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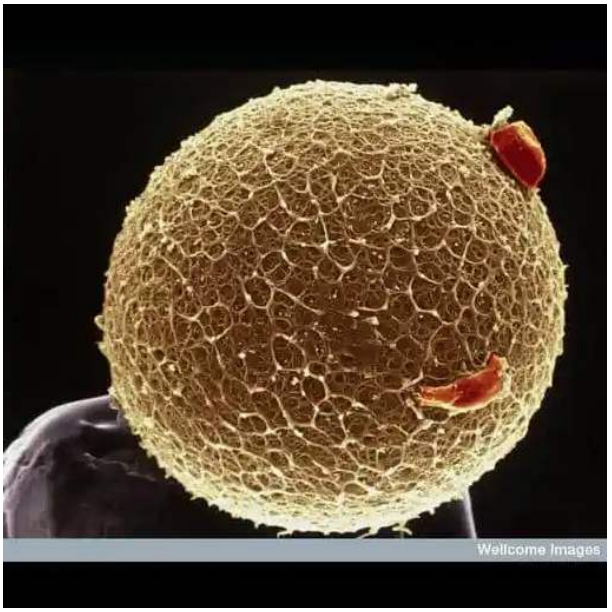
Onco-this-Week

November 24, 2018(https://sciwri.club/archives/date/2018/11/24)



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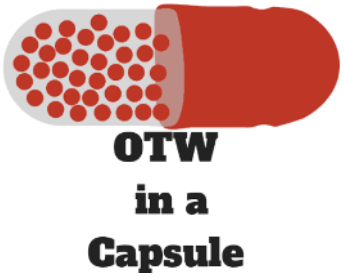
In the current edition of Onco-this-Week, check out the news about FDA approval of Roche's Venetoclax and Pfizer's Glasdegib in treating AML patients. There is more encouraging news for AML patients with GlycoMimetics beginning phase 3 trial for uproleselan. Another highlight is Poseida's P-BCMA-101 getting FDA's RMAT Status for Treatment of Multiple Myeloma. Also making news is BioLineRx announcing receipt of FDA Biological Product Designation for a Novel Cancer Immunotherapy Candidate AGI134. In a setback, Pfizer's Avelumab alone or in combination did not induce a statistically significant improvement in overall survival or PFS in patients with therapy-resistant/-refractory ovarian cancer. In our trivia section, find out more about Biosimilars and how they differ from generics. There is even more oncology news from across the world and conference updates from recently concluded annual meeting of the Society for Neuro-Oncology. -Abhi Dey



1. **Dual approvals in elderly AML patients this week.** Frontline frail elderly AML patients who are ineligible for intensive induction chemotherapy (due to age or a coexisting medical conditions) got two approvals this week – first one of Bcl-2 inhibitor Venetoclax in combination with hypomethylating agents (an accelerated approval), and the other one of Glasdegib (hedhehog pathway inhibitor) in combination with low-dose cytarabine. Glasdegib warrants special attention since it showed the clinical benefit in a Ph II randomized trial. Nonetheless, both approvals marked a significant day in the treatment paradigm of elderly AML patients.
2. **Roche's withdrawal of Atezolizumab's application to EMA in RCC patients.** Roche had spoken of IMmotion 151 study data as encouraging and filed application to EMA based on PFS improvement earlier when OS data was immature; however, in a recent change of stance this week, Roche pulled out the application to EMA. The decision could very well be based on the competitor's OS data (supporting Pemrolizumab + Axitinib's recent approval; or Nivolumab + Ipilimumab's EU approval etc.). It would be interesting to see how the OS data, once it matures, fares against these competitors.
3. **Failure of JAVELIN ovarian 200 trial of Avelumab +/- PLD in patients with platinum-resistant or -refractory**

ovarian cancer. Ovarian cancer patients who are resistant or refractory to platinum chemotherapy are a challenging group to treat. This patient segment has very few treatment options to try and hence a lot of hope was pinned on Avelumab to see if it could become the first checkpoint inhibitor to benefit such patients and could replicate IO success of lung cancer, melanoma or urothelial cancer. However, its failure to demonstrate significant OS (or even PFS) improvement only highlights the challenges these patients fail. It also marks a hat trick of failure for Avelumab after gastric cancer and NSCLC disappointments in 2017 and early 2018.

DRUG APPROVALS

Venetoclax + hypomethylating agent (azacitidine or decitabine) or low dose cytarabine (LDAC) get FDA approval for the treatment of frontline elderly AML patients (https://www.roche.com/media/releases/med-cor-2018-11-21.htm)

> Is venetoclax a game changer in AML therapy? https://t.co/KPdqhiqvGV (https://t.co/KPdqhiqvGV) pic.twitter.com/jSTfl5uxt4 (https://t.co/jSTfl5uxt4)
>
> — Oncology Tube (@oncologytube) November 14, 2018 (https://twitter.com/oncologytube/status/1062769797887225856?ref_src=twsrc%5Etfw)

"Today's approval marks a significant advance for people with acute myeloid leukemia, a highly aggressive and difficult-to-treat blood cancer," said Sandra Horning, MD, Roche's Chief Medical Officer and Head of Global Product Development. "Many people with acute myeloid leukemia are unable to tolerate standard intensive chemotherapy, and the Venclexta combination regimens represent important new options for these patients."

Glasdegib + low-dose cytarabine (LDAC) gets FDA approval in frontline elderly AML patients (https://www.pfizer.com/news/press-release/press-release-detail/u_s_fda_approves_daurismo_glasdegib_for_adult_patients_with_newly_diagnosed_acute_myeloid_leukemia_aml_for_whom_intensive_chemo

"As our second medicine approved in the last 14 months for patients with acute myeloid leukemia, DAURISMO reinforces our commitment to delivering new medicines to patients living with some of the most difficult-to-treat cancers, especially those for which there are limited treatment options available," said Andy Schmeltz, Global President, Pfizer Oncology. "We are proud to now offer these patients for whom intensive chemotherapy is not an option a new oral medicine, taken in combination with low-dose chemotherapy, that may improve their chances of survival."

> #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) approves #glasdegib (https://twitter.com/hashtag/glasdegib?src=hash&ref_src=twsrc%5Etfw) for #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) https://t.co/BcThtnT8sn (https://t.co/BcThtnT8sn) #leukemia (https://twitter.com/hashtag/leukemia?src=hash&ref_src=twsrc%5Etfw) #Daurismo (https://twitter.com/hashtag/Daurismo?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/dxhYUYgQoD (https://t.co/dxhYUYgQoD)
>
> — HematologyTimes.com (@HematologyTimes) November 21, 2018 (https://twitter.com/HematologyTimes/status/1065340710327595008?ref_src=twsrc%5Etfw)

“The randomized Phase 2 study, which formed the basis for today’s approval, included patients with cardiac disease or mild to moderate kidney disease, who are often excluded from clinical trials,” said Jorge Cortes, M.D., deputy chair and professor of medicine in the Department of Leukemia, University of Texas, MD Anderson Cancer Center. “In the trial, DAURISMO plus low-dose chemotherapy reduced the risk of death during the study period by 54 percent compared to chemotherapy alone. This provides a much-needed treatment for those patients for whom intensive chemotherapy is not an option.”

REGULATORY NEWS

Priority review granted to FLT3i Quizartinib for R/R FLT3-ITD AML patients based on results of Ph III QuANTUM-R trial; PDUFA: May 25, 2019 (https://www.prnewswire.com/news-releases/fda-grants-priority-review-for-daiichi-sankyos-new-drug-application-for-flt3-inhibitor-quizartinib-for-treatment-of-patients-with-relapsedrefractory-flt3-itd-aml-300754221.html)

> FDA Grants Quizartinib Priority Review for FLT3-ITD+ AML https://t.co/4BU10ko8gb (https://t.co/4BU10ko8gb) #Leusm (https://twitter.com/hashtag/Leusm?src=hash&ref_src=twsrc%5Etfw)
>
> — Silas Inman (@SilasInman) November 22, 2018 (https://twitter.com/SilasInman/status/1065454959968337922?ref_src=twsrc%5Etfw)

“If approved, quizartinib has the potential to meaningfully advance treatment for patients with relapsed or refractory FLT3-ITD AML. Patients need more treatment options for this type of AML, which is particularly aggressive and difficult to treat. We are pleased that the FDA has filed our application for quizartinib for patients with relapsed or refractory FLT3-ITD AML, and granted priority review,” said Arnaud Lesegretain, Vice President, Oncology Research and Development and Head, AML Franchise, Daiichi Sankyo. “Coupled with the recent acceptances of marketing applications for quizartinib in Japan and EU, we look forward to working with regulatory authorities in the U.S., Japan and EU to bring quizartinib to patients.”

EMA grants accelerated assessment to ELZONRIS (tagraxofusp; SL-401) MAA for the treatment of patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) (https://www.stemline.com/newsArticleDetails.asp?id=206)

> Investigational Drug Shows Promising Results in Phase II Study of Aggressive Fatal Blood Disorder: NewsA Phase III study reports an investigational drug called tagraxofusp has demonstrated high response rates in patients with... https://t.co/thgA2Tml13 (https://t.co/thgA2Tml13) #drugs (https://twitter.com/hashtag/drugs?src=hash&ref_src=twsrc%5Etfw) #prescriptiondrugs (https://twitter.com/hashtag/prescriptiondrugs?src=hash&ref_src=twsrc%5Etfw)
>
> — Prescription Drugs News & Research (@PrescriptionBio) November 14, 2018 (https://twitter.com/PrescriptionBio/status/1062791033266663424?ref_src=twsrc%5Etfw)

Ivan Bergstein, M.D., Stemline’s CEO, commented, “The granting of accelerated assessment to the ELZONRIS planned MAA underscores the robust clinical data, clear unmet medical need, and the heightened awareness of BPDCN worldwide. We look forward to working closely with the EMA to ensure that this important new treatment reaches patients in the European Union as quickly as possible. In the U.S., we are continuing our interactions with the FDA, and our commercial team is poised to rapidly execute a U.S. launch following possible approval of ELZONRIS for BPDCN.”

CHMP issues positive opinion on split dosing regimen for daratumumab based on data from the Ph Ib EQUULEUS (MMY1001) trial (https://ir.genmab.com/news-releases/news-release-details/chmp-issues-positive-opinion-split-dosing-regimen-darzalexr)

> #ASH (https://twitter.com/hashtag/ASH?src=hash&ref_src=twsrc%5Etfw) data helps cement #Darzalex (https://twitter.com/hashtag/Darzalex?src=hash&ref_src=twsrc%5Etfw)‘s place in #multiple (https://twitter.com/hashtag/multiple?src=hash&ref_src=twsrc%5Etfw)-myeloma #standard (https://twitter.com/hashtag/standard?src=hash&ref_src=twsrc%5Etfw)-of-care https://t.co/JUBBjPvL27 (https://t.co/JUBBjPvL27) via @BioPharmaDive (https://twitter.com/BioPharmaDive?ref_src=twsrc%5Etfw)
>
> — SelectClinicalTrials (@AngelaStrongSCT) November 21, 2018 (https://twitter.com/AngelaStrongSCT/status/1065335790312595456?ref_src=twsrc%5Etfw)

“We are very pleased to receive this positive opinion from the CHMP as it is a step closer to potentially providing a more flexible dosing option to multiple myeloma patients in Europe who are receiving their initial infusion of DARZALEX,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

Positive CHMP opinion to ribociclib in HR-positive, HER2-neg advanced or metastatic breast cancer based on Ph III MONALEESA-3 and-7 trials data (https://www.novartis.com/news/media-releases/novartis-receives-positive-chmp-opinion-expand-kisqali-combination-therapy-all-women-hrher2-locally-advanced-or-metastatic-breast-cancer)

> #OncologyNews (https://twitter.com/hashtag/OncologyNews?src=hash&ref_src=twsrc%5Etfw) MONALEESA-2 Subgroup Results of First-Line Ribociclib in Advanced, HR+ #BreastCancer (https://twitter.com/hashtag/BreastCancer?src=hash&ref_src=twsrc%5Etfw) https://t.co/h6uNTQPvkZ (https://t.co/h6uNTQPvkZ) pic.twitter.com/4UboekqvXf (https://t.co/4UboekqvXf)
>
> — Elsevier Oncology (@ELS_Oncology) November 22, 2018 (https://twitter.com/ELS_Oncology/status/1065560785097756672?ref_src=twsrc%5Etfw)

"Today's CHMP opinion brings us one step closer to providing more women with HR+/HER2- advanced breast cancer in Europe with a treatment option," said Liz Barrett, CEO, Novartis Oncology. "The MONALEESA Phase III program enrolled more than 2,000 women, giving Kisqali by far the most extensive first-line evidence in clinical trials among any of the CDK4/6 inhibitors. This is another testament to how we are reimagining cancer."

TRIAL RESULTS

ESMO Asia 2018: Cetuximab + chemotherapy showed promising data in Ph III CHANGE II trial in Chinese patients with 1L SCCHN (https://www.merckgroup.com/content/dam/web/corporate/non-images/press-releases/2018/nov/en/CHANGE-II-ESMOAsia-Global-Press-Release-en.pdf?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)

"We are hopeful these results will help to bring the EXTREME regimen to China in a patient population where an unmet need for wider and more efficacious options in first-line treatment still exists," said Professor Ye Guo, Shanghai East Hospital, Tongji University, China. "The CHANGE II study has demonstrated superior results for the EXTREME regimen specifically for Chinese patients with recurrent or metastatic squamous cell carcinoma of the head and neck when compared with standard chemotherapy treatment – the current standard of care in China."

"We are excited about these positive results from the CHANGE II study confirming the role of ERBITUX® and the EXTREME regimen for Chinese patients," said Luciano Rossetti, Head of Global Research & Development at the Biopharma business of Merck. "We are now planning interactions with the Chinese National Medical Products Administration (NMPA) to discuss how best to make this treatment formally available to Chinese patients, continuing our commitment to bring transformative cancer treatments to patients who can benefit from them most."

SNO 2018: Updated interim data from Ph III trial of DCVax®-L for Glioblastoma announced (https://www.nwbio.com/updated-interim-data-phase-3-trial-dcvax-l-glioblastoma/)

Ms. Powers, CEO of NWBio commented "We are excited to see how the data are maturing, and we are grateful to our Scientific Advisory Board for their strong advice not to unblind the trial too early. Had we unblinded earlier, the opportunity to see the fuller extent of patient survival would have been lost, and the potential would never have been known."

> Updated Interim Data from Phase 3 Trial of DCVax®-L for Glioblastoma Presented at Society for Neuro-Oncology Co.. https://t.co/2jxxirRDYD (https://t.co/2jxxirRDYD)
>
> — Financial Buzz (@financialbuzz) November 22, 2018 (https://twitter.com/financialbuzz/status/1065488400738742272?ref_src=twsrc%5Etfw)

"Until we reach data lock, the data will continue to mature. As we have cautioned before, the data may get either better or worse as they further mature. Also, the interim data are blinded aggregate data, and we do not know the breakdown between the treatment arm and the control arm of the trial."

Ms. Powers continued: "We believe it is now appropriate for the Company to move forward with the several stages of work that are needed to reach completion of this trial program, despite the fact that there are good arguments for allowing the data to mature even further. The upcoming stages include finalizing the Statistical Analysis Plan, conducting the final data collection, data validation and data lock, and then unblinding and analyzing the data.

"Each of these are multi-month processes, and will involve tremendous work by both our team and teams of outside experts. In addition, virtually all aspects of the Company's work involve pioneering. There is no well established pathway, and any projections or predictions are subject to material changes as we go along."

SNO 2018: Controlled IL-12 update announced with positive data from Ph I trial (https://ir.ziopharm.com/news-releases/news-release-details/ziopharm-oncology-provides-controlled-il-12-update-positive-data)

> $ZIOP (https://twitter.com/search?q=%24ZIOP&src=ctag&ref_src=twsrc%5Etfw) Ziopharm Oncology Provides Controlled IL-12 Update with Positive Data from Phase 1 Trial Presented at SNO ... $ONCS (https://twitter.com/search?q=%24ONCS&src=ctag&ref_src=twsrc%5Etfw)
>
> — BioBreakout (@BioBreakout) November 16, 2018 (https://twitter.com/BioBreakout/status/1063518775390154753?ref_src=twsrc%5Etfw)

"Glioblastoma at recurrence is a dreadful cancer with few treatment options that have demonstrated success. These updated data show a promising extension of patients' survival and demonstrate how controlling the powerful

cytokine IL-12 can engage the body's own immune system to generate an anti-tumor response against rGBM," said Dr. Antonio Chiocca, M.D., Ph.D., lead author of this poster and Professor of Neurosurgery at Harvard Medical School, Surgical Director of the Center for Neuro-oncology at Dana-Farber Cancer Institute, and Chairman of Neurosurgery and Co-Director of the Institute for the Neurosciences at Brigham and Women's Hospital.

Updated data announced from Ph I dose escalation trial of IDH1/2 inhibitor AG-881 in IDH+ glioma patients (http://investor.agios.com/news-releases/news-release-details/agios-presents-updated-data-phase-1-dose-escalation-study-ag-881)

> Today at #SNO18 (https://twitter.com/hashtag/SNO18?src=hash&ref_src=twsrc%5Etfw), we presented updated data from Phase 1 dose-escalation study of AG-881 in patients with IDH mutant positive advanced #glioma (https://twitter.com/hashtag/glioma?src=hash&ref_src=twsrc%5Etfw) https://t.co/fc8voSBd9Q (https://t.co/fc8voSBd9Q) pic.twitter.com/2CV7uMoi22 (https://t.co/2CV7uMoi22)
>
> — Agios (@AgiosPharma) November 16, 2018 (https://twitter.com/AgiosPharma/status/1063440813735186435?ref_src=twsrc%5Etfw)

"With additional follow-up, the AG-881 Phase 1 dose-escalation data continue to show a favorable safety profile at the doses selected for the perioperative study. Longer treatment duration and a reduction in tumor growth rates are encouraging signs of clinical activity in low-grade glioma," said Ingo Mellinghoff, M.D., Memorial Sloan Kettering Cancer Center, an investigator for the study. "Ultimately, use of an IDH inhibitor in this difficult-to-treat disease has the potential to improve the current treatment paradigm by delaying the multiple rounds of surgery, radiation and chemotherapy that many patients endure."

"With no curative or approved targeted therapies and a high frequency of IDH1 mutations in low-grade glioma, we are committed to advancing one of our IDH inhibitors to a registrational study in this disease," said Chris Bowden, M.D., chief medical officer at Agios. "We are continuing to collect clinical data for both ivosidenib and AG-881, along with feedback from regulators and the neuro-oncology community, to make an internal decision on our glioma pivotal strategy by the end of this year."

FAILED TRIAL: Ph II trial of BER pathway inhibitor TRC102 + Temozolomide in recurrent GBM patients failed to meet primary endpoint of ORR (https://traconpharma.gcs-web.com/news-releases/news-release-details/tracon-pharmaceuticals-presents-data-phase-2-trial-trc102-and)

> TRACON Pharma presents mixed results of Ph2 #clinicaltrial (https://twitter.com/hashtag/clinicaltrial?src=hash&ref_src=twsrc%5Etfw) of TRC102 + Temodar vs recurrent #glioblastoma (https://twitter.com/hashtag/glioblastoma?src=hash&ref_src=twsrc%5Etfw) at #SNO2018 (https://twitter.com/hashtag/SNO2018?src=hash&ref_src=twsrc%5Etfw)
>
> Combo tolerable but did not meet primary OR endpoint; will look for prognostic #biomarkers (https://twitter.com/hashtag/biomarkers?src=hash&ref_src=twsrc%5Etfw)https://t.co/Rsx11QUS6O (https://t.co/Rsx11QUS6O)#oncology (https://twitter.com/hashtag/oncology?src=hash&ref_src=twsrc%5Etfw) #biopharma (https://twitter.com/hashtag/biopharma?src=hash&ref_src=twsrc%5Etfw) #cancer (https://twitter.com/hashtag/cancer?src=hash&ref_src=twsrc%5Etfw) @NeuroOnc (https://twitter.com/NeuroOnc?ref_src=twsrc%5Etfw) pic.twitter.com/boEbOmctqe (https://t.co/boEbOmctqe)
>
> — DDNews Online (@DDNewsOnline) November 19, 2018 (https://twitter.com/DDNewsOnline/status/1064579307241009152?ref_src=twsrc%5Etfw)

"We recognized that the primary endpoint of objective response in the Phase 2 trial of Temodar and TRC102 represented a high efficacy hurdle, that of resensitizing recurrent glioblastoma patients to Temodar treatment. We were encouraged to see certain patients demonstrate prolonged clinical benefit that was associated with evidence of activation of the BER pathway of resistance that is inhibited by TRC102," said Dr. Charles Theuer, President and CEO of TRACON Pharmaceuticals. "Our efforts will continue to focus on identifying possible biomarkers that are prognostic of response to TRC102 in four ongoing clinical trials supported by the National Cancer Institute."

FAILED TRIAL: Ph III JAVELIN ovarian 200 trial of Avelumab +/- PLD did not meet primary endpoint of OS or PFS in patients with platinum-resistant or -refractory ovarian cancer (https://www.merckgroup.com/content/dam/web/corporate/non-images/press-releases/2018/nov/en/JAVELIN-Ovarian-200-Press-Release-EN.pdf?utm_source=press-release&utm_medium=email&utm_campaign=press-mailer&utm_content=en)

> Avelumab alone or in combination with PLD did not induce a statistically significant improvement in overall survival or PFS versus PLD alone in patients with platinum-resistant/-refractory ovarian cancer #gyncsm (https://twitter.com/hashtag/gyncsm?src=hash&ref_src=twsrc%5Etfw) #ovca (https://twitter.com/hashtag/ovca?src=hash&ref_src=twsrc%5Etfw) https://t.co/DKV2URQPX0 (https://t.co/DKV2URQPX0)
>
> — OncLive.com (@OncLive) November 21, 2018 (https://twitter.com/OncLive/status/1065089934476918784?ref_src=twsrc%5Etfw)

"JAVELIN Ovarian 200 enrolled a high proportion of patients with aggressive, refractory disease that had no response to prior platinum-based chemotherapy, a population known to have disease that is challenging to treat; as

such, this group of patients is typically not included in Phase III ovarian cancer trials," said Chris Boshoff, M.D., Ph.D., Senior Vice President and Head of Immuno-Oncology, Early Development and Translational Oncology, Pfizer Global Product Development. "We initiated the JAVELIN Ovarian 200 trial as the first Phase III study of a checkpoint inhibitor in the platinum-resistant or -refractory setting recognizing these patients have the most pressing need for new treatment options. The results speak to the significant challenges these women face."

"Although OS and PFS did not reach statistical significance, study results indicate potential clinical activity of the combination of avelumab and chemotherapy which will be analyzed further," said Luciano Rossetti, M.D., Executive Vice President, Global Head of Research & Development at the Biopharma business of Merck. "We thank the patients, their families and the investigators who participated in the JAVELIN Ovarian 200 trial, and wish to underscore that the alliance remains committed to driving advances in ovarian cancer, a commitment that includes two ongoing Phase III trials in previously untreated patients testing avelumab in combination with chemotherapy and, separately, one in combination with chemotherapy followed by maintenance treatment of avelumab in combination with a PARP inhibitor."

SPECIAL STATUSES

Novel cancer immunotherapy candidate AGI-134 receives FDA Biological Product designation (http://www.biolinerx.com/default.asp?pageid=16&itemid=638)

> BioLineRx Announces Receipt of FDA Biological Product Designation for Novel Cancer Immunotherapy Candidate AGI134: Tel Aviv Israel November 20 2018 BioLineRx Ltd. NASDAQTASE BLRX a clinical stage biopharmaceutical company focused on oncology and... https://t.co/aBRJF7ZbxX (https://t.co/aBRJF7ZbxX) pic.twitter.com/rDdFvkskjx (https://t.co/rDdFvkskjx)
>
> — Clinical Trials News (@ClinicalPhase) November 20, 2018 (https://twitter.com/ClinicalPhase/status/1064957330402369536?ref_src=twsrc%5Etfw)

"We are extremely pleased to receive the FDA's Biological Product Designation for AGI-134, our second lead oncology asset. This classification as a biological product is very significant, since it provides us with additional valuable exclusivity and confirms the FDA's acceptance of AGI-134's main mechanism of action as a vaccine," said Philip Serlin, Chief Executive Officer of BioLineRx. "Pre-clinical studies have demonstrated that treatment with AGI-134 leads to complete regression of primary tumors, prevents growth of untreated distal secondary tumors, and triggers a vaccine effect that may prevent the development of future metastases. Furthermore, in prior studies, the combination of AGI-134 with an anti-PD-1 immune checkpoint inhibitor demonstrated a synergistic effect in protection from secondary tumor growth. We recently initiated a Phase 1/2a study of this promising product in solid tumors, as both monotherapy and in combination with checkpoint inhibitors, and we anticipate initial top-line results from this important study by the end of 2020."

RMAT designation granted to BCMA-targeting CART P-BCMA-101 (https://poseida.com/2018/11/05/poseida-therapeutics-receives-regenerative-medicine-advanced-therapy-rmat-designation-from-fda-for-p-bcma-101/)

> FDA Grants Poseida's P-BCMA-101 RMAT Status for Treatment of Multiple Myeloma https://t.co/OZjmYDuAa2 (https://t.co/OZjmYDuAa2) pic.twitter.com/LqofD8FweC (https://t.co/LqofD8FweC)
>
> — BioNews Services (@bionewsservices) November 20, 2018 (https://twitter.com/bionewsservices/status/1064768503834705920?ref_src=twsrc%5Etfw)

"P-BCMA-101 is the first anti-BCMA CAR-T therapy to receive RMAT designation from the FDA and underscores the urgent need for new treatment options for multiple myeloma," said Eric Ostertag, M.D., Ph.D., chief executive officer of Poseida Therapeutics. "Initial Phase 1 data presented at the CAR-TCR Summit earlier this year included encouraging response rates and safety data, including meaningful responses in a heavily pretreated population, with some patients reaching VGPR and stringent CR. We expect to have an additional data update by the end of the year and look forward to working closely with the FDA to expedite development of P-BCMA-101."

TRIAL STATUSES

Ph 1b/II trial evaluating DPX-survivac + epacadostat in recurrent ovarian cancer patients amended – trial to continue as monotherapy (https://ir.imv-inc.com/news-releases/news-release-details/imv-moves-develop-dpx-survivac-monotherapy-recurrent-ovarian)

> In Canada, IMV @imv_inc (https://twitter.com/imv_inc?ref_src=twsrc%5Etfw) shares rising almost 10% today — after our 3 years of TCR coverage (The Calandra Report) of Halifax# immunotherapy# lab's Phase II step for DPX-Survivac as a mono-therapy vs. (and in cooperation with) Incyte# epacadostat IDO inhibitor re: ovarian cancer
>
> — Thom Calandra (@thomcalandra) November 22, 2018 (https://twitter.com/thomcalandra/status/1065700334830411776?ref_src=twsrc%5Etfw)

"The goal of the trial was to evaluate combination therapies. However, the new data indicate that DPX-Survivac

shows activity as a monotherapy in late-stage patients, which can potentially translate into clinical benefit," said Frederic Ors, Chief Executive Officer, IMV. "In parallel to the amended monotherapy trial, we will continue to investigate other combinations with our lead product candidate as we continue our work to deliver new immunotherapy options that may benefit more patients in multiple cancers."

"We are very pleased that the phase 1b trial results to date validate the mechanism of action of DPX-Survivac, helping us to identify patients more likely to benefit from our drug candidate," said Gabriela Nicola Rosu, MD, Chief Medical Officer at IMV. "Identifying which patients have the greatest potential for responding to a drug candidate is key for the success of immunotherapy clinical trials, and we look forward to continued work with investigators and trial sites to advance the study of DPX-Survivac to help address the significant unmet medical needs of these patients."

First patient enrolled in Ph III trial of E-selectin inhibitor Uproleselan in R/R AML patients (https://ir.glycomimetics.com/news-releases/news-release-details/glycomimetics-enrolls-first-patient-global-phase-3-clinical)

> GlycoMimetics begins phase 3 AML trial for uproleselanhttps://t.co/zpTQrVSRHJ (https://t.co/zpTQrVSRHJ)
>
> — mediFuture.ca (@MedifutureCa) November 22, 2018 (https://twitter.com/MedifutureCa/status/1065647423123529728?ref_src=twsrc%5Etfw)

"The dosing of the first patient in our pivotal Phase 3 trial for uproleselan is an important milestone for GlycoMimetics," said Helen Thackray, M.D., FAAP, Senior Vice President, Clinical Development, and Chief Medical Officer of GlycoMimetics. "This is a rigorously designed Phase 3 trial that has the potential to bring us one step closer to meeting the significant unmet needs of individuals living with relapsed/refractory AML. The trial is an important component of our comprehensive late-stage development program for uproleselan that positions us to evaluate the use of our product candidate across the spectrum of AML. It is the first of three randomized, controlled trials for uproleselan in AML, which we believe should provide clear efficacy and safety outcome measures in each of the settings being assessed."

"Our clinical development pipeline sets us up for multiple, value-creating clinical data readouts," added Rachel K. King, GlycoMimetics Chief Executive Officer. "During 2019, we anticipate topline data from the Phase 3 study of rivipansel being conducted by Pfizer in patients with sickle cell disease. Then, beginning at the end of 2020, we expect to generate topline data from the several trials that we will have underway in AML."

Enrolment completed in Ph III INVICTUS trial of KIT/PDGFRα dual inhibitor, DCC-2618, in advanced GIST patients (https://investors.deciphera.com/news-releases/news-release-details/deciphera-pharmaceuticals-completes-enrollment-invictus-pivotal)

> Suzanne George presenting our data on DCC-2618 in #gist (https://twitter.com/hashtag/gist?src=hash&ref_src=twsrc%5Etfw) @ctosociety (https://twitter.com/ctosociety?ref_src=twsrc%5Etfw) . Looks promising! pic.twitter.com/bTe9B83HQP (https://t.co/bTe9B83HQP)
>
> — Jon Trent, MD, PhD (@JTrentMDPhD) November 15, 2018 (https://twitter.com/JTrentMDPhD/status/1063099206959804417?ref_src=twsrc%5Etfw)

"We are very pleased to have completed enrollment in the INVICTUS pivotal Phase 3 study, initiated in January 2018. We expect to report top-line data from this randomized, double-blind study in mid-2019 and, if successful, we believe the results would support a New Drug Application (NDA) for full approval in fourth-line and fourth-line-plus GIST patients," said Michael D. Taylor, Ph.D., President and Chief Executive Officer of Deciphera. "Currently there are no treatments approved for fourth-line and fourth-line-plus GIST and we are grateful to those patients who participated in our study and to the GIST community for its support. In addition, we look forward to initiating later this year a second pivotal Phase 3 study, the INTRIGUE study, in second-line GIST patients who have progressed or are intolerant to front-line therapy with imatinib, including those with any KIT or PDGFRα mutation."

COLLABORATIONS

Zenith Epigenetics and Pfizer to evaluate ZEN-3694 in combination with Talazoparib in TNBC patients (https://www.zenithepigenetics.com/newsroom/news-releases?article=28)

"Zenith is excited to announce this partnership with Pfizer, a leader in oncology," said Don McCaffrey, Chief Executive Officer of Zenith. "This novel approach of combining a BETi and a PARPi in patients who do not have inherited BRCA gene mutations may prove to significantly increase the potential of PARP inhibition in different indications, with an initial focus on triple negative breast cancer."

> Pfizer and Zenith Epigenetics Collaborates to Evaluate ZEN-3694 & Talazoparib for TNBC @Pfizer (https://twitter.com/pfizer?ref_src=twsrc%5Etfw) https://t.co/ud17afoXiD (https://t.co/ud17afoXiD) pic.twitter.com/loUT23eerJ (https://t.co/loUT23eerJ)
>
> — PharmaShots (@Pharmashot) November 22, 2018 (https://twitter.com/Pharmashot/status/1065524339271884801?ref_src=twsrc%5Etfw)

OTW Trivia

Q: What is a biosimilar? What is a generic drug?

A: A biosimilar drug is a biological drug that is approved based on demonstration of non-inferior efficacy or safety from a FDA-approved biological drug (***reference drug***). Biosimilar drugs may have some clinically inactive components though.

Generic drugs are copies of small molecules and can be chemically synthesized to mimic the structure of reference drug. However, biologics are large and complex molecules and hence cannot be replicated easily.

Q: What is the difference in process of development of a biosimilar and a generic drug?

A: The process of development of biosimilars and generics is very different due to different levels of complexities in replicating their structure. A generic molecule can be made much faster and a substantially lower cost than a biosimilar molecule, which in turn is faster and cheaper than a new medicine.

Q: Why developing a generic takes lesser time than a biosimilar?

A: Generics only have to go through bioequivalence studies after the analytical assessment. On the other hand, biosimilars have to take analytical, nonclinical, clinical/pharmacological tests before they can be assessed in clinical trials.

Q: Which is an example of a recent biosimilar approval in Oncology?

A: A recent example would be Pfizer's TRAZIMERA, a trastuzumab biosimilar receiving EU approval in HER2-overexpressing breast cancer and metastatic gastric or GEJ adenocarcinoma.

Source: *https://www.pfizerbiosimilars.com/characteristics-of-biosimilars (https://www.pfizerbiosimilars.com/characteristics-of-biosimilars)*

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

Cover image: (CellImageLibrary) Colorized scanning electron micrograph of a human egg. The egg is surrounded by a glycoprotein coat called the zona pellucida which aids in trapping and binding the sperm. Two residual coronal cells from the ovarian follicle are attached to the zona pellucida. The egg is sitting on the point of a pin. Yorgos Nikas (2012) CIL:38990, Homo sapiens, corona radiata cell, egg cell. CIL. Dataset. https://doi.org/doi:10.7295/W9CIL38990 Source (http://flagella.crbs.ucsd.edu/images/38990)

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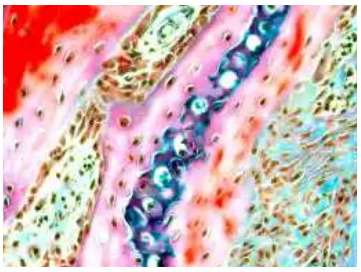

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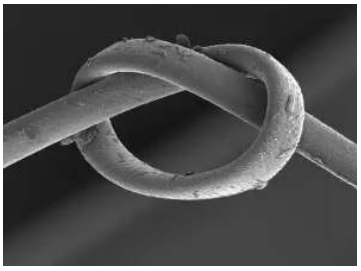

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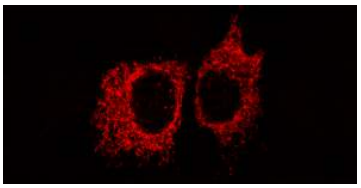

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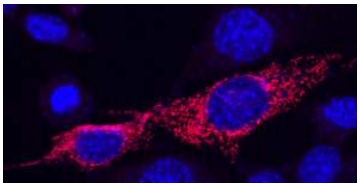

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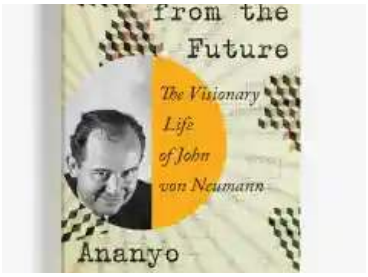

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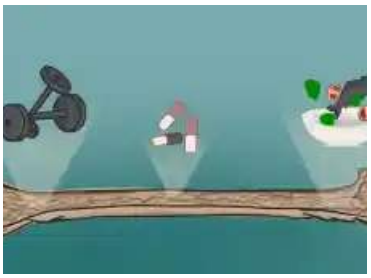

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