://twitter.com/search?q=%24AZN&src=ctag&ref_src=twsrc%5Etfw) $JUNO (https://twitter.com/search?q=%24JUNO&src=ctag&ref_src=twsrc%5Etfw) $OMED (https://twitter.com/search?q=%24OMED&src=ctag&ref_src=twsrc%5Etfw) $RCPT (https://twitter.com/search?q=%24RCPT&src=ctag&ref_src=twsrc%5Etfw) #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/Ciuak8IHZn (http://t.co/Ciuak8IHZn)
>
> — Mad Sam (@samadacus) July 16, 2015 (https://twitter.com/samadacus/status/621762763279454210?ref_src=twsrc%5Etfw)

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. He is currently an Assistant Scientist at Emory University (Atlanta, GA) studying mechanisms of tumor recurrence in kids with brain tumors. As a postdoctoral fellow, he was the recipient of two Young Investigator Awards from Alex Lemonade Stand Foundation (Philadelphia, PA) and Rockland Immunochemicals. His current research has been funded by Northwestern Mutual Foundation (Milwaukee, WI), CURE Childhood Cancer Foundation (Atlanta, GA) and American Association for Cancer Research (AACR). When he is not on the bench you will find him spending time with his family or exploring the world through traveling and blogging.

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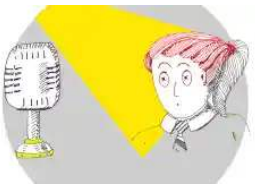

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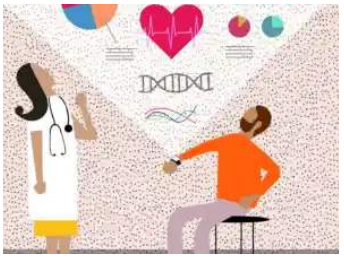

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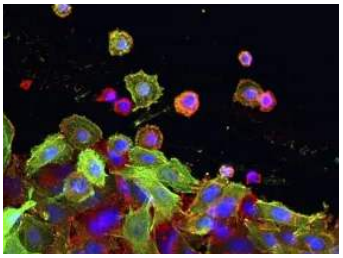

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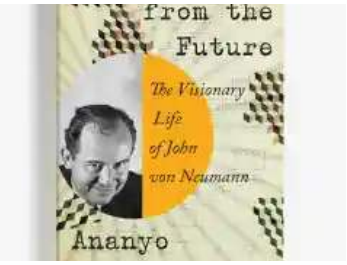

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