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Onco-this-Week

July 21, 2018(<https://sciwri.club/archives/date/2018/07/21>)



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This edition of Onco-this-Week by Richa Tewari highlights positive results from lower phase trials – Breakthrough therapy designation for Atezolizumab + Bevacizumab combo in (first line) ≥ 1 Hepatocellular Carcinoma (HCC patients); FDA-approval of Ivosidenib in R/R (recurrent/relapsed) IDH1+ (isocitrate dehydrogenase 1-positive) AML (acute myeloid leukemia) patients based on Ph I trial results; Priority review to sacituzumab govitecan in 3L (third line) + mTNBC (metastatic Triple negative Breast Cancer) based on Ph I/II trial data; and fast track designation to Galinpepimut-S in multiple myeloma patients based on Ph II trial results. In the trivia section, we discuss the newly introduced Real Time Oncology Review by FDA.

The companies that we have covered this week include Agios, Astellas, Pfizer, Novartis, Mersana, Karyopharm, MaxCyte, Roche, Immunomedics, Sellas, Race Oncology, Adaptimmune, Cellectar Biosciences, Atossa Genetics, Bristol-Myers Squibb, Gritstone Oncology, Gilead, Puma Biotechnology and Strata Oncology.

Also if you need info about any cancer-related term then key it in the NCI widget.

<https://www.cancer.gov/publishedcontent/Js/TermDictionaryWidgetEnglish.js> (<https://www.cancer.gov/publishedcontent/Js/TermDictionaryWidgetEnglish.js>)

ONCO-THIS-WEEK TRIVIA

WHAT IS REAL-TIME ONCOLOGY REVIEW?

Real-Time Oncology Review is one of two new pilot programs announced by FDA earlier this year that collectively aim to make the development and review of cancer drugs more efficient, while improving FDA's rigorous standard for evaluating efficacy and safety.

With this real-time review, the FDA is able to start evaluating the clinical data as soon as the trial results become available, enabling FDA to be ready to approve the new indication upon filing of a formal application with the Agency.

HOW DOES IT WORK?

The pilot focuses on early submission of data that are the most relevant to assessing safety and effectiveness of the product. Then, when the sponsor submits the application with the FDA, the review team will already be familiar with the data and in a better position to conduct a more efficient, timely, and thorough review.

WHEN DOES FDA REVIEW MUCH OF THE DATA?

After the clinical trial results become available and the database is locked, before the information is formally submitted to the FDA.

WHAT IS THE SCOPE OF REAL-TIME ONCOLOGY REVIEW?

Currently Real-Time Oncology Review is being used for supplemental applications for already-approved cancer drugs and could later be expanded to original drugs and biologics.

WHICH IS THE FIRST DRUG APPROVAL GRANTED AS A PART OF REAL-TIME ONCOLOGY REVIEW?

Kisqali (ribociclib) in combination with an aromatase inhibitor (for the treatment of pre/peri/postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy)

Kisqali in combination with fulvestrant (for the treatment of postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine based therapy or following disease progression on endocrine therapy)

Source: FDA News Release, Jul 2018
(<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613801.htm>)

([https://](https://io.wp.com/sciwri.club/wp-content/uploads/2018/07/Onco-this-Week-Trivia-3.png?ssl=t)

io.wp.com/sciwri.club/wp-content/uploads/2018/07/Onco-this-Week-Trivia-3.png?ssl=t)

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



(<https://goo.gl/XM63s6>)





(https://i0.wp.com/sciwiki.club/wp-content/uploads/2018/07/quantitative_imaging.png?ssl=1)

Note from our Sponsor: "Our FluoTag-Q series feature high affinity monovalent binding, low steric constraints and a defined fluorophore number per molecule. This ensures a linear relation between target molecule number and fluorescence intensity."

"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."

DRUG APPROVALS

Ivosidenib approved in R/R IDH1+ AML patients based on Ph I trial results (<https://agiospharmaceuticalsinc.gcs-web.com/node/1686>)

 Breaking News – @US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) approves ivosidenib for the treatment of people with with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation. #leusm (https://twitter.com/hashtag/leusm?src=hash&ref_src=twsrc%5Etfw) <https://t.co/XSdEEIAQMT> (<https://t.co/XSdEEIAQMT>) pic.twitter.com/9sNRER1Q8k (<https://t.co/9sNRER1Q8k>)
— Memorial Sloan Kettering Cancer Center (@sloan_kettering) July 20, 2018 (https://twitter.com/sloan_kettering/status/102039465403709440?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

"The FDA approval of TIBSOVO® – our first wholly owned drug and the second approved medicine from our research platform in less than a year – is an incredibly exciting milestone for our company and, importantly, for the approximately 6-10% of AML patients with an IDH1 mutation who have been waiting for new treatment options that work radically different than conventional chemotherapy," said David Schenkein, M.D., chief executive officer at Agios. "I want to thank the patients and their caregivers, nurses and physicians who participated in our clinical trials. With their support and the dedication of Agios' employees, we are well on our way to becoming a sustainable multi-product biopharmaceutical company delivering medicines that have the potential to change how serious diseases are treated."

Enzalutamide approved for the treatment of men with non-metastatic Castration-Resistant Prostate Cancer (CRPC) (<http://press.pfizer.com/press-release/us-fda-approves-xtandi-enzalutamide-treatment-men-non-metastatic-castration-resistant->)

prIME LINES—Addition of #enzalutamide (https://twitter.com/hashtag/enzalutamide?src=hash&ref_src=twsrc%5Etfw) to #ADT (https://twitter.com/hashtag/ADT?src=hash&ref_src=twsrc%5Etfw) prolongs time to #metastasis (https://twitter.com/hashtag/metastasis?src=hash&ref_src=twsrc%5Etfw) in #nonmetastatic (https://twitter.com/hashtag/nonmetastatic?src=hash&ref_src=twsrc%5Etfw) #CRPC (https://twitter.com/hashtag/CRPC?src=hash&ref_src=twsrc%5Etfw) <https://t.co/VoDoK98qeo> (<https://t.co/VoDoK98qeo>) pic.twitter.com/8GqE8nbCHx (<https://t.co/8GqE8nbCHx>)
— prIME Oncology (@prIMEoncology) July 19, 2018 (https://twitter.com/prIMEoncology/status/1019997512961323010?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

"With today's approval, there is now a new option for men with non-metastatic CRPC, who are in between the failure of androgen deprivation therapy resulting in CRPC and the onset of metastatic disease," said Jonathan Simons, M.D., Prostate Cancer Foundation President and CEO. "As a foundation that drives research aimed at improving patient outcomes, it is exciting to see approvals like this, which are vital to help address unmet patient needs."

FDA expands ribociclib indication in HR-positive, HER2-negative advanced or metastatic breast cancer based on Ph III MONALEESA-7 trial data (<https://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm613803.htm>)

utm_campaign=Oncology%207%2F18%2F2018&utm_medium=email&utm_source=Eloqua&elqTrackId=2e2958c1b0e426b9153c5f59546cc06&elq=6e33cb2e52a246e4f4

@US_FDA (https://twitter.com/US_FDA?ref_src=twsrc%5Etfw) expands use of ribociclib in #breastcancer (https://twitter.com/hashtag/breastcancer?src=hash&ref_src=twsrc%5Etfw) <https://t.co/YPkATVZXOO> (<https://t.co/YPkATVZXOO>) pic.twitter.com/YzUzrxoJOI (<https://t.co/YzUzrxoJOI>)
— AJMC (@AJMC_Journal) July 20, 2018 (https://twitter.com/AJMC_Journal/status/1020342570486939648?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

FDA expanded the indication for ribociclib in combination with an aromatase inhibitor for pre/perimenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy.

FDA also approved ribociclib in combination with fulvestrant for postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy.

Ribociclib was previously approved for postmenopausal women with HR-positive, HER2-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine therapy.

REGULATORY NEWS

FDA uses 'Real-Time Oncology Review' to speed up drug development (<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm613801.htm>)

Our CDK4/6 inhibitor will be approved using the FDA's Real-Time Oncology Review and the Assessment Aid pilot programs. Read more about our new indications here: <https://t.co/ZTjafJU5aw> (<https://t.co/ZTjafJU5aw>) pic.twitter.com/uepEQBSTwD (<https://t.co/uepEQBSTwD>)

— Novartis Cancer (@NovartisCancer) July 18, 2018 (https://twitter.com/NovartisCancer/status/1019643000098623488?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

"With this approval, we've demonstrated some of the benefits of the new programs that we're piloting for our review of cancer drugs, to improve regulatory efficiency while enhancing the process for evaluating the data submitted to us. This shows that, with smart policy approaches, we can gain efficiency while also improving the rigor of our process. These new programs were designed to reduce some of the administrative issues that can add to the time and cost of the review process, including the staffing burdens on the FDA. For example, by analyzing data earlier in the process, before formal submission to the FDA, and evaluating submissions in a structured template, we can make it easier to identify earlier when applications are missing key analysis or information that can delay reviews," said FDA Commissioner Scott Gottlieb, M.D. "With today's approval, the FDA used these new approaches to allow the review team to start analyzing data before the actual submission of the application and help guide the sponsor's analysis of the top-line data to tease out the most relevant information. This enabled our approval less than one month after the June 28 submission date and several months ahead of the goal date."

CLINICAL HOLD: Partial clinical hold put on Ph I trial of HER2-targeting Dolaflexin ADC, XMT-1522 (<http://ir.mersana.com/news-releases/news-release-details/mersana-therapeutics-announces-partial-clinical-hold-xmt-1522>)

Patient death prompts FDA hold on Mersana's lead #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) ADC | FierceBiotech <https://t.co/oQOjrtzAnD> (<https://t.co/oQOjrtzAnD>) pic.twitter.com/bnvXlQ2aqj (<https://t.co/bnvXlQ2aqj>)

— Advera Health (@AdveraHealth) July 20, 2018 (https://twitter.com/AdveraHealth/status/1020369512288473088?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

"Patient safety is our utmost concern," said Anna Protopapas, CEO of Mersana. "Based on the totality of the data we have for XMT-1522, we believe that it continues to be a promising drug candidate in the solid tumor setting and we will be initiating the proper steps with the objective of resuming enrollment."

Karyopharm initiates rolling submission of NDA for Selinexor in penta-refractory multiple myeloma patients (<http://investors.karyopharm.com/news-releases/news-release-details/karyopharm-initiates-rolling-submission-new-drug-application-us>)

Ongoing Randomized Studies of Selinexor – Selinexor with chemotherapy, single-agent activity, etc <https://t.co/PShRhfB8Rp> (<https://t.co/PShRhfB8Rp>) pic.twitter.com/7iFqblKWvX (<https://t.co/7iFqblKWvX>)

— Oncology Tube (@oncologytube) July 19, 2018 (https://twitter.com/oncologytube/status/1019781372905312256?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

"We believe that selinexor has the potential to address the critical unmet need for patients with highly resistant, penta-refractory myeloma, where the disease is no longer responsive to standard approved therapies," said Sharon Shacham, PhD, MBA, Founder, President and Chief Scientific Officer of Karyopharm. "The commencement of this rolling submission for the oral selinexor NDA marks the first-ever application for regulatory approval of an Exportin 1 (XPO1) inhibitor and represents a major milestone for the Company. We are proud of the positive Phase 2b STORM study results underlying this application and we will work expeditiously to complete the submission this year."

IND clearance received for trial of mRNA-based CAR-T, MCY-Mu, in patients with ovarian cancer and peritoneal mesothelioma (<https://www.maxcyte.com/maxcyte-receives-us-fda-investigational-new-drug-clearance-for-first-clinical-program/>)

MaxCyte CEO Says FDA OK Of IND For Its CAR Receptor Candidate Major Milestone <https://t.co/pkjwjIM18s> (<https://t.co/pkjwjIM18s>) #PharmaScrip (https://twitter.com/hashtag/PharmaScrip?src=hash&ref_src=twsrc%5Etfw)

— Scrip (@PharmaScrip) July 19, 2018 (https://twitter.com/PharmaScrip/status/1019944973964398592?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

"The IND clearance marks an important milestone for MaxCyte. We are excited to advance MCY-Mu, our first therapeutic candidate in solid tumors into the clinic and we hope that the upcoming study will serve as validation of our proprietary CARMA™ (CAR therapeutic) drug platform as a whole," said MaxCyte CEO Doug Doerfler. "This initial study will help determine the safety and potential effectiveness of the CARMA platform, and if successful, will mark its place as a new autologous cell-therapy platform for developing improved targeted cell-based immune therapies."

SPECIAL STATUSES

Breakthrough therapy designation for Atezolizumab + Bevacizumab combo in 1L HCC patients based on Phase Ib study (NCT02715531) data (<http://hugin.info/174806/R/2205644/857058.pdf>)

First-Line Atezolizumab Plus Bevacizumab Receives Breakthrough Therapy Designation for HCC <https://t.co/tPLrfl9DXu> (<https://t.co/tPLrfl9DXu>) via @CancerTherAdvsr (https://twitter.com/CancerTherAdvsr?ref_src=twsrc%5Etfw)

— Cure GI Cancers (@RueschCenter) July 20, 2018 (https://twitter.com/RueschCenter/status/1020319153171959814?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

"Hepatocellular carcinoma is an aggressive cancer with limited treatment options and a major cause of cancer deaths worldwide," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "Preliminary data from the combination of Tecentriq and Avastin in this disease are promising and we look forward to working with health authorities to make this potential treatment regimen available to people with hepatocellular carcinoma as soon as possible."

Priority review granted to sacituzumab govitecan in 3L+ mTNBC based on Ph I/II trial data; PDUFA: Jan 18, 2019 (<https://immunomedics.com/2018/fda-accepts-biologics-license-application-for-filing-and-grants-priority->

review-for-sacituzumab-govitecan-for-the-treatment-of-metastatic-triple-negative-breast-cancer/)

FDA Grants Sacituzumab Govitecan Priority Review for Triple-Negative Breast Cancer <https://t.co/ZXlQBH5r2n> (<https://t.co/ZXlQBH5r2n>) pic.twitter.com/Pabiryew5V (<https://t.co/Pabiryew5V>)

— Immuno-Oncology (@immuno_onc) July 19, 2018 (https://twitter.com/immuno_onc/status/1019960580155703296?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

“We are delighted that the FDA has accepted the sacituzumab govitecan BLA for Priority Review,” commented Michael Pehl, President and Chief Executive Officer. “We will continue to work closely with the regulatory agency as we strive to bring this potential new treatment to mTNBC patients expeditiously.”

Galinpepimut-S receives fast track designation for the treatment of multiple myeloma patients based on Ph II trial results (<https://www.sellaslifesciences.com/investors/news/News-Details/2018/SELLAS-Receives-Fast-Track-Designation-from-FDA-for-Galinpepimut-S-for-the-Treatment-of-Patients-with-Multiple-Myeloma/default.aspx>)

FDA grants Fast Track to SELLAS lead galinpepimut-S (GPS) in multiple #myeloma (https://twitter.com/hashtag/myeloma?src=hash&ref_src=twsrc%5Etfw)

Licensed from MSKCC, #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) targets Wilms #Tumor (https://twitter.com/hashtag/Tumor?src=hash&ref_src=twsrc%5Etfw) 1 & performed well in Ph2 #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw)<https://t.co/X3xejArrSB> (<https://t.co/X3xejArrSB>)#biopharma (https://twitter.com/hashtag/biopharma?src=hash&ref_src=twsrc%5Etfw) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) #oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/mDVofir3k (<https://t.co/mDVofir3k>)

— DDNews Online (@DDNewsOnline) July 20, 2018 (https://twitter.com/DDNewsOnline/status/1020315099339214848?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

“The designation of Fast Track for GPS represents important recognition by the FDA of the potential of this novel immunotherapeutic to address the significant unmet need in the treatment of patients with high-risk multiple myeloma in patients with poor-risk cytogenetics at diagnosis who still harbor minimal residual disease (MRD) after autologous stem cell transplant,” said Angelos Stergiou, M.D., Sc.D. h.c., President and Chief Executive Officer of SELLAS. “We are fully committed to working closely with the FDA as we continue development of our potential first-in-class novel WT1-targeting cancer vaccine for select high-risk MM patients in the post-autotransplant maintenance setting after standard first-line treatment.”

Race Oncology granted FDA ‘Rare Paediatric Disease’ designation for Bisantrene for the treatment of childhood Acute Myeloid Leukaemia (AML) (<https://www.raceoncology.com/bisantrene-receives-rare-paediatric-disease-designation-from-fda/>)

Bisantrene announcement making headlines. \$RAC (https://twitter.com/search?q=%24RAC&src=ctag&ref_src=twsrc%5Etfw) <https://t.co/N6e83sdEER> (<https://t.co/N6e83sdEER>) pic.twitter.com/CLRXCLEWMH (<https://t.co/CLRXCLEWMH>)

— Race Oncology (@RaceOncology) July 18, 2018 (https://twitter.com/RaceOncology/status/1019473866979201024?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

“This is a game-changing outcome for Race that adds substantial value to the Company,” said Race CEO, Peter Molloy.

“We already have clear evidence of efficacy in paediatric AML,” said Mr Molloy, referring to the case reports of two French girls who were successfully treated with Bisantrene during the 1980s and 1990s (see ASX releases of 4 June and 26 June 2018). “To date, we have focused our clinical development plan on adult AML, which is the largest population of AML patients,” said Race CEO, Peter Molloy. “Now, in parallel to the adult program, we plan to expedite a paediatric program directed towards securing the PRV.”

TRIAL RESULTS

Phase III IMpower132 study met its co-primary endpoint of progression-free survival (PFS) in 1L non-squamous NSCLC patients (<https://www.roche.com/media/releases/med-cor-2018-07-19.htm>)

Another positive readout in 1L NSCLC, this time for \$RHHBY (https://twitter.com/search?q=%24RHHBY&src=ctag&ref_src=twsrc%5Etfw) with Tecentriq+Alimta in IMpower132: positive PFS benefit, but OS improvement not statistically significant. I’m curious how this data compares to \$MRK’s exceptional Keynote-189<https://t.co/oGnnBrwuty> (<https://t.co/oGnnBrwuty>) pic.twitter.com/baDdCSE0jh (<https://t.co/baDdCSE0jh>)

— Matthew Maryniak (@drug_czar) July 19, 2018 (https://twitter.com/drug_czar/status/1019915286194122752?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

“The IMpower132 study showed Tecentriq plus chemotherapy prolonged the time people with this type of advanced lung cancer lived without their disease worsening. We will discuss these results with health authorities,” said Sandra Horning, MD, Roche’s Chief Medical Officer and Head of Global Product Development.

Favorable safety data observed in SPEAR T cells targeting MAGE-A10 in NSCLC patients; Safety Review Committee (SRC) recommends dose escalation (<http://ir.adaptimmune.com/phoenix.zhtml?c=253991&p=irol-newsArticle&ID=2358788>)

NEWS (<https://t.co/Zl0lrYmECs>) (<https://t.co/Zl0lrYmECs>): “Our MAGE-A10 studies now dosing up to 6 billion cells in conjunction w/ higher intensity preconditioning, which, based on our NY-ESO trials data, may result in greater therapeutic potential,” said Rafael Amado \$ADAP (https://twitter.com/search?q=%24ADAP&src=ctag&ref_src=twsrc%5Etfw) CMO #immunotherapy (https://twitter.com/hashtag/immunotherapy?src=hash&ref_src=twsrc%5Etfw) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/6f3Hau36Kc (<https://t.co/6f3Hau36Kc>)

— Adaptimmune (@Adaptimmune) July 18, 2018 (https://twitter.com/Adaptimmune/status/1019619052510015489?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

“We are pleased that the SRC has recommended proceeding with dose escalation to the final dose group, as our MAGE-A10 SPEAR T-cells appear to be well-tolerated without evidence of off-target or non-specific reactivity,” said Rafael Amado, Adaptimmune’s Chief Medical Officer. “These studies will continue dosing up to 6 billion cells in conjunction with a higher intensity preconditioning regimen, which, based on our data from the NY-ESO trials, may result in greater therapeutic potential. This final dose escalation represents excellent progress toward our goal of delivering response data by the end of 2018. As we get more data throughout 2018, we will share meaningful safety and response data from this and our other wholly owned programs.”

Positive Ph II interim data for CLR 131 in R/R DLBCL patients – 33% ORR and 50% CBR observed (<https://www.collectar.com/news-media/press-releases/detail/182/collectar-reports-positive-phase-2-interim-data-for-clr-131>)

[CLRBB](https://twitter.com/search?q=%24CLRBB&src=ctag&ref_src=twsrc%5Etfw) (https://twitter.com/search?q=%24CLRBB&src=ctag&ref_src=twsrc%5Etfw) Collectar Reports Positive Phase 2 Interim Data for CLR 131 in Relapsed/Refractory #DLBCL (https://twitter.com/hashtag/DLBCL?src=hash&ref_src=twsrc%5Etfw) Patients <https://t.co/SqMKGRswip> (<https://t.co/SqMKGRswip>) [pic.twitter.com/ABrnZ3cGM5](https://t.co/ABrnZ3cGM5) (<https://t.co/ABrnZ3cGM5>)

— Collectar Bioscience (@CollectarBio) July 18, 2018 (https://twitter.com/CollectarBio/status/1019579220601786368?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

“We are very encouraged by the strong response rates and meaningful reductions in tumor volumes seen in the trial to date in this very sick and heavily pretreated relapsed/refractory DLBCL patient population,” stated James Caruso, president and chief executive officer of Collectar Biosciences. “We believe these data combined with the activity seen to date in other hematologic malignancies further validate the continued development of CLR 131.”

TRIAL STATUSES

Patient enrollment starts in Ph II trial of oral Endoxifen in HER2neg HR+ patients (<http://ir.atossagenetics.com/press-releases/detail/859/atossa-genetics-opens-enrollment-in-phase-2-study-of-oral>)

[ATOS](https://twitter.com/search?q=%24ATOS&src=ctag&ref_src=twsrc%5Etfw) (https://twitter.com/search?q=%24ATOS&src=ctag&ref_src=twsrc%5Etfw) #Atossa (https://twitter.com/hashtag/Atossa?src=hash&ref_src=twsrc%5Etfw) Genetics Inc. Atossa Genetics – Endoxifen to start Phase II studies shortly: Atossa Genetics is preparing to start Phase II studies of both its oral and topical endoxifen formulations in Q218. Endoxifen, an estrogen receptor (ER)... <https://t.co/kNxxHhrjqc> (<https://t.co/kNxxHhrjqc>) [pic.twitter.com/89x9bafKel](https://t.co/89x9bafKel) (<https://t.co/89x9bafKel>)

— ResearchPool (@ResearchPool) April 26, 2018 (https://twitter.com/ResearchPool/status/98946775205699585?ref_src=twsrc%5Etfw)

<https://platform.twitter.com/widgets.js> (<https://platform.twitter.com/widgets.js>)

“Once a patient is diagnosed with breast cancer, there is a window of time, typically a number of weeks, before definitive surgery is performed,” commented Steve Quay, Ph.D., MD, President and CEO of Atossa. “Our goal with this study is to show that our proprietary oral Endoxifen can modify the cancer activity in estrogen-receptor-positive patients during this ‘window of opportunity.’ Tamoxifen, the current standard of care, has not been effective in this setting, probably because it can take 50-200 days to reach steady-state of Endoxifen blood levels, while the surgery is usually completed within 30 to 45 days of diagnosis. Because our Phase I study indicated that our oral Endoxifen reaches therapeutic levels within 8 hours and therapeutic steady-state levels in only seven days, we are optimistic we can achieve a valuable treatment effect,” added Dr. Quay.

COLLABORATIONS

BMS and Gritstone Oncology to evaluate novel immunotherapy approach, GRANITE-001, in advanced solid tumors in Ph I trials (<https://gritstoneoncology.com/news-1/bristol-myers-squibb-and-gritstone-oncology-announce-clinical-research-collaboration-to-evaluate-novel-immunotherapy-approach-in-advanced-solid-tumors>)

[@bmsnews](https://twitter.com/bmsnews?ref_src=twsrc%5Etfw) (https://twitter.com/bmsnews?ref_src=twsrc%5Etfw) [BMY](https://twitter.com/search?q=%24BMY&src=ctag&ref_src=twsrc%5Etfw) (https://twitter.com/search?q=%24BMY&src=ctag&ref_src=twsrc%5Etfw) and [@gritstoneonc](https://twitter.com/gritstoneonc?ref_src=twsrc%5Etfw) (https://twitter.com/gritstoneonc?ref_src=twsrc%5Etfw) announce clinical research collaboration to evaluate Gritstone’s personalized immunotherapy GRANITE-001 in combo w/ BMS’ Opdivo, and Opdivo plus Yervoy in patients with advanced solid tumors <https://t.co/O5Ge561w45> (<https://t.co/O5Ge561w45>)

— Dan Budwick (@DanBudwick) July 19, 2018 (https://twitter.com/DanBudwick/status/101990189973045248?ref_src=twsrc%5Etfw)

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“The emergence of immunotherapies in the last decade has transformed the way we think about treating cancer, yet there remains a need for new therapies, which can initiate immune system recognition of tumors,” said Andrew Allen, Ph.D., president and chief executive officer, Gritstone Oncology. “We have developed our programs using insights from our proprietary tumor antigen discovery platform, EDGE™, together with an immunotherapy platform which has demonstrated the ability to elicit an enhanced antigen-directed T-cell response in preclinical primate models. We are excited to work closely with the experienced Bristol-Myers Squibb team to advance this novel combination approach into clinical trials.”

Kite and Gadeta announce strategic collaboration to advance Gamma Delta T Cell Receptor Technology for Solid Tumors (<http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-newsArticle&ID=2359025>)

Kite and #Gadeta (https://twitter.com/hashtag/Gadeta?src=hash&ref_src=twsrc%5Etfw) Announce Strategic Collaboration to Advance Gamma Delta T Cell Receptor Technology for Solid #Tumors (https://twitter.com/hashtag/Tumors?src=hash&ref_src=twsrc%5Etfw) <https://t.co/wFCyyixMEJ> (<https://t.co/wFCyyixMEJ>) #biotech (https://twitter.com/hashtag/biotech?src=hash&ref_src=twsrc%5Etfw) [pic.twitter.com/HPvE2frc7k](https://t.co/HPvE2frc7k) (<https://t.co/HPvE2frc7k>)

— B3C newswire (@B3Cnewswire) July 19, 2018 (https://twitter.com/B3Cnewswire/status/1019927552985587713?ref_src=twsrc%5Etfw)

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“We continue to invest in research approaches that support the development of innovative cell therapies for people living with cancer,” said Alessandro Riva, MD, Gilead’s Executive Vice President, Oncology Therapeutics & Head, Cell Therapy. “We are excited to work with Gadeta on its gamma delta TCR technology. This research collaboration adds an additional new platform to our current capabilities in research and cell manufacturing, and deepens our commitment to develop novel approaches to treat solid tumors.”

Puma Biotechnology and Strata Oncology Announce Collaboration to Accelerate Enrollment in Neratinib HER2 Mutation Basket Study (SUMMIT Trial)<https://t.co/bFojp3smQH> (<https://t.co/bFojp3smQH>)

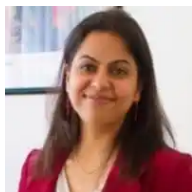
— Strata Oncology (@StrataOncology) July 18, 2018 (https://twitter.com/StrataOncology/status/1019580281458749440?ref_src=twsrc%5Etfw)

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"We are pleased to partner with Puma Biotechnology to accelerate the path to new approvals for neratinib," said Dan Rhodes, Ph.D., CEO of Strata Oncology. "We frequently identify HER2-mutant patients across the Strata Precision Oncology Network and we believe this partnership will greatly facilitate patient access to this promising clinical trial."

"Puma's ultimate goal is to deliver new treatment options and improve the lives of patients with various types of cancer," said Alshad S. Lalani, V.P., Translational Medicine of Puma Biotechnology. "We believe Puma's partnership with Strata will help us reach patients with multiple tumor types who may not otherwise know about the SUMMIT study, giving them a chance to participate in research that's designed to provide important new information for future treatment."

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://ii.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

Cover image: Colour-enhanced scanning electron micrograph image of a breast cancer cell. (Technical Details) Image B0006522 from the 2006 Collection: Wellcome Images Copyrighted work available under Creative Commons by-nc-nd 2.0 UK: England & Wales, see <http://images.wellcome.ac.uk/indexplus/page/Prices.html>

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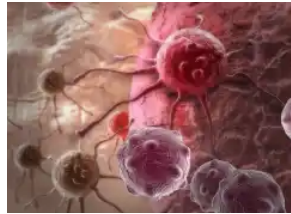
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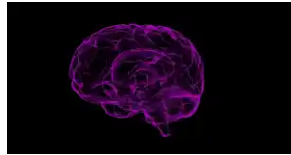
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