

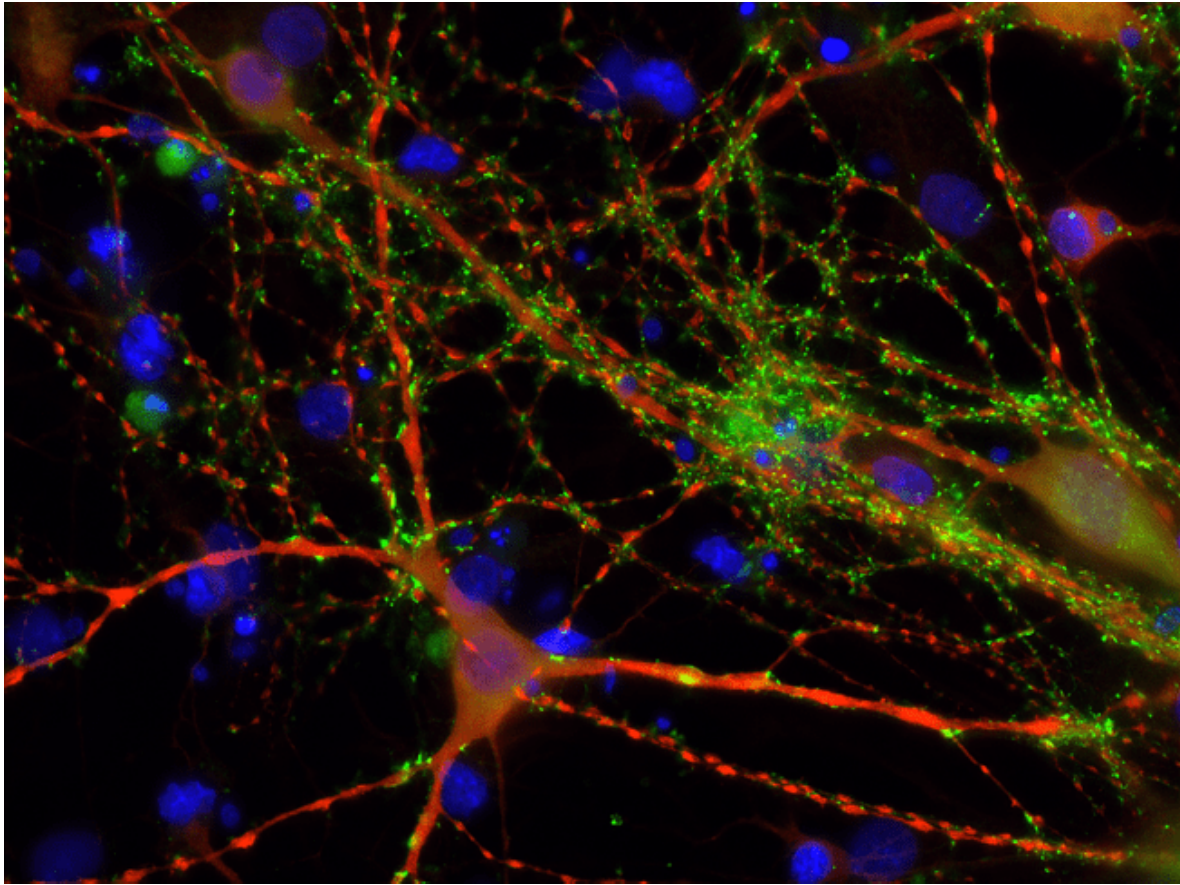


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Onco-this-Week

May 12, 2018(<https://sciwri.club/archives/date/2018/05/12>)



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(<https://pixabay.com/en/thermometer-headache-pain-pills-1539191/>)

Editor's Note: In this edition of Onco-this-Week, Richa Tewari highlights the FDA-approval of Daratumumab as a first-line treatment in multiple myeloma patients and a failed Phase 3 trial of Roche's Atezo + Cobimetinib for colon cancer patients along with the priority review to Atezolizumab + Bevacizumab + Paclitaxel and carboplatin chemotherapy in a category of lung cancer patients on the basis of Ph 3 IMpower150 trial. Also catching our attention is the Fast Track designation to Debio 1347 for its effectiveness in unresectable, metastatic tumors and all this is just a fraction of the comprehensive coverage by Richa on the latest in Oncology. In addition, our educational video section talks about the introductory concepts of orphan drugs, and check out the infographic on the successful advancements in cervical cancer.- Abhi Dey (<https://www.linkedin.com/in/abhinavdey/>)

This edition of Onco-this-Week is Sponsored by Nano-Tag Biotechnologies (<https://goo.gl/XM63s6>)



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Note from our Sponsor: “Did you Know Steric hindrance is minimal with our FluoTags? This means that FluoTags will find more epitopes than conventional IgGs. This results in a more uniform decoration of the structures under investigation.”

“NanoTag Biotechnologies is a German company founded in July 2015 by scientists with a strong background in biochemistry as well as quantitative super-resolution imaging. Situated in Göttingen, we are in constant exchange with scientists developing and applying tools for innovative cutting-edge research. The inspiring atmosphere created by leading scientists and an excellent network of entrepreneurship is an ideal breeding ground for our vision to produce thoroughly validated high-quality tools for life-sciences, biotechnology and bio-medical research. Currently, our portfolio mainly focuses on single-domain antibody-based affinity reagents (“Tags”) for biochemical and fluorescence-based applications. In the near future, we are going to expand our portfolio to enzymes, affinity resins and secondary reagents for various immunoassays (IP, IF, IHC, IHC-P, WB...). Feel free to contact us (<http://nano-tag.com/about-us>) anytime to discuss custom projects.”

Cover image: [Courtesy: Felipe Opazo (<https://www.linkedin.com/in/felipe-opazo-472484a4/>) (CEO) Nano-Tag Biotechnologies (<https://goo.gl/XM63s6>)] Direct immunofluorescence labeling of a cultured hippocampus neuron (1:500). Nerve-terminals positive for VGLUT1 were visualized with FluoTag-X2 anti-VGLUT1 AbberiorSTAR® 580 (false color representation in green). Counterstaining with rabbit anti-MAP2 Cy5 (false color representation in red) and dapi (blue). (For more info click here (<http://nano-tag.com/products/fluotag-x2-anti-vglut1>))

Educational Video: “An orphan drug is a pharmaceutical agent (<https://en.wikipedia.org/wiki/Medication>) that has been developed specifically to treat a rare medical condition, the condition itself being referred to as an orphan disease (https://en.wikipedia.org/wiki/Orphan_disease). The assignment of **orphan status** to a disease and to any drugs developed to treat it is a matter of public policy ([https://en.wikipedia.org/wiki/Public_policy_\(law\)](https://en.wikipedia.org/wiki/Public_policy_(law))) in many countries and has resulted in medical breakthroughs that may not have otherwise been achieved due to the economics of drug research and development (https://en.wikipedia.org/wiki/Medical_research).” Source: Wikipedia (https://en.wikipedia.org/wiki/Orphan_drug)



DRUG APPROVALS

Dabrafenib + Trametinib combination approved by FDA for BRAF V600E mutation positive anaplastic thyroid cancer patients (<https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm606708.htm>)

FDA approved dabrafenib (TAFINLAR®, Novartis Pharmaceuticals Corp.) and trametinib (MEKINIST®, Novartis Pharmaceuticals Corp.) in combination for the treatment of patients with locally advanced or metastatic anaplastic thyroid cancer (ATC) with BRAF V600E mutation and with no satisfactory locoregional treatment options.

Approval was based on a nine-cohort, non-randomized trial, BR117019 (NCT02034110) enrolling patients with rare cancers with the BRAF V600E mutation, including locally advanced, unresectable, or metastatic ATC with no locoregional treatment options. The overall response rate was 61% (95% CI: 39%, 80%) in 23 patients with ATC who were evaluable for response. The complete and partial response rates were 4% and 57%, respectively. Response duration was at least 6 months in 64% of responding patients.

The adverse reaction profile among all patients in the trial and among patients in the ATC cohort was similar to that observed in other approved indications.

“FDA Approves Dabrafenib/Trametinib Combination for **BRAF**-Positive Anaplastic Thyroid Cancer” <https://t.co/oDIgCqkyoo> (<https://t.co/oDIgCqkyoo>) via @ascopost (https://twitter.com/ASCOPost?ref_src=twsrc%5Etfw) [pic.twitter.com/UUWpU3O3N1](https://t.co/UUWpU3O3N1) (<https://t.co/UUWpU3O3N1>)

— Anthony M Magliocco MD (@MaglioccoTony) May 5, 2018 (https://twitter.com/MaglioccoTony/status/992916514541133825?ref_src=twsrc%5Etfw)

Daratumumab approved in Frontline, Transplant Ineligible Multiple Myeloma based on data from Ph III ALCYONE study (<https://www.prnewswire.com/news-releases/janssen-announces-daralex-daratumumab-us-fda-approval-for-newly-diagnosed-patients-with-multiple-myeloma-who-are-transplant-ineligible-300644142.html>)

“This approval is significant as we now have the first antibody-based regimen for treating newly diagnosed multiple myeloma patients who are not eligible for a stem cell transplant,” said Andrzej Jakubowiak, M.D., Ph.D., Director of the Multiple Myeloma Program at University of Chicago Medical Center, Chicago, Illinois and a

DARZLAEX® clinical study investigator. “In clinical studies, patients who received treatment with daratumumab experienced a lower risk of disease progression and higher rates of response.”

“A patient’s best chance at lasting remission often begins with a durable response to frontline therapy, because multiple myeloma can become more difficult to treat after relapse,” said Maria-Victoria Mateos, M.D., Ph.D., Director of the Myeloma Unit at University Hospital of Salamanca-IBSAL, Salamanca, Spain and ALCYONE primary investigator. “Combination therapy with daratumumab resulted in deep and durable responses in newly diagnosed patients with multiple myeloma who are transplant ineligible, supporting this regimen as an important new treatment option for these patients.”

Daratumumab now first-line in #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw) in US: <https://t.co/hkg6P5r46P> (<https://t.co/hkg6P5r46P>) [pic.twitter.com/UfhOMyCWXR](https://t.co/hkg6P5r46P) (<https://t.co/UfhOMyCWXR>)

— Medscape Oncology (@MedscapeOnc) May 11, 2018 (https://twitter.com/MedscapeOnc/status/995034783716663296?ref_src=twsrc%5Etfw)

EMA approved maintenance Olaparib for heavily-pretreated ovarian cancer patients with CR/PR with chemo regardless of BRCA status – new formulation reduces dosing (<https://www.astrazeneca.com/media-centre/press-releases/2018/lynparza-tablets-receive-eu-approval-for-the-treatment-of-platinum-sensitive-relapsed-ovarian-cancer08052018.html>)

Dave Fredrickson, Executive Vice President, Head of the Oncology Business Unit at AstraZeneca, said: “With this new approval for *Lynparza*, we will now be able to offer more women with platinum-sensitive ovarian cancer, regardless of their *BRCA* status, a chance to achieve long-term disease control with an oral medicine that has a well-characterised safety and tolerability profile.”

Roy Baynes, Senior Vice President and Head of Global Clinical Development, Chief Medical Officer, MSD Research Laboratories, said: “This is an important development for the thousands of women in Europe living with advanced ovarian cancer, historically a difficult-to-treat disease. Working with AstraZeneca, we are able to bring this innovative, targeted treatment that helps delay progression of the disease to a broader group of women.”

“Olaparib tablets (Lynparza) have been approved by the European Commission as a maintenance therapy for patients with platinum-sensitive relapsed high-grade, epithelial ovarian, fallopian tube or primary peritoneal cancer...”<https://t.co/LiMw96oyy2> (<https://t.co/LiMw96oyy2>)#OvarianCancer (https://twitter.com/hashtag/OvarianCancer?src=hash&ref_src=twsrc%5Etfw) [pic.twitter.com/I4M1oEZ2rM](https://t.co/LiMw96oyy2) (<https://t.co/I4M1oEZ2rM>)

— Targeted Oncology (@TargetedOnc) May 11, 2018 (https://twitter.com/TargetedOnc/status/995015797331423232?ref_src=twsrc%5Etfw)

RESULTS

FAILED TRIAL: Ph III IMblaze370 study of Atezolizumab+Cobimetinib did not meet its primary endpoint of OS vs regorafenib in heavily pre-treated CRC patients (https://www.roche.com/media/store/releases/med-cor-2018-05-10.htm?utm_source=360Works%20CloudMail&utm_medium=email&utm_campaign=13003)

“While these results are not what we hoped for, we remain committed to applying our deep experience to develop medicines that will improve outcomes for people living with gastrointestinal cancers,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development. “In particular, we have a number of studies evaluating medicines in colorectal cancer that could play an important role in the treatment of people with this disease in the future.”

#Tecentriq (https://twitter.com/hashtag/Tecentriq?src=hash&ref_src=twsrc%5Etfw) #Atezolizumab (https://twitter.com/hashtag/Atezolizumab?src=hash&ref_src=twsrc%5Etfw) #PDL1 (https://twitter.com/hashtag/PDL1?src=hash&ref_src=twsrc%5Etfw) plus #Cotellic (https://twitter.com/hashtag/Cotellic?src=hash&ref_src=twsrc%5Etfw) #Cobimetinib (https://twitter.com/hashtag/Cobimetinib?src=hash&ref_src=twsrc%5Etfw) #MEK (https://twitter.com/hashtag/MEK?src=hash&ref_src=twsrc%5Etfw) combo failed to increase OS significantly in #coloncancer (https://twitter.com/hashtag/coloncancer?src=hash&ref_src=twsrc%5Etfw) patients with microsatellite stable tumors. Apparently, inhibition of MEK didnt make tumors immunogenic. News via @endpts (https://twitter.com/endpts?ref_src=twsrc%5Etfw) @johncendpts (https://twitter.com/JohnCendpts?ref_src=twsrc%5Etfw)<https://t.co/tIiLKl5HX6> (<https://t.co/tIiLKl5HX6>)

— Anand Rotte (@AnandRotte) May 11, 2018 (https://twitter.com/AnandRotte/status/994769906125099008?ref_src=twsrc%5Etfw)

Positive Ph Ib results for multi-cytokine inhibitor BNZ-1 in LGL and rCTCL (<https://bioniz.com/bioniz-therapeutics-announces-positive-phase-ib-clinical-study-results-investigational-agent-bnz-1/>)

“This Phase Ib study further characterizes BNZ-1’s encouraging safety and tolerability profile while producing sustained, dose-dependent, and highly IL-2/15-specific pharmacodynamic effects with multiple dosing,” said Paul Frohna, MD, PhD, PharmD, Chief Medical Officer of Bioniz Therapeutics. “These results establish initial clinical validation of BNZ-1’s potential to treat a variety of IL-2/9/15 cytokine-driven conditions with a novel mechanism.” Dr. Frohna continued, “We now look forward to investigating BNZ-1 in multiple patient populations, including Alopecia Areata, where we believe BNZ-1 may provide advantages over currently available therapies.”

Developmental remedy for alopecia areata of new mechanism of action: BNZ-1 Bioniz Therapeutics, Inc.<https://t.co/OdOoKr1WRo> (<https://t.co/OdOoKr1WRo>) [pic.twitter.com/INVtqgqaRV](https://t.co/INVtqgqaRV) (<https://t.co/INVtqgqaRV>)

— Fuji Maru Kagurazaka (@FKagurazaka) May 4, 2018 (https://twitter.com/FKagurazaka/status/992244083975376898?ref_src=twsrc%5Etfw)

Quizartinib significantly prolongs OS vs chemo in R/R AML pts with FLT3-ITD mutations in QuANTUM-R study (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006846.html)

“Single agent quizartinib is the first FLT3 inhibitor to show a significant improvement in overall survival compared to cytotoxic chemotherapy in a randomized phase 3 study of patients with relapsed/refractory AML with FLT3-ITD mutations, a very aggressive form of the disease with limited treatment options,” said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. “We sincerely thank all of the investigators and patients who participated in this study and will share the results of the QuANTUM-R study at an upcoming medical meeting. We look forward to working with regulatory authorities worldwide to potentially bring quizartinib to patients as quickly as possible.”

“Single-agent quizartinib is the first FLT3 inhibitor to show a significant improvement in overall survival compared to cytotoxic chemotherapy...[for] relapsed/refractory AML with FLT3-ITD mutations,” said Dr. Yver.<https://t.co/QMBLWon4Bo> (<https://t.co/QMBLWon4Bo>)#AcuteMyeloidLeukemia (https://twitter.com/hashtag/AcuteMyeloidLeukemia?src=hash&ref_src=twsrc%5Etfw) [pic.twitter.com/WnOfI8EiYG](https://t.co/WnOfI8EiYG) (<https://t.co/WnOfI8EiYG>)

— Targeted Oncology (@TargetedOnc) May 10, 2018 (https://twitter.com/TargetedOnc/status/994698661258059777?ref_src=twsrc%5Etfw)

Ph III TAGS trial of Lonsurf (trifluridine/tipiracil) meets Primary Endpoint of OS improvement in patients with metastatic gastric cancer refractory to standard therapies (<https://www.businesswire.com/news/home/20180508006198/en/Phase-III-Study-Evaluating%2Aothe-Efficacy-Safety-Lonsurf>)

Servier and Taiho Pharmaceutical Co., Ltd. announced today that the pivotal Phase III trial (TAGS) evaluating Lonsurf® (trifluridine/tipiracil) plus best supportive care (BSC) versus Placebo plus BSC in patients with advanced metastatic gastric cancer (mGC) met its primary objective to improve overall survival (OS). The results will be presented at an upcoming conference.

TAS-102 (trifluridine/tipiracil; Lonsurf) extended overall survival (OS) in previously treated patients with metastatic gastric cancer <https://t.co/2UY8iQ9Kkq> ([#stomach](https://t.co/2UY8iQ9Kkq) (https://twitter.com/hashtag/stomach?src=hash&ref_src=twsrc%5Etfw) cancer#cancertreatment (https://twitter.com/hashtag/cancertreatment?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/sfETSi4m5X (<https://t.co/sfETSi4m5X>)

— StomachCancerCa (@StomachCancerCa) May 10, 2018 (https://twitter.com/StomachCancerCa/status/994611773624877056?ref_src=twsrc%5Etfw)

REGULATORY NEWS

FDA grants priority review to Atezolizumab + Bevacizumab + Paclitaxel and carboplatin chemotherapy in 1L non-sq mNSCLC on the basis of Ph III IMpower150 results; PDUFA Sep 5, 2018 (<https://www.gene.com/media/press-releases/14715/2018-05-06/fda-grants-priority-review-to-genentechs>)

“Our Phase III results showed TECENTRIQ in combination with Avastin, paclitaxel and carboplatin has the potential to provide a significant survival benefit in the initial treatment of metastatic non-squamous non-small cell lung cancer,” said Sandra Horning, M.D., chief medical officer and head of Global Product Development. “We are working closely with the FDA to bring this treatment regimen to people with this type of lung cancer as soon as possible.”

@genentech (https://twitter.com/genentech?ref_src=twsrc%5Etfw) “Phase III IMpower 150 trial showing that Tecentriq and Avastin plus Carboplatin and Paclitaxel helped people with advanced lung cancer live longer compared to Avastin plus Carboplatin and Paclitaxel” <https://t.co/1PcOD8Ewtl> (<https://t.co/1PcOD8Ewtl>)

— LUNGeivity Foundation (@LUNGeivity) March 26, 2018 (https://twitter.com/LUNGeivity/status/978284844957536257?ref_src=twsrc%5Etfw)

Amgen receives positive CHMP opinion to add OS results from Ph III ASPIRE trial to Carfilzomib label (<https://www.amgen.com/media/news-releases/2018/04/amgen-receives-positive-chmp-opinion-to-add-overall-survival-results-from-the-phase-3-aspire-study-to-kyprolis-carfilzomib-label/>)

“This latest positive CHMP opinion marks the second time Amgen will add overall survival data from a Phase 3 study to the label, further validating the fundamental role of KYPROLIS in treating patients with relapsed or refractory multiple myeloma,” said David M. Reese, M.D., senior vice president of Translational Sciences and Oncology at Amgen. “This is a major step towards advancing KYPROLIS-based regimens as standard of care, and we look forward to the European Commission’s decision later this year.”

ADD – Is Kyprolis (carfilzomib) a treatment option for a first relapse of myeloma? <https://t.co/9hPjb8WVDA> (<https://t.co/9hPjb8WVDA>) pic.twitter.com/sSigglf4wo (<https://t.co/sSigglf4wo>)

— Oncology Tube (@oncologytube) May 10, 2018 (https://twitter.com/oncologytube/status/994411669546721280?ref_src=twsrc%5Etfw)

Delcath announces another DSMB recommendation for Ph III FOCUS trial – trial to continue without modification (<http://delcath.com/reuters-news/?id=2346786>)

“The DSMB’s continued recommendation to proceed without modification with the FOCUS Trial as planned confirms once again our own observations of the safety profile of PHP therapy based on prior research and our commercial experience with CHEMOSAT in Europe,” said Jennifer K. Simpson, Ph.D., MSN, CRNP President and CEO of Delcath. “Given that safety concerns with the previous generation product and procedure were the primary issue in the FDA’s previous assessment, we are pleased with the safety profile demonstrated by our therapy in the trial thus far.”

What is ocular melanoma? Medical mystery shines light on rare eye cancer <https://t.co/RpaUWssTNJ> (<https://t.co/RpaUWssTNJ>)

— UtahCouncil_Blind (@UCBInfo) May 12, 2018 (https://twitter.com/UCBInfo/status/995314629814333441?ref_src=twsrc%5Etfw)

Oncolytics Biotech receives Special Protocol Assessment agreement from FDA for Ph III trial of Pelareorep in metastatic Breast Cancer (<https://www.oncolyticsbiotech.com/press-releases/detail/412/oncolytics-biotech-receives-special-protocol-assessment>)

“This agreement with the FDA, outlining the specific clinical pathway forward in metastatic breast cancer, is an important milestone in advancing pelareorep along a path to potential regulatory approval,” said Dr. Matt Coffey, President and CEO of Oncolytics Biotech. “It’s a confirmation from the FDA that our design and protocols will support an application for approval and advances pelareorep to be a phase 3 asset. We now look forward to implementation of the Agency’s guidance and to the advancement of pelareorep through this final phase of clinical development.”

Warm congratulations to CEO Dr. Matthew Coffey and all of Oncolytics Biotech (\$ONCYF) for fetching SPA designation: pelareorep in metastatic breast cancer ph.3. Lots of happy folks in Calgary this am. <pic.twitter.com/5M1zEhOzDu> (<https://t.co/5M1zEhOzDu>)

— KSS, MD, PhD (@KSSMDPhD) May 10, 2018 (https://twitter.com/KSSMDPhD/status/994537349781622784?ref_src=twsrc%5Etfw)

MediciNova Announces Opening of INDA for PDE4/10 inhibitor MN-166 (ibudilast) in GBM (<http://investors.medicinova.com/phoenix.zhtml?c=183833&p=irol-newsArticle&ID=2348327>)

“We are very pleased that this important regulatory step is now completed, as we can now pursue clinical development of MN-166 in GBM, a devastating type of cancer with a high recurrence rate and very poor prognosis. As we previously reported, combination treatment of MN-166 (ibudilast) and TMZ improved survival compared to TMZ-only treatment in a GBM animal model study,” commented Yuichi Iwaki, MD, PhD, President and CEO of MediciNova, Inc.

Dr Kerrie McDonald speaks on repurposing ibudilast for people with #GBM (https://twitter.com/hashtag/GBM?src=hash&ref_src=twsrc%5Etfw). #asnocogno2016 (https://twitter.com/hashtag/asnocogno2016?src=hash&ref_src=twsrc%5Etfw) #btsm (https://twitter.com/hashtag/btsm?src=hash&ref_src=twsrc%5Etfw) <pic.twitter.com/LEKidNnguz> (<https://t.co/LEKidNnguz>)

— Anna Nowak (@perth_meso_dr) September 13, 2016 (https://twitter.com/perth_meso_dr/status/775500327592136710?ref_src=twsrc%5Etfw)

SPECIAL STATUSES

Anti-CD47 mAb, 5F9, gets Fast Track Designation for treatment of DLBCL and FL (<http://>)

“The FDA’s decision to grant Fast Track designations to 5F9 for the treatment of DLBCL and FL reflects the urgent need for safe and effective therapies for people living with these cancers, and the potential of 5F9 to help patients for whom existing options are limited,” said Mark McCamish, M.D., Ph.D., President and Chief Executive Officer of Forty Seven, Inc. “We look forward to working closely with the FDA as we advance our ongoing Phase 2 trial of 5F9 in combination with rituximab and continue to learn about the safety and efficacy profile of 5F9 in patients with B-cell NHL.”

Forty Seven’s 5F9 Immunotherapy on FDA Fast Track for DLBCL, Follicular Lymphoma <https://t.co/d9Q6rpG4To> (<https://t.co/d9Q6rpG4To>) [pic.twitter.com/ofDyigLO3E](https://t.co/ofDyigLO3E) (<https://t.co/ofDyigLO3E>)

— BioNews Services (@bionewsservices) May 9, 2018 (https://twitter.com/bionewsservices/status/994102958618005504?ref_src=twsrc%5Etfw)

FDA grants Fast Track designation to FGFR1-3 inh Debio 1347 for patients with unresectable or metastatic tumors with a specific FGFR gene alteration (<https://www.debiopharm.com/medias/press-release/item/3860-fda-grants-fast-track-designation-to-debiopharm-international-s-debio-1347-for-the-treatment-of-patients-with-unresectable-or-metastatic-tumors-with-a-specific-fgfr-gene-alteration>)

“This Fast Track designation is an encouraging step in our innovative approach to advance the care of the patients with unresectable or metastatic tumors with a specific FGFR gene alteration, who have little or no other treatment options.” said Peggy Lipp, Director, Regulatory Affairs, Market Intelligence & Market Access, Debiopharm International. “It is critical that we address the unmet medical need of these patients and we are looking forward to working with the FDA to accelerate the development of this potential therapy.”

.@US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) grants fast track designation to Debio 1347 for FGFR-mutated tumors. <https://t.co/DCJG7CGjJJ> ([@DebiopharmNews](https://t.co/DCJG7CGjJJ) (https://twitter.com/DebiopharmNews?ref_src=twsrc%5Etfw))

— HemOnc Today (@HemOncToday) May 8, 2018 (https://twitter.com/HemOncToday/status/993912711972081666?ref_src=twsrc%5Etfw)

SELLAS Life Sciences Receives FDA Orphan Drug Designation for Galinpepimut-S (GPS) for Treatment of Multiple Myeloma (<https://www.sellaslifesciences.com/investors/news/News-Details/2018/SELLAS-Life-Sciences-Receives-FDA-Orphan-Drug-Designation-for-Galinpepimut-S-GPS-for-Treatment-of-Multiple-Myeloma-MM/default.aspx>)

“We are delighted to receive this orphan drug designation as it underscores the great need for innovative, effective treatments for this rare cancer, and recognizes the potential benefits that GPS may provide for patients with MM,” said Angelos Stergiou, MD, ScD h.c., President & Chief Executive Officer of SELLAS. “Receiving orphan drug designation for the treatment of MM is a significant regulatory milestone in the development of GPS. We have reported median progression-free survival (PFS) of 23.6 months in the high-risk MM disease setting, compared to historically inferior outcomes in such a patient cohort of around 12 months, and GPS stimulated time-dependent and robust CD4+ T cell or CD8+ T cell immune responses as well as multifunctional cross-epitope T cell reactivity.”

Last night, SELLAS Life Sciences Group, Inc. announced that the @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) granted orphan drug designation to galinpepimut-S (#GPS (https://twitter.com/hashtag/GPS?src=hash&ref_src=twsrc%5Etfw)) for the treatment of multiple #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw).

READ: <https://t.co/zMRiPfITLG> (<https://t.co/zMRiPfITLG>) [pic.twitter.com/WjekPVoRdm](https://t.co/WjekPVoRdm) (<https://t.co/WjekPVoRdm>)

— Rare Disease Report (@RareDR) May 10, 2018 (https://twitter.com/RareDR/status/994581082992463872?ref_src=twsrc%5Etfw)

Radioiodinated PDC asset CLR131 gets orphan drug designation in Rhabdomyosarcoma (<https://investor.cellectar.com/press-releases/detail/174/cellectar-granted-orphan-drug-designation-for-clr-131-to>)

“Rhabdomyosarcoma is the most common type of tissue sarcoma in children. While initial response to treatment is generally favorable, there is an important need for new treatments, especially in children who experience relapse.” said John Friend, M.D., chief medical officer of Cellectar. “Cellectar is committed to working closely with the FDA to fully evaluate the potential for targeted delivery of CLR 131 to address this currently unmet medical need.”

Phospholipid drug conjugate CLR131 granted orphan drug designation by FDA for #neuroblastoma (https://twitter.com/hashtag/neuroblastoma?src=hash&ref_src=twsrc%5Etfw) Clinical trial will open soon @uwhealthkids (https://twitter.com/uwhealthkids?ref_src=twsrc%5Etfw) @UWCarbone (https://twitter.com/UWCarbone?ref_src=twsrc%5Etfw) for this and other pediatric tumors #DIPG (https://twitter.com/hashtag/DIPG?src=hash&ref_src=twsrc%5Etfw) #sarcoma (https://twitter.com/hashtag/sarcoma?src=hash&ref_src=twsrc%5Etfw) <https://t.co/jrdBkbDqVr> (<https://t.co/jrdBkbDqVr>)

— Christian Capitini (@CapitiniMD) March 20, 2018 (https://twitter.com/CapitiniMD/status/976110082349060096?ref_src=twsrc%5Etfw)

TRIAL STATUSES

EpicientRx Announces First Ever Treatment of Cancer Patient with Personalized, Custom-Made Viral Vaccines (<https://www.prnewswire.com/news-releases/epicentrx-announces-first-ever-treatment-of-cancer-patient-with-personalized-custom-made-viral-vaccines-300641065.html>)

Dr. Corey A. Carter, CEO of EpicientRx, added that while current treatment paradigm in oncology relies on off the shelf, one size fits all therapies, “we know that every patient and patient’s tumor is different. To target an individual tumor in individual patients is nothing short of a revolution.”

Drs. Carter and Reid felt that further development of personalized viral vaccines is warranted in combination with other immunotherapy weapons such as checkpoint inhibitors, which also trigger immune responses against cancer neoantigens, albeit non-specifically. “The reality is that other immunotherapies, such as checkpoint inhibitor drugs, only benefit 20-25% of patients in selected tumor types. There’s nothing for the other 75-80% of patients that don’t benefit. We can and must do better. These viruses are potentially a way to increase response rates so that the other 75-80% of patients start to benefit,” said Dr. Carter.

EpicientRx treated the first patient with personalized viral vaccines – <https://t.co/e00e6bp2sf> (<https://t.co/e00e6bp2sf>) [pic.twitter.com/dkvOjFyfS5](https://t.co/dkvOjFyfS5) (<https://t.co/dkvOjFyfS5>)

— GMPnews.Net (@GMPnewsNet) May 12, 2018 (https://twitter.com/GMPnewsNet/status/995114223020728325?ref_src=twsrc%5Etfw)

Patient enrollment completed in Ph Ib trial of oncolytic immunotherapy drug PV-10 + Pembrolizumab in

metastatic melanoma patients (<https://www.provectusbio.com/news/press-releases/provectus-pr-20180507-1>)

Provectus announced the completion of metastatic melanoma patient enrollment (N=24) into the Phase 1b portion of the Phase 1b/2 trial of intralesional PV-10 in combination with Pembrolizumab (ClinicalTrials.gov identifier: NCT02557321 (<https://clinicaltrials.gov/ct2/show/NCT02557321?term=Provectus%2C+PV-10>)). This trial's primary endpoints include PFS and safety assessments.

Provectus today announced the completion of enrollment of 24 patients with metastatic #melanoma (https://twitter.com/hashtag/melanoma?src=hash&ref_src=twsrc%5Etfw) into the Phase 1b portion of the Co's Phase 1b/2 study of intralesional PV-10 in combination with KEYTRUDA® (pembrolizumab), Merck & Co's systemic anti-PD-1 \$pvct (https://twitter.com/search?q=%24pvct&src=ctag&ref_src=twsrc%5Etfw) #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) #PV (https://twitter.com/hashtag/PV?src=hash&ref_src=twsrc%5Etfw)-10

— \$PVCT (@Ablate_Cancer) May 7, 2018 (https://twitter.com/Ablate_Cancer/status/993527464855912448?ref_src=twsrc%5Etfw)

First patient treated in Phase 1b trial of personal neoantigen vaccine, NEO-PV-01 + Pembrolizumab + chemo in 1L non-squamous NSCLC cohort (<http://neontherapeutics.com/neon-therapeutics-announces-first-patient-treated-in-clinical-trial-evaluating-personal-cancer-vaccine-neo-pv-01-in-combination-with-keytruda-pembrolizumab-and-chemotherapy/>)

“Treating our first patient in this clinical study marks an important milestone for Neon,” said Richard Gaynor, M.D., president of research and development at Neon Therapeutics. “We see a strong mechanistic rationale to explore the combination and sequence of a personal neoantigen cancer vaccine, anti-PD-1 therapy and chemotherapy. These data will help us understand the potential of NEO-PV-01 to improve durability and response rates of patients treated in combination with existing immuno-oncology drugs.”

#PMWC18 (https://twitter.com/hashtag/PMWC18?src=hash&ref_src=twsrc%5Etfw) 9:15am: Richard Gaynor, president of Neon Therapeutics speaks on The Promises of Combination Therapies <https://t.co/aGg2aeymb> (<https://t.co/aGg2aeymb>) [Track 2] #biomarker (https://twitter.com/hashtag/biomarker?src=hash&ref_src=twsrc%5Etfw) #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) #PD1 (https://twitter.com/hashtag/PD1?src=hash&ref_src=twsrc%5Etfw) #CTLA4 (https://twitter.com/hashtag/CTLA4?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/fFoMyecsy5 (<https://t.co/fFoMyecsy5>)

— Precision Medicine World Conference PMWC Est. 2009 (@PMWCintl) January 22, 2018 (https://twitter.com/PMWCintl/status/955489030489231360?ref_src=twsrc%5Etfw)

COLLABORATIONS & ACQUISITIONS

Merck KGaA and SFJ Pharmaceuticals to develop Abituzumab + Cetuximab + chemo in 1L RAS WT mCRC patients with high $\alpha\beta6$ integrin expression (<https://www.prnewswire.com/news-releases/merck-kgaa-darmstadt-germany-to-develop-abituzumab-in-metastatic-colorectal-cancer-with-sfj-pharmaceuticals-group-681479941.html>)

“Our collaboration with SFJ illustrates Merck KGaA, Darmstadt, Germany’s increasing focus on strategic partnering in order to further diversify our development risks as well as enable a more efficient pipeline prioritization,” said Belén Garijo, member of the Executive Board of Merck KGaA, Darmstadt, Germany, and CEO Healthcare. “Together with SFJ, we aim to progress the understanding of the potential of abituzumab as a targeted treatment for patients suffering from mCRC.”

“We are delighted to partner with Merck KGaA, Darmstadt, Germany, to pursue this new clinical development

project,” said Robert DeBenedetto, Chief Executive Officer of SFJ. “Our expertise in oncology and renowned ability to successfully carry out various late stage clinical development projects is gaining wider acceptance and enables industry players like Merck KGaA, Darmstadt, Germany, to develop their promising assets by risk-sharing with us.”

Merck KGaA/SFJ’s Abituzumab Evaluated For Left-Sided Metastatic Colon Cancer – Scrip <https://t.co/MN4HKGwP2k>

— Colon Cancer (@ColonSurgeons) May 4, 2018 (https://twitter.com/ColonSurgeons/status/992218568598085632?ref_src=twsrc%5Etfw)

Atara Biotherapeutics expands T-cell immunotherapy collaboration to advance next-gen CAR-T technology in oncology (<https://atarabio.gcs-web.com/news-releases/news-release-details/atarabio-biotherapeutics-expands-t-cell-immunotherapy-collaboration>)

Dr. Sadelain, M.D., Ph.D., Director, Center for Cell Engineering at MSK, stated, “We are eager to work with Atara to continue advancing promising allogeneic T-cell immunotherapy technologies that originated at MSK. The new CAR T technologies seek to overcome persistent therapeutic challenges, such as safety and tolerability, durability of treatment response, and activity in areas of significant unmet medical need that are underserved by the current generation of CAR T immunotherapies.”

“Our earlier MSK collaboration has been highly productive, highlighted by tab-cel™, Atara’s off-the-shelf, allogeneic T-cell immunotherapy currently in Phase 3 development,” said Isaac Ciechanover, M.D., Chief Executive Officer and President of Atara Biotherapeutics. “The deepening of our collaboration with MSK allows us to rapidly advance novel gene-edited CAR T development programs leveraging our existing off-the-shelf T-cell immunotherapy technology platform, manufacturing expertise and research and development capabilities. Going forward, we plan to continue to assemble complementary genetic engineering technologies to grow our pipeline and realize the full potential of our platform.”

Atara Biotherapeutics expands collab w/ Sloan Kettering to develop next-gen CAR-T immunotherapies

Earlier efforts advanced off-the-shelf allogeneic #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) tab-cel into Ph3 #clinicaltrials (https://twitter.com/hashtag/clinicaltrials?src=hash&ref_src=twsrc%5Etfw) <https://t.co/oaj9uK2SvK> ([#biopharm](https://t.co/oaj9uK2SvK) (https://twitter.com/hashtag/biopharm?src=hash&ref_src=twsrc%5Etfw) #immunology (https://twitter.com/hashtag/immunology?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #autoimmunity (https://twitter.com/hashtag/autoimmunity?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/qKeEYru3dm (<https://t.co/qKeEYru3dm>)

— DDNews Online (@DDNewsOnline) May 9, 2018 (https://twitter.com/DDNewsOnline/status/994220291130769408?ref_src=twsrc%5Etfw)

OncoSec and Merck to Evaluate ImmunoPulse® IL-12 + Pembrolizumab for 2L+ TNBC (<https://ir.oncosec.com/press-releases/detail/1945/oncosec-expands-relationship-with-merck-announces-clinical>)

“We are pleased to initiate a second clinical trial collaboration with Merck – one of the world’s leading immunoncology companies – in late stage TNBC, a disease which has few treatment options,” said Daniel J. O’Connor, Chief Executive Officer of OncoSec. “This collaboration is another example of OncoSec’s strategy to work with innovative immuno-oncology leaders, combining our ImmunoPulse® IL-12 program with checkpoint inhibitor therapies to advance the care of patients.”

OncoSec to combine ImmunoPulse device with Merck's #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) in breast cancer trial. \$ONCS (https://twitter.com/search?q=%24ONCS&src=ctag&ref_src=twsrc%5Etfw) \$MRK (https://twitter.com/search?q=%24MRK&src=ctag&ref_src=twsrc%5Etfw) <https://t.co/S8f5e5mFvI> (<https://t.co/S8f5e5mFvI>) [pic.twitter.com/nvo6bFnMZB](https://t.co/nvo6bFnMZB) (<https://t.co/nvo6bFnMZB>)

— Drug Delivery News (@DrugDeliveryNow) May 8, 2018 (https://twitter.com/DrugDeliveryNow/status/993836241543225345?ref_src=twsrc%5Etfw)

Lilly Announces Agreement To Acquire ARMO BioSciences (<https://investor.lilly.com/news-releases/news-release-details/lilly-announces-agreement-acquire-armo-biosciences>)

“At Lilly Oncology, we are dedicated to developing cancer medicines that will make a meaningful difference for patients,” said Sue Mahony, Ph.D., Lilly senior vice president and president of Lilly Oncology. “The acquisition of ARMO BioSciences adds a promising next generation clinical immunotherapy asset to Lilly’s portfolio of innovative oncology medicines.”

“As we develop our immuno-oncology portfolio, Lilly will pursue medicines that use the body’s immune system in new ways to treat cancer,” added Levi Garraway, M.D., Ph.D., senior vice president, global development and medical affairs, Lilly Oncology, “We believe that pegilodecakin has a unique immunologic mechanism of action that could eventually allow physicians to offer new hope for many cancer patients.”

“ARMO is proud of the work we have done to advance the study of immunotherapies and of the development of pegilodecakin to-date,” said Peter Van Vlasselaer, Ph.D., President and Chief Executive Officer of ARMO BioSciences. “Given the resources that Lilly, a leader in oncology R&D, can bring to bear to maximize the value of pegilodecakin and the rest of the ARMO pipeline, we believe it is in the best interest of ARMO, our stockholders and the patients we serve, to execute this transaction.”

Eli Lilly Drops \$1.6 Billion for Armo BioSciences and its Phase III Immuno-Oncology Drug <https://t.co/M6vYAXSk9R> (<https://t.co/M6vYAXSk9R>) [pic.twitter.com/I45ZxKpqvW](https://t.co/I45ZxKpqvW) (<https://t.co/I45ZxKpqvW>)

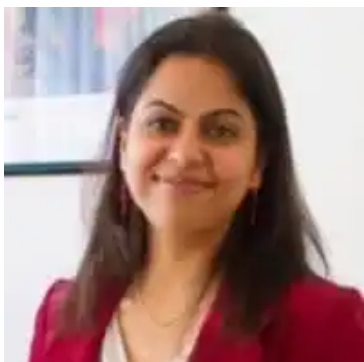
— Biotechnology (@Biotechnology) May 10, 2018 (https://twitter.com/Biotechnology/status/994590600056913920?ref_src=twsrc%5Etfw)

Infographically speaking....

Foundation Debuts Cervical Cancer Prevention (https://visual.ly/community/infographic/health/foundation-debuts-cervical-cancer-prevention/?utm_source=visually_embed)

From Visually (https://visual.ly?utm_source=content-embed&utm_medium=embed).

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:



(<https://i1.wp.com/www.sciwri.club/wp-content/uploads/2016/06/Self2015.jpg>)

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.

Image Sources: Wikipedia and Twitter

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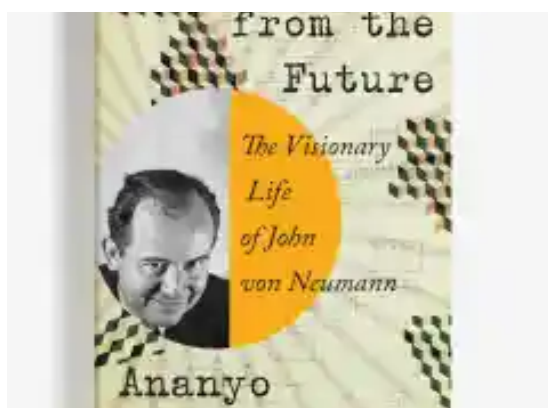
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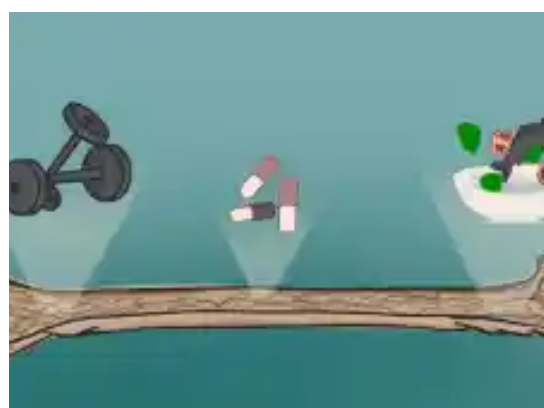
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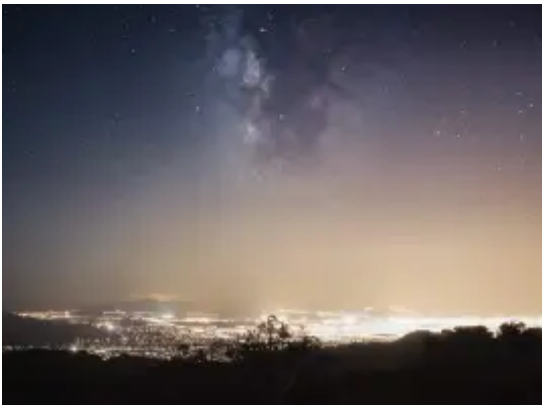
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