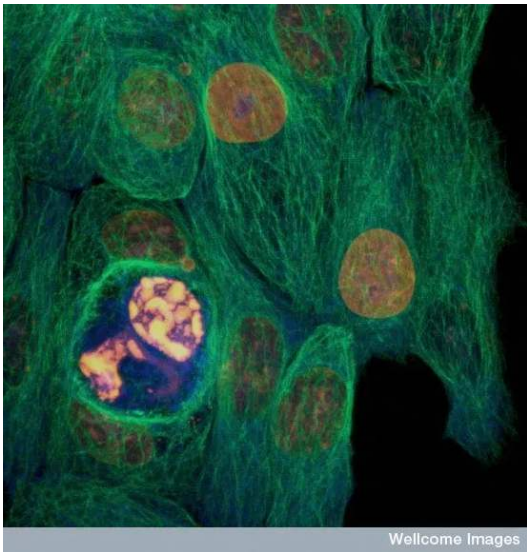
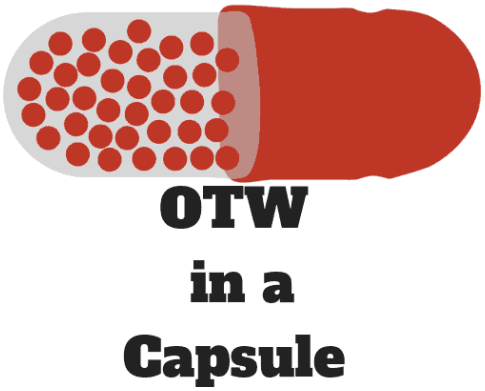
Onco-this-Week

December 22, 2018(https://sciwri.club/archives/date/2018/12/22)





OTW in a Capsule

HIGHLIGHTS

1. **Olaparib in Ovarian cancer:** This was an exceptional week for Olaparib as it covered not one but two major milestones in BRCA-mutated ovarian cancer treatment paradigm. It got FDA approval for frontline maintenance in BRCA mutation positive Ovarian Cancer based on Ph III SOLO-1 trial results; essentially featuring in maintenance settings after all lines of therapy. In addition to this, Olaparib met the primary endpoint of ORR improvement in relapsed BRCA-mutated advanced ovarian cancer patients in SOLO-3 trial – the first Ph III trial for a PARP inhibitor to demonstrate a positive result. These results reinforce the efficacy of Olaparib in ovarian cancer patients.
2. **Top-line interim safety data of Topsalysin in localized Prostate Cancer:** After Topalysin's safety and tolerability performance in Ph IIa proof of concept trial, Sophiris Bio was hoping for a better outcome after administration of second Topalysin's dose; however, doubling down on the treatment just didn't help the patients – the reduction in the tumor was clinically insignificant and sent the company's stocks plunging. Wisely enough, Sophiris plans to test single dose of the drug in Ph III trial.
3. **Revised Oncology Clinical Trial Endpoints guidance.** This week FDA released revised Oncology clinical trial endpoints guidelines by FDA – these guidelines replace the former version that came more than a decade before, May 2007 to be more precise. This latest guidelines explain the differential use of certain oncology endpoints in different contexts to provide a clearer view of factors considered important in determining suitable endpoints in different contexts. These guidelines also include emerging endpoints and intermediate/ surrogate endpoints in the context of accelerated approval.

(https://goo.gl/XM63s6)

DRUG APPROVALS

FDA approves Olaparib for 1L maintenance in Ovarian Cancer patients based on Ph III SOLO-1 trial results (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)

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit, AstraZeneca, said: "Women with ovarian cancer are often first diagnosed with advanced disease, which is associated with poor outcomes. In SOLO-1, Lynparza in the first-line maintenance setting reduced the risk of disease progression or death by 70 percent for patients with BRCAm advanced ovarian cancer. Today's approval is a critical advancement and brings us closer to our goal of helping these patients achieve long-term remission."

> FDA Approves Olaparib for Frontline Maintenance Treatment in Ovarian Cancer: Clinical trial #SOLO1 (https://twitter.com/hashtag/SOLO1?src=hash&ref_src=twsrc%5Etfw) shows frontline #olaparib (https://twitter.com/hashtag/olaparib?src=hash&ref_src=twsrc%5Etfw) (Lynparza) can reduce risk of disease progression or death up to 70% in women w #BRCA (https://twitter.com/hashtag/BRCA?src=hash&ref_src=twsrc%5Etfw) positive, advanced epithelial #ovariancancer (https://twitter.com/hashtag/ovariancancer?src=hash&ref_src=twsrc%5Etfw). https://t.co/B7K80q8GOo (https://t.co/B7K80q8GOo)
>
> — Ovarian Cancer Research Alliance (@ocrahope) December 20, 2018 (https://twitter.com/ocrahope/status/1075867743172378625?ref_src=twsrc%5Etfw)

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: "The expanded approval of Lynparza based upon the SOLO-1 trial has the potential to change medical practice and reinforces the importance of knowing a woman's BRCA status at diagnosis. We continue to work in collaboration with AstraZeneca on our overall goal of improving outcomes for patients."

Split dosing regimen for daratumumab approved in EU based on data from the Ph 1b EQUULEUS (MMY1001) trial (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-european-commission-approval-darzalexr)

"We are hopeful that the availability of this more flexible dosing option will make the first infusion of DARZALEX more convenient for European multiple myeloma patients," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

FDA approves tagraxofusp-erzs (SL-401; Elzonris) in adult and pediatric BPDCN (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/761116s000lbl.pdf)

> On December 21, 2018, the #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) approved #Elzonris (https://twitter.com/hashtag/Elzonris?src=hash&ref_src=twsrc%5Etfw) (#tagraxofusp (https://twitter.com/hashtag/tagraxofusp?src=hash&ref_src=twsrc%5Etfw)-erzs), a CD123-directed cytotoxin, for blastic plasmacytoid dendritic cell neoplasm (#BPDCN (https://twitter.com/hashtag/BPDCN?src=hash&ref_src=twsrc%5Etfw)) in adults and in pediatric patients 2 years and older. pic.twitter.com/H68MXyqvvL (https://t.co/H68MXyqvvL)
>
> — Bichoy Gabra, R.Ph., Ph.D. (@bichoy_g) December 22, 2018 (https://twitter.com/bichoy_g/status/1076564788975730691?ref_src=twsrc%5Etfw)

"Prior to today's approval, there had been no FDA approved therapies for BPDCN," said Richard Pazdur, MD, director of the FDA's Oncology Center of Excellence, acting director of the Office of Hematology and Oncology Products, in the FDA's Center for Drug Evaluation and Research. "The standard of care has been intensive chemotherapy followed by bone marrow transplantation. Many patients with BPDCN are unable to tolerate this intensive therapy, so there is an urgent need for alternative treatment options."

FDA approves longer-acting calaspargase pegol-mknl for pediatric and young adult ALL patients (https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm628980.htm?utm_campaign=Oncology%2012%2F20%2F2018%20calaspargase&utm_medium=email&utm_source=Eloqua&elqTrackId=1f5850fb41d347e1a512790728f24244&elq=b5c66

> On December 20, 2018, the #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) approved #Asparlas (https://twitter.com/hashtag/Asparlas?src=hash&ref_src=twsrc%5Etfw) (#calaspargase (https://twitter.com/hashtag/calaspargase?src=hash&ref_src=twsrc%5Etfw) pegol-mknl), a longer-acting asparagine specific enzyme, as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia (#ALL (https://twitter.com/hashtag/ALL?src=hash&ref_src=twsrc%5Etfw)) in pediatric and young adult patients (1 month to 21 years). pic.twitter.com/IJ6Lhjitnr (https://t.co/IJ6Lhjitnr)
>
> — Bichoy Gabra, R.Ph., Ph.D. (@bichoy_g) December 21, 2018 (https://twitter.com/bichoy_g/status/1076183002965856256?ref_src=twsrc%5Etfw)

FDA approved Servier Pharmaceuticals' asparagine specific enzyme, calaspargase pegol-mknl as a component of a combination chemotherapy regimen for pediatric and young adult ALL patients. This new product ensures a longer

interval between successive doses compared to other available pegaspargase assets.

FDA approves Pembrolizumab in 1L Merkel Cell Carcinoma based on Ph II KEYNOTE-017 trial results (https://www.mrknewsroom.com/news-release/oncology/fda-approves-mercks-keytruda-pembrolizumab-treatment-adult-and-pediatric-patie)

> FDA Approval: PD-L1 pembrolizumab for the treatment for Merkel cell #carcinoma (https://twitter.com/hashtag/carcinoma?src=hash&ref_src=twsrc%5Etfw). https://t.co/eVWqoyE8wO (https://t.co/eVWqoyE8wO) pic.twitter.com/5kMztxCrio (https://t.co/5kMztxCrio)
>
> — Medscape Oncology (@MedscapeOnc) December 22, 2018 (https://twitter.com/MedscapeOnc/status/1076586930047987713?ref_src=twsrc%5Etfw)

"The CITN-09/KEYNOTE-017 trial demonstrates that first-line treatment with anti-PD1 therapy provides a meaningful advance for Merkel cell carcinoma patients who have historically had a poor long-term prognosis," said Dr. Paul Nghiem, lead investigator, professor of dermatology at the University of Washington School of Medicine in Seattle and affiliate investigator at Fred Hutchinson Cancer Research Center. "A few years ago, patients with Merkel cell carcinoma did not have treatment options beyond chemotherapy. As a practicing physician I am pleased that this approval provides another option for patients facing this rare and challenging disease."

EMA approves Pembrolizumab in adjuvant melanoma based on data from Ph III EORTC1325/KEYNOTE-054 trial (https://www.mrknewsroom.com/news-release/research-and-development-news/european-commission-approves-mercks-keytruda-pembrolizuma)

> European Commission Approves Merck's KEYTRUDA® (pembrolizumab) as Adjuvant Therapy for Adults with Resected Stage III Melanoma – Business Wire https://t.co/WPw58sGMSY (https://t.co/WPw58sGMSY) • https://t.co/MmJAa7KXeT (https://t.co/MmJAa7KXeT)
>
> — MedFirst – MedComms (@MedFirstLtd) December 17, 2018 (https://twitter.com/MedFirstLtd/status/1074701015411130368?ref_src=twsrc%5Etfw)

"Merck's long-term commitment to melanoma patients includes a particular focus on bringing new treatment options to these patients earlier in the treatment paradigm," said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. "This approval, which is the first for KEYTRUDA in the adjuvant setting in the European Union, builds upon the foundation established by KEYTRUDA in the advanced and metastatic melanoma settings."

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

> Celltrion and Teva Announce FDA Approval of HERZUMA® (trastuzumab-pkrb), a Biosimilar to HERCEPTIN®, for the Treatment of HER2-Overexpressing Breast Cancer for Certain Indications https://t.co/Pk2lQbuhGs (https://t.co/Pk2lQbuhGs) #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) $TEVA (https://twitter.com/search?q=%24TEVA&src=ctag&ref_src=twsrc%5Etfw) pic.twitter.com/y94tlkhHDs (https://t.co/y94tlkhHDs)
>
> — Impactfolio (@zia_eu) December 21, 2018 (https://twitter.com/zia_eu/status/1076122646335684611?ref_src=twsrc%5Etfw)

"We are excited about building Teva's presence in biosimilars," said Brendan O'Grady, Executive Vice President and Head of North America Commercial at Teva. "The addition of HERZUMA to our biosimilars portfolio will allow us to leverage our strengths from Oncology and Generics."

REGULATORY NEWS

PDUFA extended by three months to Apr 2019 for Pemrolizumab's sBLA for KEYNOTE-042 trial (https://www.mrknewsroom.com/news-release/oncology/merck-provides-update-keytruda-pembrolizumab-supplemental-biologics-license-ap)

> Keytruda has gained priority review as monotherapy in #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw) based on data from the phase 3 KEYNOTE-042 trialhttps://t.co/4Luffkrl59 (https://t.co/4Luffkrl59) pic.twitter.com/kGj5emD5Ff (https://t.co/kGj5emD5Ff)
>
> — AJMC (@AJMC_Journal) September 26, 2018 (https://twitter.com/AJMC_Journal/status/1044759710275035136?ref_src=twsrc%5Etfw)

FDA extended PDUFA for Pembrolizumab's sBLA as monotherapy in 1L PD-L1+ve, EGFR/ALK WT NSCLC patients. The sBLA was based on data from Ph 3 KEYNOTE-042 trial where Pembrolizumab monotherapy demonstrated significant OS improvement compared with chemotherapy. The recently submitted additional results and analyses could be the reason behinf PDUFA's extension. The revised PDUFA is April 11, 2019.

FDA revises oncology clinical trial endpoints guidelines after more than a decade (https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm628853.htm?utm_campaign=121918_FIB_FDA+issues+guidance+on+endpoints+for+cancer+clinical+trials&utm_medium=email&utm_source=Eloqua)

> FDA Updates Guidance for Clinical Trial Design in Oncology (MedPage Today) — Expands available surrogate endpoints based on recent drug approvals https://t.co/uMJWrCcyIN (https://t.co/uMJWrCcyIN)
>
> — Healthy News Daily (@eHealthyDaily) December 20, 2018 (https://twitter.com/eHealthyDaily/status/1075662486584606723?ref_src=twsrc%5Etfw)

This week FDA released revised Oncology clinical trial endpoints guidelines by FDA – these guidelines replace the

former version that came more than a decade before, May 2007 to be more precise.

This latest guidelines explain the differential use of certain oncology endpoints in different contexts to provide a clearer view of factors considered important in determining suitable endpoints in different contexts. These guidelines also include emerging endpoints and intermediate/surrogate endpoints in the context of accelerated approval.

No BTD for Poziotinib in EGFR ex20+ mNSCLC patients based on Ph II ZENITH20 trial data (http://investor.sppirx.com/news-releases/news-release-details/spectrum-pharmaceuticals-provides-poziotinib-update)

> That's gotta hurt. #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) turns thumbs down on Spectrum's 'breakthrough' pitch for cancer drug poziotinib and shares tumble https://t.co/6IMSvS6t38 (https://t.co/6IMSvS6t38)
>
> — Endpoints News (@endpts) December 20, 2018 (https://twitter.com/endpts/status/1075863159162966016?ref_src=twsrc%5Etfw)

"Our enthusiasm for poziotinib, our commitment to the program, and our overall development plan remain unchanged," said Joe Turgeon, President and Chief Executive Officer of Spectrum Pharmaceuticals. "We will continue to work with the FDA to achieve the fastest route to approval of poziotinib based on our ZENITH20 study."

"Poziotinib's overall development program is robust, and the clinical profile remains very attractive in an area of high unmet need," said Francois Lebel, M.D., F.R.C.P.C, Chief Medical Officer of Spectrum Pharmaceuticals. "Data required for the NDA filing for previously treated NSCLC patients with EGFR exon 20 insertion mutations is expected to come from an 87-patient cohort in our ZENITH20 study. We expect to complete enrollment in this cohort in the first quarter of 2019, and announce topline data in the second half of 2019."

DMC completes planned safety and data review of Ph III OPTIMA trial of ThermoDox in HCC patients; study to continue (http://investor.celsion.com/news-releases/news-release-details/data-monitoring-committee-dmc-completes-planned-safety-and-o)

> Data Monitoring Committee (DMC) Completes Planned Safety and Data Review of Celsion's Phase III OPTIMA Study of ThermoDox® for Treatment of Primary Liver Cancer. $CLSN (https://twitter.com/search?q=%24CLSN&src=ctag&ref_src=twsrc%5Etfw) $ARQL (https://twitter.com/search?q=%24ARQL&src=ctag&ref_src=twsrc%5Etfw) $IMGN (https://twitter.com/search?q=%24IMGN&src=ctag&ref_src=twsrc%5Etfw) $EXEL (https://twitter.com/search?q=%24EXEL&src=ctag&ref_src=twsrc%5Etfw) $SPPI (https://twitter.com/search?q=%24SPPI&src=ctag&ref_src=twsrc%5Etfw) $ZIOP (https://twitter.com/search?q=%24ZIOP&src=ctag&ref_src=twsrc%5Etfw) $ECYT (https://twitter.com/search?q=%24ECYT&src=ctag&ref_src=twsrc%5Etfw) $XLV (https://twitter.com/search?q=%24XLV&src=ctag&ref_src=twsrc%5Etfw) https://t.co/RgT12ql32q (https://t.co/RgT12ql32q)
>
> — Blue Healthcare Now (@BlueBioNow) December 18, 2018 (https://twitter.com/BlueBioNow/status/1075106046559940609?ref_src=twsrc%5Etfw)

"This DMC review is the first since enrollment completion in the OPTIMA Study and focused on patient safety and demographics," said Nicholas Borys, M.D., Celsion's senior vice president and chief medical officer. "We are pleased to see that event data such as PFS and OS is tracking very closely to what we saw in the HEAT Study subgroup. Furthermore, the OPTIMA patient demographics and risk factors are consistent with what we saw in our HEAT Study subgroup and our data quality metrics are meeting expectations. The collection of all data endpoints is meeting expectations. Finally, we are grateful for the excellent work being done at the sites by our investigators and the oversight that the OPTIMA DMC is providing."

Positive CHMP opinion for Bevacizumab-biosimilar Zirabev (https://www.pfizer.com/news/press-release/press-release-detail/pfizer_receives_positive_chmp_opinion_for_oncology_biosimilar_zirabev_bevacizumab)

> Pfizer receives positive CHMP opinion for bevacizumab biosimilar, Zirabev https://t.co/EEISjNYOIA (https://t.co/EEISjNYOIA)
>
> — Biosimilar News (@biosimilar_news) December 19, 2018 (https://twitter.com/biosimilar_news/status/1075425475852451841?ref_src=twsrc%5Etfw)

"If approved, ZIRABEV has the potential to expand access to this life-changing biologic cancer therapy for appropriate patients and healthcare professionals across Europe," said Joe McClellan, Vice President, Biosimilars Development at Pfizer. "Today's positive CHMP opinion underscores Pfizer's strong heritage in oncology and its ongoing commitment to bringing high-quality biosimilars to market, providing additional options for people living with certain cancers."

Positive CHMP opinion for dasatinib in pediatric 1L Ph+ ALL patients (https://news.bms.com/press-release/corporatefinancial-news/bristol-myers-squibb-receives-positive-chmp-opinion-recommen-2)

> Bristol-Myers Squibb Receives Positive CHMP Opinion Recommending Sprycel (dasatinib) for Pediatric Patients with Newly Diagnosed Philadelphia Chromosome-Positive #AcuteLymphoblastic#Leukemia @bmsnews (https://twitter.com/bmsnews?ref_src=twsrc%5Etfw) @EMA_News (https://twitter.com/EMA_News?ref_src=twsrc%5Etfw) #ALL (https://twitter.com/hashtag/ALL?src=hash&ref_src=twsrc%5Etfw) https://t.co/gFLYxCTgok (https://t.co/gFLYxCTgok) pic.twitter.com/E5CTqb3mrv (https://t.co/E5CTqb3mrv)
>
> — Hematopoiesis News (@Hema_News) December 19, 2018 (https://twitter.com/Hema_News/status/1075523674772508672?ref_src=twsrc%5Etfw)

"We are pleased with today's CHMP recommendation for Sprycel in pediatric patients with Ph+ ALL, and look forward to the possibility of expanding Sprycel's pediatric indications in the EU to include young patients with this particularly high-risk leukemia," said Fouad Namouni, M.D., head, oncology development, Bristol-Myers Squibb.

SPECIAL STATUSES

FDA Fast Track Designation granted to personalized immunotherapy containing patient-specific neoantigens, GRANITE-001, for mCRC (https://ir.gritstoneoncology.com/news-releases/news-release-details/gritstone-oncology-announces-fda-fast-track-designation-granite)

> Gritstone Oncology Announces FDA Fast Track Designation for GRANITE001: Gritstone Oncology NasdaqGRTS a clinicalstage biotechnology company developing the next generation of cancer... https://t.co/JHYZUepiNu (https://t.co/JHYZUepiNu) #cancertreatment (https://twitter.com/hashtag/cancertreatment?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) #prostatecancer (https://twitter.com/hashtag/prostatecancer?src=hash&ref_src=twsrc%5Etfw) #braincancer (https://twitter.com/hashtag/braincancer?src=hash&ref_src=twsrc%5Etfw)
>
> — Cancer News (@Cancer_bio) December 21, 2018 (https://twitter.com/Cancer_bio/status/1076186062207107072?ref_src=twsrc%5Etfw)

"Colorectal cancer remains a major contributor to cancer deaths and has not yet proved very amenable to first generation immunotherapy," said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. "We believe GRANITE-001 has the potential to be a valuable therapeutic option for these patients through its highly personalized design. The ability to leverage tumor markers, or neoantigens, specific to a patient's own tumor cells in the development of a personalized immunotherapy is regarded as the next frontier of cancer therapy. We look forward to continuing our productive dialogue with the FDA under their Fast Track program as we seek to advance GRANITE-001 expeditiously for the potential benefit of patients."

Orphan Drug Designation granted to MB-102 (CD123 CAR T) in BPDCN patients (http://ir.mustangbio.com/file/Index?KeyFile=396171382)

> Mustang Bio $MBIO (https://twitter.com/search?q=%24MBIO&src=ctag&ref_src=twsrc%5Etfw) Receives Orphan Drug Designation for MB-102 (CD123 CAR T) for the Treatment of Blastic Plasmacytoid Dendritic Cell Neoplasmhttps://t.co/wIsIAJECSW (https://t.co/wIsIAJECSW)
>
> — LifeSci Advisors (@LifeSciAdvisors) December 20, 2018 (https://twitter.com/LifeSciAdvisors/status/1075797569194864643?ref_src=twsrc%5Etfw)

Martina Sersch, M.D., Ph.D., Chief Medical Officer of Mustang, said, "We are pleased to receive Orphan Drug Designation for MB-102, which has shown the potential to address an area of high unmet medical need. This significant milestone for Mustang will provide additional market exclusivity and financial benefits to advance MB-102, which we believe is an important new treatment for patients with BPDCN. Based on the Phase 1 data presented at the American Society of Hematology (ASH) Annual Meeting in December 2017 and the American Association for Cancer Research (AACR) Special Conference on Tumor Immunology and Immunotherapy in November 2018, we expect to initiate a multicenter Phase 1/2 clinical trial in patients with acute myeloid leukemia (AML), BPDCN and high-risk myelodysplastic syndrome in 2019."

EMA Orphan Drug Designation granted to anti-TGFbeta x anti-PD-L1 bifunctional immunotherapy M7824 in Biliary Tract Cancer (https://www.merckgroup.com/content/dam/web/corporate/non-images/press-releases/2018/dec/en/M7824-ODD-EMA-Press-Release-EN.pdf?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)

> Merck Announces EMA Orphan Drug Designation for Bifunctional Immunotherapy M7824 in Biliary Tract Cancer https://t.co/zZm1SaHit6 (https://t.co/zZm1SaHit6) pic.twitter.com/Bi2pSQ3Qg9 (https://t.co/Bi2pSQ3Qg9)
>
> — brandaktuell.at (@brandaktuellat) December 20, 2018 (https://twitter.com/brandaktuellat/status/1075769304937750528?ref_src=twsrc%5Etfw)

"EMA orphan drug designation is another recognition of Merck's determination to bring innovative therapies to people suffering from challenging cancers like biliary tract cancer," said Luciano Rossetti, Head of Global Research & Development at the Biopharma Business of Merck. "This is the second orphan drug designation for M7824 in a matter of weeks and Merck is eager to further explore the potential of this new class of immunotherapy to advance outcomes in a number of difficult-to-treat tumors."

TRIAL RESULTS

Failed trial: JAVELIN Ovarian 100 trial of Avelumab didn't support initial hypothesis of PFS improvement in interim analysis, to be terminated (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)

> Merck KGaA & Pfizer Decide To Discontinue JAVELIN Ovarian 100 Study Of Avelumab: NEW YORK CITY dpaAFX Merck KGaA and Pfizer Inc. PFE on Friday announced that data from a planned interim analysis of the Phase III JAVELIN Ovarian 100 study of avelumab did... https://t.co/YjQNgQUPrR (https://t.co/YjQNgQUPrR) pic.twitter.com/AXfnNwkSDT (https://t.co/AXfnNwkSDT)
>
> — Clinical Trials News (@ClinicalPhase) December 22, 2018 (https://twitter.com/ClinicalPhase/status/1076604809497608193?ref_src=twsrc%5Etfw)

Pfizer and Merck announced that results from planned interim analysis of Avelumab's Ph III JAVELIN Ovarian 100 study did not support the trial's initial hypothesis of PFS improvement in previously untreated ovarian cancer patients. The trial is now slated to be terminated as per independent Data Monitoring Committee's recommendation.

Use of Time to Biochemical Failure as a surrogate endpoint in treatment of locally advanced Prostate Cancer (https://www.nrgoncology.org/News/Research-Results/Time-to-Biochemical-Failure-Could-be-Used-as-a-Surrogate-Endpoint-in-Treatment-of-Locally-Advanced-Prostate-Cancer)

> An analysis of NRG-RTOG 9202 showed that the interval of time to biochemical failure could be used as a surrogate endpoint for locally advanced prostate cancer. Press release: https://t.co/CPtyjX1WxI (https://t.co/CPtyjX1WxI) #prostatecancer (https://twitter.com/hashtag/prostatecancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/WVEqBI3ZKB (https://t.co/WVEqBI3ZKB)
>
> — NRG Oncology (@NRGonc) December 20, 2018 (https://twitter.com/NRGonc/status/1075768008692232193?ref_src=twsrc%5Etfw)

"The main goal of this trial study was to determine if time interval free of biochemical failure could stand as a surrogate endpoint for the effect of long-term androgen deprivation on two clinical endpoints: prostate cancer-specific survival and overall survival," stated James Dignam, PhD, of the Department of Public Health Sciences at University of Chicago and the NRG Oncology Statistics and Data Management Center, a member of the Cancer Prevention and Control research program at the University of Chicago Medicine Comprehensive Cancer Center, and the lead author of the NRG-RTOG 9202 analysis.

"Men who remained free of biochemical failure for three years had significantly more favorable overall survival and prostate cancer-specific survival," added Dr. Dignam. "Additionally, data showed that 50% of the men who experienced biochemical failure by three years died of prostate cancer as of 15 years, as opposed to 19% among the men who were still free of biochemical failure at three years."

Failed trial: Ph II TRAXAR trial of engolglin-targeting antibody Carotuximab (TRC105) + axitinib fails to meet primary endpoint of PFS improvement in mRCC patients (https://traconpharma.gcs-web.com/news-releases/news-release-details/tracon-pharmaceuticals-announces-top-line-data-phase-2-traxar)

> TRACON Pharmaceuticals shares are trading lower after the company announced its Phase 2 TRAXAR trial did not meet its primary endpoint.
>
> — Hot Stocks NYC (@HotStocks_NYC) December 21, 2018 (https://twitter.com/HotStocks_NYC/status/1076132663885553664?ref_src=twsrc%5Etfw)

"We are disappointed that TRC105 in combination with Inlyta did not demonstrate clinically meaningful efficacy in patients with advanced or metastatic renal cell carcinoma. Importantly, data from TRAXAR, including analyses of an extensive biomarker panel, will contribute to our understanding of the role of endoglin inhibition in combination with VEGF inhibitors, and may inform our broad TRC105 clinical development program," said Charles Theuer, M.D., Ph.D., President and CEO of TRACON. "We remain focused on the interim analysis to determine the final sample size of the Phase 3 TAPPAS trial of TRC105 and Votrient in angiosarcoma, which is expected in the first quarter of 2019."

Positive topline results from randomized Ph II trial of Trilaciclib show multi-lineage myelopreservation benefits in 2L/3L SCLC patients (https://g1therapeutics.gcs-web.com/news-releases/news-release-details/g1-therapeutics-announces-positive-topline-results-randomized?field_nir_news_date_value%5bmin%5d=2018)

> G1 Therapeutics Announces Positive Topline Results from Randomized Phase 2 Trial of Trilaciclib: G1 Therapeutics NasdaqGTHX a clinicalstage oncology company today announced positive topline... https://t.co/UX77VrXZYm (https://t.co/UX77VrXZYm) #cancertreatment (https://twitter.com/hashtag/cancertreatment?src=hash&ref_src=twsrc%5Etfw) #prostatecancer (https://twitter.com/hashtag/prostatecancer?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) #research (https://twitter.com/hashtag/research?src=hash&ref_src=twsrc%5Etfw)
>
> — Cancer News (@Cancer_bio) December 20, 2018 (https://twitter.com/Cancer_bio/status/1075812849631387648?ref_src=twsrc%5Etfw)

"This is the third positive Phase 2 trial of trilaciclib in small cell lung cancer showing significant reductions in the duration and occurrence of Grade 4 neutropenia, and lower rates of G-CSF administrations and red blood cell transfusions. Small cell lung cancer is difficult to treat, particularly in later lines of therapy, and trilaciclib has shown potential to improve outcomes for these patients," said Raj Malik, M.D., Chief Medical Officer and Senior Vice President, R&D. "We now have four randomized Phase 2 trials showing trilaciclib's multi-lineage myelopreservation benefits. We plan to meet with U.S. and European regulatory authorities in 2019 to discuss the totality of trilaciclib data and pathways to approval."

Ph III ARCHES trial of enzalutamide met primary endpoint of rPFS improvement in mCSPC patient (https://www.astellas.com/us/news/3951)

> Astellas and Pfizer Announce Positive Top-Line Results from Phase 3 ARCHES Trial of XTANDI® (enzalutamide) in Men with Metastatic Hormone-Sensitive Prostate Cancer https://t.co/cO291id1hC (https://t.co/cO291id1hC) pic.twitter.com/pVCZJ2d6Bq (https://t.co/pVCZJ2d6Bq)
>
> — Latest News from Business Wire (@NewsFromBW) December 20, 2018 (https://twitter.com/NewsFromBW/status/1075754478056353792?ref_src=twsrc%5Etfw)

"The results from ARCHES demonstrate a statistically significant improvement in a key marker of disease progression – radiographic progression-free survival," said Steven Benner, M.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development, Astellas. "Based on the top-line results of ARCHES, we look forward to discussing the data with relevant health authorities to potentially support expanding the indication for XTANDI."

Ph III SOLO-3 trial meets primary endpoint of ORR improvement in relapsed BRCA-mutated advanced ovarian cancer patients (https://www.astrazeneca.com/media-centre/press-releases/2018/lynparza-meets-primary-endpoint-in-phase-iii-solo-3-trial-for-the-treatment-of-relapsed-brca-mutated-advanced-ovarian-cancer20122018.html)

Sean Bohen, Executive Vice President, Global Medicines Development and Chief Medical Officer, said: "We are very excited about SOLO-3, which is the first Phase III trial for a PARP inhibitor to demonstrate a positive result versus chemotherapy in advanced ovarian cancer where effective options are needed. We look forward to sharing the full results at a forthcoming medical meeting."

Sophiris Bio reports top-line interim safety data for its Ph IIb trial of Topsalysin in localized Prostate Cancer (http://investor.sophirisbio.com/news-releases/news-release-details/sophiris-bio-reports-top-line-interim-safety-and-biopsy-findings)

> $A1W39X #Sophiris (https://twitter.com/hashtag/Sophiris?src=hash&ref_src=twsrc%5Etfw) Bio SPHS: Ready to Move Topsalysin into Phase 3 for Localized Clinically Significant Prostate Cancer...: | https://t.co/3yiuaMs4uD (https://t.co/3yiuaMs4uD) pic.twitter.com/eKUKEym7un (https://t.co/eKUKEym7un)
>
> — ResearchPool (@ResearchPool) December 21, 2018 (https://twitter.com/ResearchPool/status/1075928152742842368?ref_src=twsrc%5Etfw)

"We are very encouraged by the safety and biopsy results from a single administration of topsalysin in the Phase 2b study. Biopsy results improved from what we saw in the Phase 2a proof of concept trial and safety and tolerability remains in-line with what we have seen historically," stated Mr. Woods. "We believe that the safety and biopsy data from the first administration of topsalysin supports moving forward into potential registration studies. We will continue to evaluate whether future clinical development will include an option to administer a second dose as we receive more information about the patient death and additional information from the 10 patients who received a second dose. We will be able to evaluate this towards the end of this year."

Exploratory subgroup analyses of the MONARCH 2 and MONARCH 3 trials in HER2neg HR+ breast cancer patients reinforce clinical benefit of Abemaciclib + endocrine therapy (https://investor.lilly.com/news-releases/news-release-details/lilly-announces-publication-analyses-showing-benefit-addition)

> Lilly announces publication of analyses showing benefit of the addition of Verzenio® (abemaciclib) in multiple subgroups of patients with advanced breast cancer identified as having a more concerning prognosis – PRNewswire https://t.co/CYMEUHwxDo (https://t.co/CYMEUHwxDo)
>
> — Follement-bijoux (@Follementbijoux) December 18, 2018 (https://twitter.com/Follementbijoux/status/1075075777400586241?ref_src=twsrc%5Etfw)

"Not all patients with HR+, HER2- metastatic breast cancer are the same. Each patient presents with unique patterns of clinical factors – with some patients having particularly concerning clinical characteristics that can signal a poor prognosis to oncologists. Therefore, treatment decisions must be tailored to each patient's individual presentation," said Joyce O'Shaughnessy, M.D., Celebrating Women Chair in Breast Cancer Research and chair, Breast Cancer Research Program, Baylor University Medical Center, Texas Oncology and U.S. Oncology, Dallas, TX. "Understanding the prognostic value of certain clinical factors and how patients with or without these factors may respond to the addition of Verzenio can help us as we seek to individualize treatment decisions."

Top line results from Ph III NALA trial of Neratinib in 3L HER2+ metastatic breast cancer patients, significant PFS improvement but OS improvement insignificant (http://www.pumabiotechnology.com/pr20181217.html)

> Puma Biotechnology Reports Results of Neratinib (PB272) in P-III NALA Trial for 3L HER2-Positive Metastatic Breast Cancer https://t.co/KKTvnp68jJ (https://t.co/KKTvnp68jJ) pic.twitter.com/LR02TGd40T (https://t.co/LR02TGd40T)
>
> — PharmaShots (@Pharmashot) December 19, 2018 (https://twitter.com/Pharmashot/status/1075372903594684416?ref_src=twsrc%5Etfw)

Alan H. Auerbach, Chief Executive Officer and President of Puma Biotechnology, said, "We are highly encouraged by these results from the NALA trial with the combination of neratinib plus capecitabine in patients with HER2-positive metastatic breast cancer who have failed two or more prior lines of HER2-directed treatments. We look forward to working with the regulatory authorities in the hope of bringing another potential treatment option to patients with HER2-positive metastatic breast cancer as soon as possible."

TRIAL STATUSES

Ph I/II trial of BTK inhibitor LOXO-305 initiated in BTKi-refractory CLL, SLL, or NHL patients (https://ir.loxooncology.com/press-releases/2381458-Loxo-oncology-announces-initiation-of-phase-12-clinical-trial-for-highly-selective-non-covalent-btk-inhibitor-loxo-305)

> Loxo Oncology Announces Initiation of Phase 12 Clinical Trial for Highly Selective NonCovalent BTK Inhibitor LOXO305: STAMFORD Conn. Dec. 21 2018 GLOBE NEWSWIRE Loxo Oncology Inc.ÂNasdaqLOXO a biopharmaceutical company focused on the development and... https://t.co/87CGr4JwjC (https://t.co/87CGr4JwjC)
>
> — Drug Discovery News (@DiscoveryDrug) December 21, 2018 (https://twitter.com/DiscoveryDrug/status/1076084624965521408?ref_src=twsrc%5Etfw)

"We are pleased to initiate the clinical trial for our fourth novel drug candidate," said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. "FDA-approved BTK inhibitors, which all covalently (irreversibly) bind to their targets, have meaningfully improved the lives of patients with certain B-cell leukemias and lymphomas. However, we are now learning that many patients are discontinuing these therapies due to disease progression or intolerance. When disease progression is caused by a resistance mechanism known as a C481 mutation, we believe that LOXO-305 has the potential to re-induce a response in affected patients. We also believe that the selectivity profile of LOXO-305 has the potential to avoid certain side effects. We look forward to working with our clinical investigators to determine whether LOXO-305 can deliver against these exciting possibilities."

Pivotal Ph III INTRIGUE trial of KIT/PDGFRα dual kinase inhibitor Ripretinib (DCC-2618) started in 2L GIST patients (https://investors.deciphera.com/news-releases/news-release-details/deciphera-pharmaceuticals-initiates-pivotal-phase-3-clinical)

"We are extremely pleased that the INTRIGUE Phase 3 study of ripretinib is now open to enroll second-line GIST patients, regardless of their mutational status, who have progressed on, or are intolerant to front-line therapy with imatinib," said Michael D. Taylor, Ph.D., President and Chief Executive Officer of Deciphera. "If successful, we believe this Phase 3 study could serve as the basis for a regulatory submission for broad use in all second-line GIST patients."

> We are pleased that the INTRIGUE Phase 3 study of ripretinib (DCC-2618) is open to enroll 2nd-line GIST patients, regardless of their mutational status, who have progressed on, or are intolerant to front-line therapy with imatinib.https://t.co/OMc2UrqLXY (https://t.co/OMc2UrqLXY) pic.twitter.com/OYm4CudRsp (https://t.co/OYm4CudRsp)
>
> — Deciphera Pharma (@Deciphera) December 20, 2018 (https://twitter.com/Deciphera/status/1075725571202650112?ref_src=twsrc%5Etfw)

"INTRIGUE is the second pivotal Phase 3 study of ripretinib that Deciphera has initiated in less than one year. As recently announced, we expect to report top-line data from our first Phase 3 clinical study, INVICTUS, in fourth-line and fourth-line-plus GIST patients in mid-2019," continued Dr. Taylor.

"While imatinib is an effective treatment for most patients with early-stage GIST, in almost all patients the disease will eventually progress due to the development of secondary drug resistance mutations," said Professor Michael Heinrich, MD, Cell and Developmental Biology, OHSU Knight Cancer Institute. "A well-tolerated therapy with broad coverage and efficacy across the spectrum of KIT and PDGFRα mutations would represent a much-needed improvement over currently approved therapies for patients with GIST."

Ph Ib/II trials of EP4R antagonist ARY-007 + Pembrolizumab started in checkpoint-refractory and -resistant solid tumors (https://kyntherapeutics.com/press-releases/kyn-therapeutics-announces-initiation-of-phase-1b-2-clinical-studies-of-ary-007-in-collaboration-with-merck/)

> Kyn Therapeutics Announces Initiation of Phase 1b/2 Clinical Studies of EP4 receptor antagonist Grapiprant, (ARY-007) in Collaboration with Merck https://t.co/fAp6j20Tq1 (https://t.co/fAp6j20Tq1) pic.twitter.com/FRtMmnwzJp (https://t.co/FRtMmnwzJp)
>
> — Krishan Maggon (@kkmaggon) December 21, 2018 (https://twitter.com/kkmaggon/status/1076022021165862912?ref_src=twsrc%5Etfw)

"The Kyn team believes immunometabolism pathways hold great promise as therapeutics that could deliver breakthrough improvements for patients non-responsive to immunotherapy regimens. We believe EP4 is the right target and ARY-007 is the right molecule for overcoming the immunosuppressive effects of PGE2 in these cancers where increased pathway expression is associated with poor outcome," said Mark Manfredi, Ph.D., president and chief executive officer of Kyn Therapeutics. "We welcome the opportunity to collaborate with Merck as we initiate clinical studies."

Ph I trial initiated to evaluate the combination of FLT3i Quizartinib + MDM2i milademetan (DS-3032), R/R FLT3-ITD AML or 1L unfit FLT3-ITD AML patients (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006949.html)

> Daiichi Sankyo begins phase 1 study of quizartinib & milademetan combo in patients with relapsedrefractory FLT3ITD AML: Daiichi Sankyo announced that the first patient has been dosed in the first novelnovel combination study evaluating two... https://t.co/Pe2b4T46nH (https://t.co/Pe2b4T46nH) pic.twitter.com/lmEWa98mxA (https://t.co/lmEWa98mxA)
>
> — Clinical Trials News (@ClinicalPhase) December 21, 2018 (https://twitter.com/ClinicalPhase/status/1076079106532376576?ref_src=twsrc%5Etfw)

"We have initiated this combination study of quizartinib and milademetan in order to determine the safety and tolerability of the combination and if the addition of the MDM2 inhibitor milademetan may potentially further improve the outcomes of patients with relapsed/refractory FLT3-ITD AML beyond what has been previously reported with single agent quizartinib," said Arnaud Lesegretain, Vice President, Oncology R&D and Head, AML Franchise, Daiichi Sankyo. "In this study, we also are exploring the potential of the combination of quizartinib and milademetan in patients with newly-diagnosed FLT3-ITD AML who are unfit for intensive chemotherapy. This study is the first of several planned studies that will evaluate the potential of novel combinations within our investigational AML Franchise, as we are committed to continuously improving the standard of care for patients with AML."

First patient enrolled in pivotal Ph III AGENT trial of arfolitixorin in 1L mCRC patients (https://markets.businessinsider.com/news/stocks/first-patient-enrolled-in-isofol-s-pivotal-phase-3-agent-study-in-1st-line-metastatic-colorectal-cancer-1027817637)

> The first patient has been enrolled in the pivotal phase III AGENT trial investigating arfolitixorin with 5-FU, oxaliplatin, and bevacizumab in patients with metastatic colorectal cancer: https://t.co/H2idVTJyRn (https://t.co/H2idVTJyRn) #crcsm (https://twitter.com/hashtag/crcsm?src=hash&ref_src=twsrc%5Etfw) #coloncancer (https://twitter.com/hashtag/coloncancer?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/zi5WviSKcO (https://t.co/zi5WviSKcO)
>
> — Targeted Oncology (@TargetedOnc) December 21, 2018 (https://twitter.com/TargetedOnc/status/1076160802841939968?ref_src=twsrc%5Etfw)

Karin Ganlöv, MD, Chief Medical Officer, Isofol, commented: "We are now looking forward to quickly ramp up enrolment to meet the interest from participating hospitals and physicians. Arfolitixorin, which has shown promising efficacy and good safety, is an important new treatment option for patients since few new therapeutic agents have been introduced in 1st line treatment of mCRC the last decade."

First patient enrolled in Ph III trial of photoimmunotherapy ASP-1929 in recurrent SCCHN patients (https://www.prnewswire.com/news-releases/rakuten-aspyrian-enrolling-phase-3-trial-of-asp-1929-for-head-and-neck-cancer-300767664.html?tc=eml_cleartime)

> Rakuten Aspyrian Enrolling Phase 3 Trial of ASP-1929 for Head and Neck Cancer https://t.co/SxDhHODDR6 (https://t.co/SxDhHODDR6)
>
> — maja_t24680 (@MT24680) December 19, 2018 (https://twitter.com/MT24680/status/1075326305736904704?ref_src=twsrc%5Etfw)

"We look forward to rigorously evaluating ASP-1929 in this pivotal trial to determine if our Photoimmunotherapy results in improved survival and quality of life for patients with few treatment options," said Mickey Mikitani, chief executive officer of Rakuten Aspyrian. "We believe that treatment with ASP-1929 and Photoimmunotherapy can lead to the selective destruction of head and neck cancer cells and provide an effective therapy to manage the disease."

First patient dosed in pivotal Ph II trial of gene therapy inodiftagene vixteplasmid (BC-819) in NMIBC patients (https://www.anchiano.com/anchiano-announces-initiation-of-its-codex-study-of-inodiftagene-vixteplasmid-in-patients-with-nmibc/)

> Anchiano Therapeutics Announces Initiation of Its Pivotal Codex Study of Inodiftagene Vixteplasmid in Patients with NonMuscleInvasive Bladder Cancer: CAMBRIDGE Mass. Dec. 18 2018 GLOBE NEWSWIRE Anchiano Therapeutics TASE ANCN a clinicalstage... https://t.co/GsbuVon8Ky (https://t.co/GsbuVon8Ky)
>
> — Urology News (@Urology_Bio) December 18, 2018 (https://twitter.com/Urology_Bio/status/1075027868915195904?ref_src=twsrc%5Etfw)

"The initiation of the Codex registration trial is a significant milestone for the company," noted Dr. David Kerstein, Chief Medical Officer of Anchiano Therapeutics. "BCG-unresponsive NMIBC represents an area of high unmet medical need with limited standard treatment options, outside of surgical removal of the bladder. NMIBC is a cancer that has been lacking in new therapies for two decades, and we are excited to embark on this important next step in the development of inodiftagene vixteplasmid."

Top-line results presented from Ph IIb trial of transmembrane pore-forming protein Topsalysin in localized prostate cancer (https://investor.sophirisbio.com/news-releases/news-release-details/sophiris-bio-provides-updates-phase-2b-localized-prostate-cancer)

> Topsalysin (PRX302) is being developed as a treatment for localized (stage I or II) prostate cancer that is only activated in the presence of prostate specific antigen (PSA), associated with prostate cancer... https://t.co/8m2unoKy1R (https://t.co/8m2unoKy1R)
>
> — Surviving PCa (@SurvivingPCa) December 20, 2018 (https://twitter.com/SurvivingPCa/status/1075781613299085312?ref_src=twsrc%5Etfw)

"We remain encouraged by both the safety and biopsy data from the first administration of topsalysin and are working with Sophiris to design a protocol for a potential Phase 3 registration study using a single administration of topsalysin," stated Professor Mark Emberton, principal investigator in the Phase 2b trial and Dean of the University College London Faculty of Medical Sciences. "These data show that 27% of the patients who receive a single administration of topsalysin may avoid or delay the need for alternative treatment for their localized prostate cancer. Taking into account the observed efficacy and safety profile to date following a single administration, we believe urologists would welcome a treatment like topsalysin for men with clinically-significant localized prostate cancer."

LICENSING DEALS

Merck assigns CAR-T development rights to Intrexon (https://www.merckgroup.com/en/news/intrexon-20-12-2018.html?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)

"Merck is excited to maintain its interest in the potential of CAR-T technology, which may offer significant future benefits to patients fighting cancer," said Belén Garijo, Member of the Executive Board and CEO Healthcare, Merck. "The agreement is also illustrative of our efforts to enhance our focus on accelerating the delivery of our innovative clinical pipeline to patients."

> Merck KGaA hands off its CAR-T R&D operations to Intrexon in $175M deal https://t.co/WNQawXs0WK (https://t.co/WNQawXs0WK) #pharma (https://twitter.com/hashtag/pharma?src=hash&ref_src=twsrc%5Etfw) #CART (https://twitter.com/hashtag/CART?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/NKyuFoA7xB (https://t.co/NKyuFoA7xB)
>
> — Rochelle St. James (@MedSchoolGuru) December 23, 2018 (https://twitter.com/MedSchoolGuru/status/1076633742247116800?ref_src=twsrc%5Etfw)

Ziopharm Oncology and TriArm Therapeutics establish joint venture (Eden BioCell, Ltd) to develop and commercialize Sleeping Beauty CAR T in China, Taiwan and Korea (https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-and-triarm-therapeutics-establish-joint)

"Advancing our Sleeping Beauty platform in the China region is a key part of both our business development and clinical development strategies," said Dr. Cooper. "James Huang has an outstanding track record of creating value in China, and he and the team at TriArm are ideal partners because they have entrenched relationships with front-line physicians and officials at leading hospitals and regulatory bodies, a commitment to conduct high-quality trials, and state-of-the-art facilities with good manufacturing practices."

Daiichi Sankyo out-licenses ROS1/NTRK inhibitor DS-6051 to AnHeart Therapeutics (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006947.html)

> Daiichi Sankyo grants rights to develop manufacture & commercialize ROS1NTRK inhibitor DS6051 to AnHeart Therapeutics: Daiichi Sankyo and AnHeart Therapeutics announced they have entered into a worldwide exclusive license agreement for DS6051 Daiichi... https://t.co/QqnYuieP1s (https://t.co/QqnYuieP1s)
>
> — Clinical Trials News (@ClinicalPhase) December 19, 2018 (https://twitter.com/ClinicalPhase/status/1075320028860317696?ref_src=twsrc%5Etfw)

"We thank Daiichi Sankyo for its trust in AnHeart Therapeutics and its continued support in further developing the DS-6051 asset worldwide. DS-6051 is currently being studied in two phase 1studies for cancers bearing ROS1 or NTRK fusion mutations, and is a leading asset in our pipeline," commented Junyuan Wang, PhD, Chief Executive Officer, AnHeart Therapeutics. "It is our priority to move DS-6051 through the global regulatory pathways with a fast-to-market approach. We will communicate with regulatory agencies to initiate multiple global phase 2 trials of DS-6051 immediately after the transfer of clinical development responsibilities is completed."

COMPANION Dx

FDA approves BRACAnalysis CDx for Olaparib in advanced BRCA-mutated Ovarian Cancer patients (https://myriad.com/investors/news-release/news-release-detail/?newsItemId=20106)

"In the SOLO1 trial, Myriad's BRACAnalysis CDx test identified patients with advanced ovarian cancer who may benefit from Lynparza," said Johnathan Lancaster, M.D., Ph.D., gynecologic-oncologist and chief medical officer, Myriad Genetics. "The FDA's approval underscores the need for all patients with ovarian cancer to know their BRACAnalysis CDx results at the time of diagnosis so they can fully understand their treatment options."

CONFERENCE COVERAGE: ESMO-IO 2018

> Exciting to see F-star's latest work featured in this @myESMO (https://twitter.com/myESMO?ref_src=twsrc%5Etfw) communication. Learn more about Matt Lakins et al.'s brilliant work on our CD137/PD-L1 #bispecific (https://twitter.com/hashtag/bispecific?src=hash&ref_src=twsrc%5Etfw) #antibody (https://twitter.com/hashtag/antibody?src=hash&ref_src=twsrc%5Etfw) at ESMO-IO on Friday.https://t.co/fPpqQv1Bqa (https://t.co/fPpqQv1Bqa)#FS222 (https://twitter.com/hashtag/FS222?src=hash&ref_src=twsrc%5Etfw) #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) #immunoOncology (https://twitter.com/hashtag/immunoOncology?src=hash&ref_src=twsrc%5Etfw) #Cancer (https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw) #immunesystem (https://twitter.com/hashtag/immunesystem?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/P3hidJbOou (https://t.co/P3hidJbOou)
>
> — F-star Biotechnology (@Fstar_Biotech) December 12, 2018 (https://twitter.com/Fstar_Biotech/status/1072829417318215680?ref_src=twsrc%5Etfw)

1. Positive efficacy and safety results from tab-cel® (tabelecleucel) in EBV+ leiomyosarcoma patients presented (http://investors.atarabio.com/news-releases/news-release-details/atara-biotherapeutics-presents-positive-efficacy-and-safety)
2. Proton Pump Inhibitor therapy negatively impacts the efficacy of Nivolumab + Ipilimumab combination in Melanoma (https://www.esmo.org/Oncology-News/Proton-Pump-Inhibitor-Therapy-Negatively-Impacts-the-Efficacy-of-Nivolumab-Plus-Ipilimumab-Combination-Treatment-in-Melanoma)
3. Neoadjuvant Ipilimumab + Nivolumab demonstrates promising OS and RFS in Stage III Melanoma in PhIb OpACIN trial (https://www.esmo.org/Oncology-News/Neoadjuvant-Ipilimumab-plus-Nivolumab-Demonstrates-Promising-Overall-Survival-and-Relapse-free-Survival-in-Stage-III-Melanoma)
4. Updated Ph Ia/Ib data on Tislelizumab presented in patients with urothelial carcinoma (http://ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2380786)
5. Pembrolizumab significantly prolongs OS in previously treated advanced NSCLC patients in Ph II/III KEYNOTE-010 trial (https://www.esmo.org/Oncology-News/Pembrolizumab-Improves-Long-term-Overall-Survival-over-Docetaxel-in-Advanced-NSCLC)
6. Data from the OAK trial show fast progression is not more common with Atezolizumab (https://www.esmo.org/Oncology-News/Data-from-the-OAK-Trial-Show-Fast-Progression-Is-Not-More-Common-with-Atezolizumab)

OTW Trivia

DRUG SNAPSHOT: Ibrutinib

Q: What is the mechanism of action of Ibrutinib?

A: Ibrutinib is a Bruton's Tyrosine Kinase (BTK) Inhibitor. Bruton's Tyrosine Kinase (BTK) is a non-receptor kinase phosphorylates downstream target phospholipase C γ2 (PLCγ2), resulting in activation of NFκB, NFAT, and MAPK pathways, aberrations in which promote cancer cell proliferation, tumor cell adhesion, migration and homing. Ibrutinib covalently binds to, and ultimately inhibits BTKs in cancer cells.

Q: How are BTKs important?

A: BTKs play a primary role in healthy B cells maturation, proliferation and antibodies generation; cancers of B-cells (e.g., CLL and most NHLs) also depend on BTK to survive in the same way.

Q: For which oncology indications (tumors) is Ibrutinib approved by FDA?

A: Ibrutinib is indicated for the treatment of adult patients with:

- 2L+ Mantle cell lymphoma: MCL patients who have received at least one prior therapy. *(Accelerated approval)*
- Chronic lymphocytic leukemia (CLL)/Small lymphocytic lymphoma (SLL) with 17p deletion
- Waldenström's macroglobulinemia (WM)
- CD20 inhibitor-treated 2L+ Marginal zone lymphoma: MZL patients who require systemic therapy and have received at least one prior anti-CD20-based therapy *(Accelerated approval)*

Q: What are the common adverse reactions seen in patients treated with Ibrutinib?

A: The most common adverse reactions (≥20%) in patients with B-cell malignancies (MCL, CLL/SLL, WM and MZL) were anemia, thrombocytopenia, hemorrhage, neutropenia, diarrhea, rash, musculoskeletal pain, bruising, fatigue, nausea, and pyrexia

Sources: https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205552s025lbl.pdf (https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/205552s025lbl.pdf), https://www.pharmacyclics.com/home/our-approach/imbruvica (https://www.pharmacyclics.com/home/our-approach/imbruvica)

About the Author:

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

Richa (https://www.linkedin.com/in/richatewari/) earned her PhD at the National Brain Research Centre, India. For her thesis, she worked on the dreaded Glioblastoma multiforme. That was her first in-depth exposure to academic research in cancer biology. After her PhD, she expanded her research experience by working in the field of immunology at UCLA, USA. After her return to India, Richa switched to a corporate setting but continued her engagement with the cancer field. She is currently loving her work, which affords her the opportunity to continue developing her knowledge in the biomedical field of cancer. Outside of work, she enjoys watching, identifying and photographing birds.

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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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Cover image: "A confocal image of breast cancer cells in culture. The cell to the lower left is dying. Technical Detail: B0002411 breast cancer cells – one dying. Wellcome Images available under the following creative commons usage http://creativecommons.org/licenses/by-nc-nd/2.0/uk/" Source (http://flagella.crbs.ucsd.edu/images/38979)

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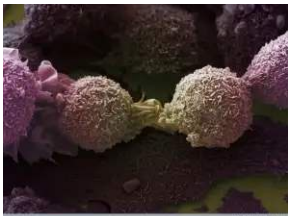

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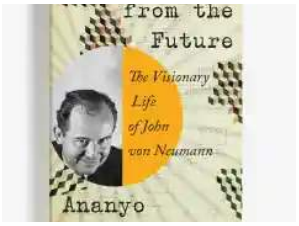

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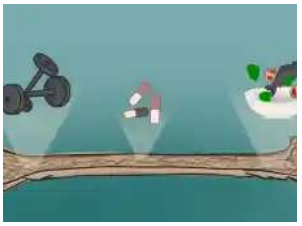

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