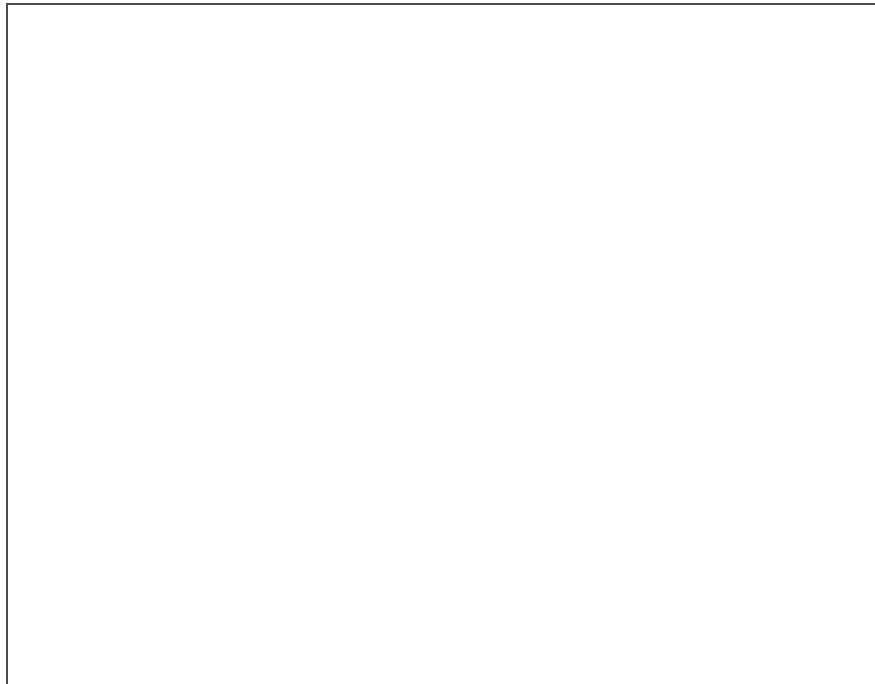


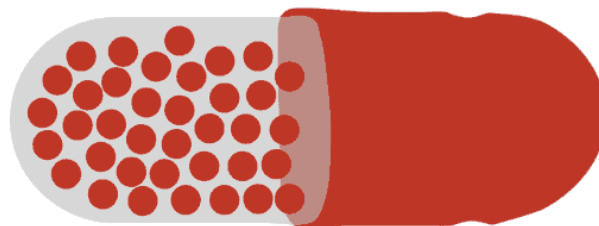
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## Onco-this-Week

March 24, 2019(<https://sciwri.club/archives/date/2019/03/24>)



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## OTW in a Capsule

### HIGHLIGHTS

1. **Discontinuation of Ph III Javelin Ovarian PARP 100 trial.** The December 2018 review of trial brought dismal news when Merck and Pfizer realized the trial would not meet the primary endpoint of PFS improvement, definitely not in all comers. Added with the changing competitive landscape (read Olaparib's recent approval in BRCA mutated patients), the companies decided to call it quits in 1L maintenance ovarian cancer settings. The breather was absence of any safety concerns with the combination of Avelumab, chemotherapy and Talazoparib.
2. **Approval of Atezolizumab + chemotherapy in 1L ED-SCLC patients.** Atezolizumab yet again registers another 'first' in by gaining foothold in 1L ED-SCLC patients just couple of days after its success in TNBC patients. Both SCLC and TNBC are aggressive conditions lacking therapeutic options, and Atezolizumab hits it big by emerging as first FDA-approved immunotherapy in respective patient segments.
3. **Partial clinical hold on all trials of Venetoclax in Multiple Myeloma.** FDA decided to place a partial hold on all Venetoclax trials in multiple myeloma post follows a review of data from the ongoing Ph III BELLINI trial in

relapsed/refractory multiple myeloma patients. The concern arose from higher number of deaths in Venetoclax arm compared to control arm (13 vs 1), prompting the regulatory agency to decide on the hold. Additional analyses of BELLINI trial data are ongoing and the results will decide the outcome of Venetoclax in multiple myeloma space.

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#### DRUG APPROVALS

FDA approves Atezolizumab + chemotherapy in 1L ED-SCLC patients based on Ph III IMpower133 results (<https://www.gene.com/media/press-releases/14783/2019-03-18/fda-approves-genentechs-tecentriq-in-com>)

Atezolizumab now FDA approved for first line treatment of ES-SCLC with carboplatin and etoposide based on IMpower 133: improvement in overall survival (HR 0.70), first in decades. Extremely proud to have been a part of this pivotal study. #LCSM ([https://twitter.com/hashtag/LCSM?src=hash&ref\\_src=twsrc%5Etfw](https://twitter.com/hashtag/LCSM?src=hash&ref_src=twsrc%5Etfw))<https://t.co/wW6RclL56> (<https://t.co/wW6RclL56>)

— Stephen V Liu (@StephenVLiu) March 19, 2019 ([https://twitter.com/StephenVLiu/status/1107817867133755392?ref\\_src=twsrc%5Etfw](https://twitter.com/StephenVLiu/status/1107817867133755392?ref_src=twsrc%5Etfw))

"Tecentriq is the first cancer immunotherapy approved for the initial treatment of extensive-stage small cell lung cancer, which is especially difficult to treat," said Sandra Horning, M.D., chief medical officer and head of Global Product Development. "Until now, there have been limited treatment advances for this disease, and we are excited to bring a potential new standard of care to patients that has been shown to improve survival compared to chemotherapy."

"Extensive-stage small cell lung cancer is a highly aggressive form of lung cancer, which until now, has seen limited treatment advances over the last 20 years," said Andrea Ferris, president and CEO of LUNgevity Foundation. "Today's approval of Tecentriq is an important step forward in ensuring that people across the spectrum of lung cancer types have effective new therapies."

#### REGULATORY NEWS

Ph III trials of Pelareorep (AN1004) in breast cancer patients in China announced (<https://www.prnewswire.com/news-releases/adlai-nortye-receives-nmpa-approval-for-pelareorep-an1004-in-china-to-initiate-phase-iii-clinical-trials-300816327.html>)

Announcing biomarker data for treatment with pelareorep and a checkpoint inhibitor at AACR. Allows physicians to predict which patients are likely to respond to treatment, allowing for clinical studies that are cheaper, faster and more likely to succeed. <https://t.co/7uEAcsHizK> (<https://t.co/7uEAcsHizK>) <https://t.co/dnQniavZat> (<https://t.co/dnQniavZat>)

— Oncolytics Biotech (@Oncolytics) February 27, 2019 ([https://twitter.com/Oncolytics/status/1100877534407749632?ref\\_src=twsrc%5Etfw](https://twitter.com/Oncolytics/status/1100877534407749632?ref_src=twsrc%5Etfw))

Carsten Lu, Chairman and CEO of Adlai Nortye said: "The incidence of breast cancer ranks No. 1 among female malignant tumors in China. Adlai Nortye focuses on discovering and developing innovative treatments in cancer patients, trying to transform cancer into a chronic disease condition. The NMPA gave detailed and constructive

guidance to the pelareorep phase III clinical program. We are very pleased and encouraged by the result. We will launch the clinical trial to join our global partner Oncolytics Biotech Inc. when they initiate their phase III registration study. We will continue to bring more options to cancer patients.”

**Ph I trial of RET inh BLU-667 to be initiated in China** (<https://www.prnewswire.com/news-releases/cstone-receives-approval-in-china-to-initiate-phase-i-clinical-trial-for-ret-inhibitor-blu-667-cs3009-300816436.html>)

@VivekSubbiah ([https://twitter.com/VivekSubbiah?ref\\_src=twsrc%5Etfw](https://twitter.com/VivekSubbiah?ref_src=twsrc%5Etfw)) Discussing the 2 selective RET superhero drugs BLU-667 and LOXO-292 @ #TAT2019 ([https://twitter.com/hashtag/TAT2019?src=hash&ref\\_src=twsrc%5Etfw](https://twitter.com/hashtag/TAT2019?src=hash&ref_src=twsrc%5Etfw)). [pic.twitter.com/Bj7BXgKQHQ](https://t.co/Bj7BXgKQHQ) (<https://t.co/Bj7BXgKQHQ>)

— Robert C. Doebele (@rdoebele) February 27, 2019 ([https://twitter.com/rdoebele/status/1100742138185293824?ref\\_src=twsrc%5Etfw](https://twitter.com/rdoebele/status/1100742138185293824?ref_src=twsrc%5Etfw))

“BLU-667 has already demonstrated its potential to produce clinical responses in several RET-altered tumor types, and there are currently no selective RET inhibitors approved globally,” noted CStone Chairman and CEO Dr. Frank Jiang. “If the data generated in Chinese patients are consistent with global results, we plan to use the global and China data from the ARROW study to support NDA filings in China.”

**Partial clinical hold on all trials of Venetoclax in MM** (<https://news.abbvie.com/news/press-releases/abbvie-provides-update-on-venclxtenclxto-venetoclax-multiple-myeloma-program.htm>)

FDA issues partial hold on all ongoing clinical trials evaluating venetoclax in Multiple Myeloma due to excessive number of deaths in BELLINI study. <https://t.co/V1RvFtVklE> (<https://t.co/V1RvFtVklE>) [pic.twitter.com/ozhUx8UoyN](https://t.co/ozhUx8UoyN) (<https://t.co/ozhUx8UoyN>)

— Medscape (@Medscape) March 21, 2019 ([https://twitter.com/Medscape/status/1108733502957195264?ref\\_src=twsrc%5Etfw](https://twitter.com/Medscape/status/1108733502957195264?ref_src=twsrc%5Etfw))

“We are committed to patient safety and are thoroughly analyzing the results observed in the BELLINI trial. We will continue working with the FDA and worldwide regulatory agencies to determine appropriate next steps for the multiple myeloma program,” said Michael Severino, M.D., vice chairman and president, AbbVie. “We will continue to further the research and development of venetoclax and other therapies with the potential to transform the standards of care in blood cancers.”

**Type II variation application submitted for Daratumumab + Len-Dex in tL transplant-ineligible MM patients based on Ph III MAIA data** ([https://www.marketwatch.com/press-release/janssen-seeks-expanded-use-of-darzetax-daratumumab-combination-therapy-for-patients-with-newly-diagnosed-multiple-myeloma-who-are-transplant-ineligible-2019-03-22?mod=mw\\_quote\\_news](https://www.marketwatch.com/press-release/janssen-seeks-expanded-use-of-darzetax-daratumumab-combination-therapy-for-patients-with-newly-diagnosed-multiple-myeloma-who-are-transplant-ineligible-2019-03-22?mod=mw_quote_news))

“Today’s submission brings us one step closer to our goal of improving treatment outcomes for people newly diagnosed with multiple myeloma,” said José Antonio Burón Vidal, VP Medical Affairs, Europe, Middle East and Africa (EMEA), Janssen-Cilag Limited. “We are incredibly grateful to the patients and investigators who participated in the MAIA clinical trial programme and look forward to working closely with the regulatory authorities to secure approval of this new combination.”

**Ph III INNOVATE-3 trial of Tumor Treating Fields (TTFs) + Paclitaxel initiated in recurrent, platinum-resistant ovarian cancer patients** (<https://www.novocure.com/novocure-initiates-phase-3-pivotal-trial-in-recurrent-ovarian-cancer/>)

Novocure launches pivotal ovarian cancer trial. \$NVCR ([https://twitter.com/search?q=%24NVCR&src=ctag&ref\\_src=twsrc%5Etfw](https://twitter.com/search?q=%24NVCR&src=ctag&ref_src=twsrc%5Etfw)) <https://t.co/DAiK5qdN8p> (<https://t.co/DAiK5qdN8p>) [pic.twitter.com/7CfD7HPAex](https://t.co/7CfD7HPAex) (<https://t.co/7CfD7HPAex>)

— Drug Delivery News (@DrugDeliveryNow) March 22, 2019 ([https://twitter.com/DrugDeliveryNow/status/1109073403758166018?ref\\_src=twsrc%5Etfw](https://twitter.com/DrugDeliveryNow/status/1109073403758166018?ref_src=twsrc%5Etfw))

“INNOVATE-3 is Novocure’s fourth phase 3 pivotal trial beyond glioblastoma, demonstrating our commitment to developing Tumor Treating Fields for a variety of solid tumors,” said Asaf Danziger, Novocure’s Chief Executive Officer. “At Novocure, we strive to extend survival in some of the most aggressive forms of cancer. Ovarian cancer has been an important area of focus for our research because of the great unmet need faced by these patients. We are now working closely with trial sites and institutional review boards to open sites and enroll patients as quickly as possible.”

## TRIAL RESULTS

**3-yr follow up data for Trastuzumab biosimilar, Ontruzant, in early or locally advanced HER2+ breast cancer patients announced (v)**

Samsung Bioepis announces three-year follow-up data for biosimilar ONTRUZANT® (trastuzumab) – Pharmafield <https://t.co/WJQXFReYg> (<https://t.co/WJQXFReYg>) [pic.twitter.com/rayWYvapTz](https://t.co/rayWYvapTz) (<https://t.co/rayWYvapTz>)

— Vienna Informer (@viennainformer) March 22, 2019 ([https://twitter.com/viennainformer/status/1109073133192003590?ref\\_src=twsrc%5Etfw](https://twitter.com/viennainformer/status/1109073133192003590?ref_src=twsrc%5Etfw))

“With the development of our biosimilar trastuzumab, we aimed to make one of the mainstays of modern cancer therapy more accessible for more people more quickly, and these long-term data underline the importance of that aim,” said Chul Kim, Senior Vice President and Head of Clinical Sciences Division, Samsung Bioepis. “We are committed to increasing access to high-quality, life-changing oncology medicines through the development of biosimilars to address some of oncology’s most pressing challenges.”

**SGO 2019: Durable responses observed with PD-1 inh Dostarlimab in Ph I/II GARNET trial in MSI-H, MSS Endometrial Cancer patients** (<http://ir.tesarobio.com/static-files/b2e72570-f2fd-464d-9d06-a68b5c04c7bf>)

Dostarlimab shows promising results in trial as treatment for women with recurrent or advanced #endometrial ([https://twitter.com/hashtag/endometrial?src=hash&ref\\_src=twsrc%5Etfw](https://twitter.com/hashtag/endometrial?src=hash&ref_src=twsrc%5Etfw)) cancer per article. #Cancer ([https://twitter.com/hashtag/Cancer?src=hash&ref\\_src=twsrc%5Etfw](https://twitter.com/hashtag/Cancer?src=hash&ref_src=twsrc%5Etfw)) #Research ([https://twitter.com/hashtag/Research?src=hash&ref\\_src=twsrc%5Etfw](https://twitter.com/hashtag/Research?src=hash&ref_src=twsrc%5Etfw)) <https://t.co/GpBUMoYwoQ> (<https://t.co/GpBUMoYwoQ>)

— Les Yonemoto, MD MBA (@protoninfo) March 20, 2019 ([https://twitter.com/protoninfo/status/1108380236146712576?ref\\_src=twsrc%5Etfw](https://twitter.com/protoninfo/status/1108380236146712576?ref_src=twsrc%5Etfw))

Mary Lynne Hedley, Ph.D., President and Chief Operating Officer of TESARO, said, “Currently, treatment options for women with advanced or recurrent endometrial cancer are limited, with only one FDA-approved agent for a subset of these patients. We intend to use these and other data from the GARNET study to seek regulatory approval of dostarlimab to potentially address the critical unmet treatment needs of women whose disease has progressed. The data presented today evaluating dostarlimab in women with recurrent/advanced endometrial cancer, combined with earlier data in patients with non-small cell lung cancer, reinforces the potential of dostarlimab in treating patients with a variety of solid tumours.”

**SGO 2019: Puma Biotechnology presents results from HER2+ Cervical cancer cohort of Ph II SUMMIT trial** (<http://www.pumabiotechnology.com/pr20190318a.html>)

Puma Biotechnology Presents Interim Results from the Phase 2 Trial Evaluating Neratinib for HER2 Mutant Metastatic Cervical Cancer: LOS ANGELES&8211;BUSINESS WIRE&8211;Puma Biotechnology Inc. Nasdaq PBYI a biopharmaceutical company announced today that... <https://t.co/sINB6bQxKi> (<https://t.co/sINB6bQxKi>)

— Clinical Trials News (@ClinicalPhase) March 19, 2019 ([https://twitter.com/ClinicalPhase/status/1108032399525335040?ref\\_src=twsrc%5Etfw](https://twitter.com/ClinicalPhase/status/1108032399525335040?ref_src=twsrc%5Etfw))

“Somatic HER2 mutations represent a distinct class of oncogenic driver mutations that appear to be clinically actionable for metastatic cervical cancers. Treatment with neratinib led to durable responses and disease control in metastatic patients with HER2-mutant cervical cancer,” said Dr. D’Souza, who practices oncology at the USC Norris Comprehensive Cancer Center.

Alan H. Auerbach, CEO and President of Puma Biotechnology, added, “We are very pleased with the activity seen with neratinib in this cohort of patients with HER2-mutated cervical cancer. We look forward to the further development of neratinib in this patient population.”

## TRIAL STATUSES

**Longer follow-up data from Ph I DREAMM-1 trial shows 60% ORR and PFS of 1 yr in RRMM patients** (<https://www.gsk.com/en-gb/media/press-releases/gsk-announces-further-positive-data-from-dreamm-1-study-of-anti-bcma-antibody-drug-conjugate/>)

Paul Giusti, President and Chief Executive Officer of the Multiple Myeloma Research Foundation (MMRF), said, “Significant advancements have been made in our knowledge, understanding and the treatment of multiple myeloma in the past decade, but there is so much more that we as a community need to do to accelerate better outcomes and quality of life for patients. Relapses are particularly challenging, so the need for treatment advances is a priority at the MMRF to ensure our patients can benefit from them in the future. We are encouraged by the results from this early study, and we look forward to seeing additional data later this year.”

**Patient enrolment initiated in Ph IIa trial of tablet formulation of Docetaxel, ModraDocoo6, in HER2neg breast cancer** (<http://www.digitaljournal.com/pr/4217859>)

“Chemotherapy remains a fundamental component of many modern cancer treatment regimens, including for

patients with breast or prostate cancer, and ModraDocoo6/r has been designed to improve the therapeutic outcomes and quality-of-life of patients as it offers a potentially safer and more efficacious solution that can be taken at home,” commented Colin Freund, CEO of Modra Pharmaceuticals. “The swift start of this trial represents an important development milestone for Modra, and, together with our planned Phase IIb clinical trial in metastatic castration resistant prostate cancer, which recently received IND approval from the FDA, builds momentum for our global clinical development strategy.”

**Patient enrolment initiated in Ph I/II GO-004 trial of personalized immunotherapy containing patient-specific neoantigens, GRANITE-001, in solid tumors** (<https://ir.gritstoneoncology.com/news-releases/news-release-details/gritstone-oncology-announces-first-patient-dosed-clinical-study>)

Gritstone Oncology Announces First Patient Dosed in a Clinical Study Evaluating its Personalized Immunotherapy GRANITE001: EMERYVILLE Calif. March 21 2019 GLOBE NEWSWIRE Gritstone Oncology Inc. Nasdaq GRTS a clinicalstage biotechnology company developing... <https://t.co/EGyseKc5ML> (<https://t.co/EGyseKc5ML>)

— Biologicals (@BiologicalB) March 21, 2019 ([https://twitter.com/BiologicalB/status/1108828147296813056?ref\\_src=twsrc%5Etfw](https://twitter.com/BiologicalB/status/1108828147296813056?ref_src=twsrc%5Etfw))

“We have been building towards this moment since our company was founded in the autumn of 2015 with just a compelling idea,” said Andrew Allen, M.D., Ph.D., co-founder, president and chief executive officer of Gritstone Oncology. “With GRANITE-001, we are analyzing the patient’s own tumor cell data through our artificial intelligence platform EDGETM and using the identified neoantigens as the basis of a potent, virus-driven, personalized immunotherapy candidate which we manufacture in-house in large part. Our team has impeccably executed the design, build-out, and implementation of this unique platform and our clinical trial collaborators have joined us in this exciting and innovative effort to apply novel scientific insights to the treatment of this grim disease. Having dosed the first patient on our previously projected timeline, we now look forward to sharing early clinical data from this study in the fourth quarter of this year.”

**Ph III pivotal study of TR002, IFN alfa-2b gene therapy, in malignant pleural mesothelioma patients announced** (<https://www.prnewswire.com/news-releases/trizell-ltd-announces-phase-3-pivotal-study-of-interferon-alfa-2b-gene-therapy-in-malignant-pleural-mesothelioma-300815572.html>)

“This is an exciting trial. The results that we noted in our previous study showed significant prolongation of life expectancy and particularly so for about 25 percent of these refractory patients who have gone on to live two and in some cases three years and more,” said Daniel H. Serman, MD, Director of the Multidisciplinary Pulmonary Oncology Program at NYU Langone Health. “We will work hard to get this potentially ground-breaking clinical trial completed.”

**Patient enrolment initiated in Ph I BrTKo4 trial of GMCI + Nivolumab in high grade glioma patients** (<https://www.prnewswire.com/news-releases/brain-cancer-study-of-viral-and-checkpoint-immunotherapy-initiates-accrual-300815935.html>)

“The data generated with GMCI in the upfront high-grade glioma setting is some of the more compelling clinical data in the field in the last few years. The scientific rationale for the combination of GMCI and nivolumab is sound and is supported by pre-clinical data. When one further considers GMCI’s compelling clinical data in various other indications, there is a strong rationale for moving forward with this combination study,” stated Dr. Wen.

**Patient enrolment initiated in trial of STAT3 inhibitor, WP1220, in CTCL patients** (<https://ir.moleculin.com/press-releases/detail/121/moleculin-announces-first-patients-enrolled-in-lymphoma>)

Moleculin Announces Approval for Third Drug to Commence Clinical Trials: MBRX will now have three distinctive oncology drugs in clinic in four ongoing clinical trials WP1220 a STAT3 inhibitor to begin clinical trials in Poland for the treatment of... <https://t.co/XtHrldsoz> (<https://t.co/XtHrldsoz>) [pic.twitter.com/FyoADL63kh](https://t.co/XtHrldsoz) (<https://t.co/FyoADL63kh>)

— Drug Approvals (@DrugApprovalBio) February 7, 2019 ([https://twitter.com/DrugApprovalBio/status/1093497746009468930?ref\\_src=twsrc%5Etfw](https://twitter.com/DrugApprovalBio/status/1093497746009468930?ref_src=twsrc%5Etfw))

“This now marks four clinical trials with patients enrolled,” commented Walter Klemp, Moleculin’s Chairman and CEO. “In this case, we are targeting CTCL with a topical p-STAT3 inhibitor in light of the significant role that STAT3 appears to play in CTCL skin lesions. Our intent is to take an early read on the first five patients in this trial to assess whether we think topical delivery is viable, so we expect preliminary data to be available during 2019.”

**Patient enrolment initiated in Ph II trial of anti-CD38 antibody TJ202/MOR202 in MM patients** (<http://www.imabbiopharma.com/en/article-302.aspx>)

I-Mab Biopharma and MorphoSys Announce Initiation of Pivotal Phase 2 Study of TJ202/MOR202 for Multiple Myeloma <https://t.co/5PTOBKSVpc> (<https://t.co/5PTOBKSVpc>) [pic.twitter.com/qNWnZCSk6x](https://t.co/qNWnZCSk6x) (<https://t.co/qNWnZCSk6x>)

— Stocks News Feed (@feed\_stocks) March 20, 2019 ([https://twitter.com/feed\\_stocks/status/1108162770262851585?ref\\_src=twsrc%5Etfw](https://twitter.com/feed_stocks/status/1108162770262851585?ref_src=twsrc%5Etfw))

“Advancing TJ202/MOR202 into a late stage phase 2 trial is a significant achievement,” said Dr. Joan Shen, M.D., Head of R&D at I-Mab. “We expect that, if approved, TJ202/MOR202 may provide multiple myeloma patients with an important biologics treatment option with its unique benefit that addresses the underlying pathology of the second most common blood cancer worldwide.”

#### **Pfizer, Merck KGaA discontinue Ph III Javelin Ovarian PARP 100 trial in 1L maintenance ovarian cancer patients**

([https://www.pfizer.com/news/press-release/press-release-detail/](https://www.pfizer.com/news/press-release/press-release-detail/merck_kgaa_darmstadt_germany_and_pfizer_announce_discontinuation_of_phase_iii_javelin_ovarian_parp_100_trial_in_previously_untreated)

[merck\\_kgaa\\_darmstadt\\_germany\\_and\\_pfizer\\_announce\\_discontinuation\\_of\\_phase\\_iii\\_javelin\\_ovarian\\_parp\\_100\\_trial\\_in\\_previously\\_untreated](https://www.pfizer.com/news/press-release/press-release-detail/merck_kgaa_darmstadt_germany_and_pfizer_announce_discontinuation_of_phase_iii_javelin_ovarian_parp_100_trial_in_previously_untreated)

Merck KGaA, Darmstadt, Germany, and Pfizer Announce Discontinuation of Phase III JAVELIN Ovarian PARP 100 Trial in Previously Untreated Advanced Ovarian Cancer – PRNewswire <https://t.co/ZoOXiyofSM> (<https://t.co/ZoOXiyofSM>) [pic.twitter.com/MWUWw6NnNb](https://t.co/MWUWw6NnNb) (<https://t.co/MWUWw6NnNb>)

— Swallow This – The War On Cancer! (@miracle\_cures) March 19, 2019 ([https://twitter.com/miracle\\_cures/status/1108155961233948673?ref\\_src=twsrc%5Etfw](https://twitter.com/miracle_cures/status/1108155961233948673?ref_src=twsrc%5Etfw))

The 2018 review of Avelumab + Chemotherapy + Talazoparib’s efficacy demonstrated the unlikelihood of trial meeting its primary endpoint of PFS improvement in unselected patients. Dismal results from Dec 2018 data review, and arrival of newer and better therapeutic options (e.g., Olaparib) brought down curtains on Pfizer and Merck’s Ph III Javelin Ovarian PARP 100 trial in 1L maintenance ovarian cancer settings.

#### **Patient enrolment started in Ph I CIB188A102 study of CD47 inh IBI188 in patients with advanced malignant tumors** (<http://innoventbio.com/en/#/news/136>)

Innovent Starts US Trial of “Pivotal” CD47 Immunotherapy: Innovent Biologics of Suzhou has begun a US Phase I trial of its antiCD47 mAb candidate IBI188 in patients with advanced malignant tumors. By binding to the CD47 antigen on tumor cells IBI188 is... <https://t.co/ndrEoOjn6x> (<https://t.co/ndrEoOjn6x>)

— Clinical Trials News (@ClinicalPhase) March 23, 2019 ([https://twitter.com/ClinicalPhase/status/1109330196136521728?ref\\_src=twsrc%5Etfw](https://twitter.com/ClinicalPhase/status/1109330196136521728?ref_src=twsrc%5Etfw))

“IBI188 is a pivotal product in our pipeline of cancer immunotherapies. There is preliminary evidence that anti-CD47 monoclonal antibodies, as monotherapy or as part of combination therapy, have shown positive biologic activities in solid tumors and in refractory/relapsed non- Hodgkin Lymphoma. Multiple different antibodies targeting the CD47-SIRP $\alpha$  signaling pathway are in development worldwide, most are in either preclinical or Phase I stage. IBI188 is the first anti-CD47 monoclonal antibody drug candidate of China approved for clinical trials in the United States. We would like to assess the potential clinical value of the drug candidate through the simultaneous clinical studies in China and the United States,” said Michael Yu, Founder, Chief Executive Officer and Chairman of Innovent.

#### **Patient dosing initiated in Ph II RAIN-701 trial of hypoxia-activated prodrug of a potent pan-HER inhibitor, Tarloxotinib, in EGFR Ex 20 Insertion or HER2-activating m+ NSCLC patients** (<https://www.rainthera.com/news/press-releases/>)

The Rain-701 clinical trial is officially recruiting #NSCLC ([https://twitter.com/hashtag/NSCLC?src=hash&ref\\_src=twsrc%5Etfw](https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw)) patients with #Exon20 ([https://twitter.com/hashtag/Exon20?src=hash&ref\\_src=twsrc%5Etfw](https://twitter.com/hashtag/Exon20?src=hash&ref_src=twsrc%5Etfw)) insertion and #HER2 ([https://twitter.com/hashtag/HER2?src=hash&ref\\_src=twsrc%5Etfw](https://twitter.com/hashtag/HER2?src=hash&ref_src=twsrc%5Etfw)) activating mutations! Check out the patient page of our website to learn more about the trial and how you can enroll: <https://t.co/wTDv5nELOK> (<https://t.co/wTDv5nELOK>)

— Rain Therapeutics (@Rain\_Thera) March 8, 2019 ([https://twitter.com/Rain\\_Thera/status/1104064491048878081?ref\\_src=twsrc%5Etfw](https://twitter.com/Rain_Thera/status/1104064491048878081?ref_src=twsrc%5Etfw))

“The dosing of the first patient in our Phase 2 trial is an important milestone for Rain as we advance Tarlox through clinical development,” said Avani Vellanki, chief executive officer of Rain Therapeutics. “We continue to be very excited about the opportunity for Tarlox in all HER-addicted tumors, especially in patients with limited treatment options.”

#### **Patient enrolment started in pivotal Ph II/III DENIM trial of MesoPher in pleural mesothelioma patients** (<http://amphera.nl/amphera-recruits-first-patients-to-pivotal-phase-ii-iii-study-of-mesopher-to-treat-pleural-mesothelioma/>)

Rob Meijer, CEO of Amphera said: “The number of pleural mesothelioma patients is on the rise and to date there is

only one therapy registered with limited clinical benefit. As such, new approaches to treating mesothelioma are much needed to improve the prognosis for these patients."

Amphera Recruits First Patients to Pivotal Phase II/III study of MesoPher to Treat Pleural Mesothelioma  
<https://t.co/DBxUEOPDZt> (<https://t.co/DBxUEOPDZt>)

— Tom Speciale (@TomSpeciale) March 18, 2019 ([https://twitter.com/TomSpeciale/status/1107712154591850496?ref\\_src=twsrc%5Etfw](https://twitter.com/TomSpeciale/status/1107712154591850496?ref_src=twsrc%5Etfw))

Ilona Enninga, COO said: "We are delighted to announce that the first patients have been recruited in our pivotal study. For Amphera the start of the study is a major milestone in our strategy to bring our dendritic cell therapy to patients. Based on this study we intend to draft the EMA Marketing Authorisation Application to register the therapy."



## OTW Trivia

*Q: What are hot tumors and cold tumors?*

A: The 'hot' and 'cold' tumors are T cell-infiltrated, inflamed or non-infiltrated, and non- inflamed tumors, respectively.

*Q: How are hot and cold tumors defined?*

A: Hot and cold tumors are defined by their 'Immunoscores' – a standardized, immune-based scoring criteria defined by quantification of CD3 and CD8 populations at both the tumour core and the invasive margin. The type, location and density of these and other immune cells within the tumor site was observed to be predictive of survival.

*Q: What is the significance of a tumor's hot or cold status?*

A: Hot tumors may have tumour- infiltrating lymphocytes (TILs), likely genomic instability, PD- L1 expression on tumor-associated immune cells, have high immunoscore, and the presence of pre-existing anti-tumor immune responses. Conversely, cold tumours are poorly infiltrated, are immunologically ignorant, have low immunoscore, lacking or having minimal PD- L1 expression, high proliferation rate but low mutational burden and low expression of MHC I.

(Source: <https://www.nature.com/articles/s41573-018-0007-y>) (<https://www.nature.com/articles/s41573-018-0007-y>), <https://www.pfizer.com/science/oncology-cancer/immuno-oncology/the-science-of-io> (<https://www.pfizer.com/science/oncology-cancer/immuno-oncology/the-science-of-io>))





# About the Author:



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

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

## Editor and Blog Design:

Abhi Dey (<https://www.linkedin.com/in/abhinavdey/>)

Abhi graduated from the Molecular Biophysics Unit of IISc (Bangalore, India) in 2011. As a Biomedical Scientist, he has worked with all three life-forms in his 13-year research career, viz., particulate, unicellular and multicellular. Currently, he is a Lead Scientist at MicroCures Inc. Previously, he served as 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 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:** "Scanning electron micrograph of a cluster of breast cancer cells showing visual evidence of programmed cell death (apoptosis) in yellow. Each cell is 15 micrometers across." Source (<http://cellimagelibrary.org/images/38810>)

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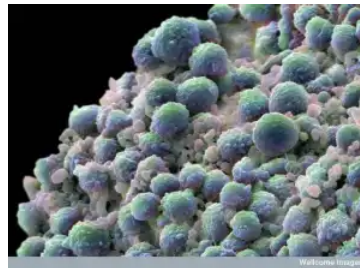
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