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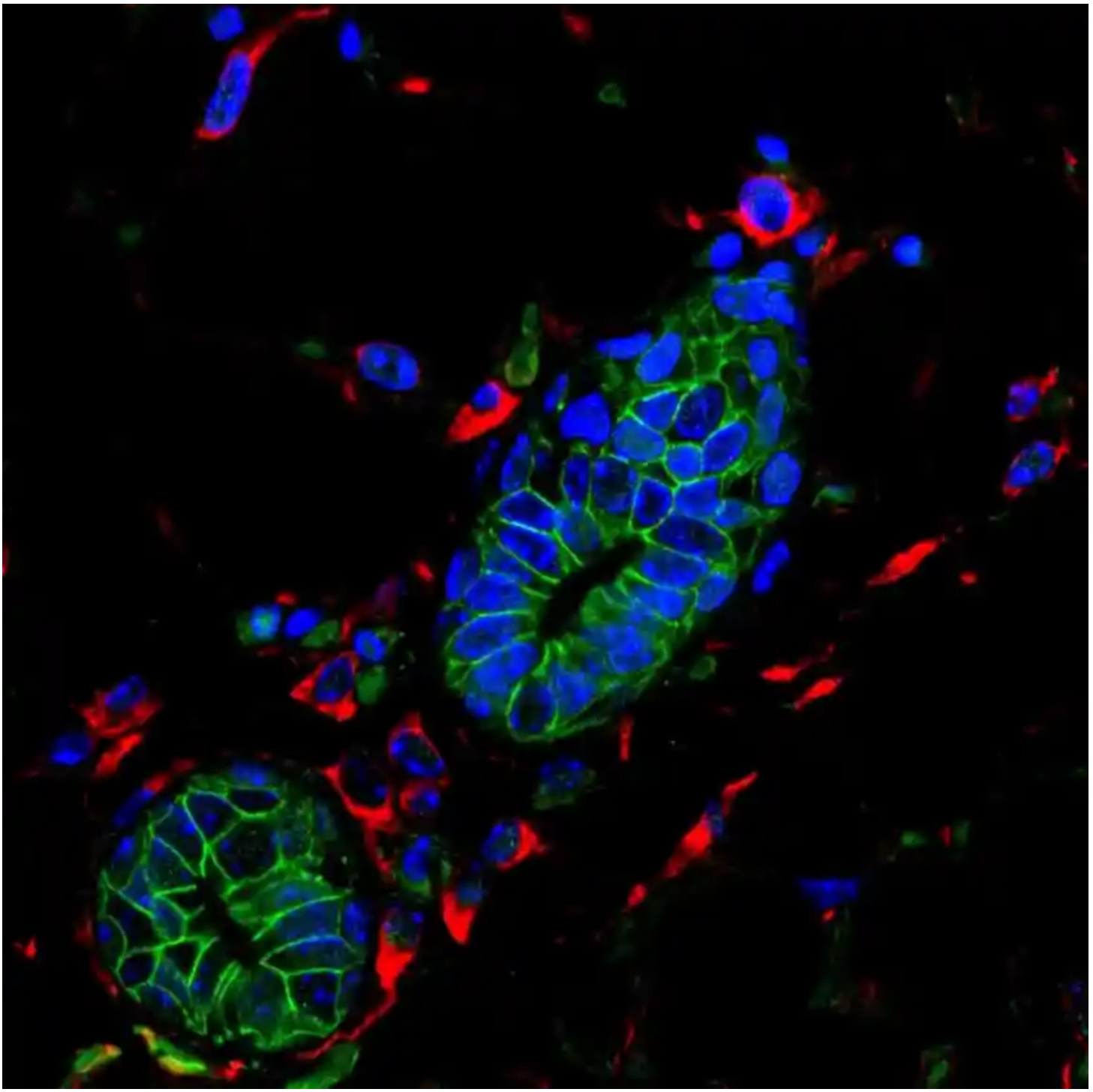
Onco-this-Week

March 31, 2019(https://sciwri.club/archives/date/2019/03/31)



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REGULATORY NEWS

Positive CHMP opinions for both Lenalidomide and Pomalidomid-based triplet combination regimens for multiple myeloma patients (https://ir.celgene.com/press-releases/press-release-details/2019/Celgene-Receives-CHMP-Positive-Opinions-for-Both-REVLIMID-lenalidomide-and-IMNOVID-pomalidomide-Based-Triplet-Combination-Regimens-for-Patients-with-Multiple-Myeloma/default.aspx)

> Celgene Receives CHMP Positive Opinions for Both REVLIMID® (lenalidomide) and IMNOVID® (pomalidomide)-Based Triplet Combination Regimens for Patients with Multiple #Myeloma (https://twitter.com/hashtag/Myeloma?src=hash&ref_src=twsrc%5Etfw). #AETOSWire (https://twitter.com/hashtag/AETOSWire?src=hash&ref_src=twsrc%5Etfw) @Celgene (https://twitter.com/Celgene?ref_src=twsrc%5Etfw) https://t.co/U6kYkQam2w (https://t.co/U6kYkQam2w) pic.twitter.com/BdPFb5WOc8 (https://t.co/BdPFb5WOc8)
>
> — AETOSWire (@AETOSWire) March 30, 2019 (https://twitter.com/AETOSWire/status/1111921209002917888?ref_src=twsrc%5Etfw)

"The CHMP positive opinions for our IMiD combinations, RVd and PVd represent very good news for patients with multiple myeloma in Europe," said Nadim Ahmed, President, Hematology/Oncology for Celgene. "We look forward to potential EMA approvals, which would make these new triplet regimens available to patients, as we aim to improve patient outcomes across multiple stages of their disease."

Breakthrough Therapy Designation granted to Ivosidenib + Azacitidine combination in IDH1 m+ adult unfit 1L AML patients (https://agiospharmaceuticalsinc.gcs-web.com/node/12311)

> Agios presented new data from the Phase 1 study of ivosidenib or enasidenib in combination with azacitidine in newly diagnosed IDHm #AML (https://twitter.com/hashtag/AML?src=hash&ref_src=twsrc%5Etfw) patients ineligible for chemotherapy #ASCO18 (https://twitter.com/hashtag/ASCO18?src=hash&ref_src=twsrc%5Etfw) https://t.co/9VKnz446NJ (https://t.co/9VKnz446NJ) pic.twitter.com/VklfFmpBkl (https://t.co/VklfFmpBkl)
>
> — Agios (@AgiosPharma) June 4, 2018 (https://twitter.com/AgiosPharma/status/1003624116614819840?ref_src=twsrc%5Etfw)

"Outcomes for newly diagnosed AML patients ineligible for intensive chemotherapy are still poor, and there are no approved options specifically for patients with an IDH1 mutation," said Chris Bowden, M.D., chief medical officer at Agios. "The Breakthrough Therapy designation provides further support that combining azacitidine and ivosidenib for these patients has the potential to be a compelling treatment option."

sBLA submitted to FDA for Daratumumab + VTD in 1L autologous stem cell transplant eligible Multiple myeloma patients based on Ph III CASSIOPEIA trial data (https://www.janssen.com/janssen-submits-application-darzalex-daratumumab-combination-therapy-us-fda-newly-diagnosed)

> sometimes biotech news is great news = long $JNJ (https://twitter.com/search?q=%24JNJ&src=ctag&ref_src=twsrc%5Etfw), #MultipleMyeloma (https://twitter.com/hashtag/MultipleMyeloma?src=hash&ref_src=twsrc%5Etfw),
> J&J files European application for expanded use of Darzalexhttps://t.co/rWNj7cgWIU (https://t.co/rWNj7cgWIU)https://t.co/xBohbpJFKx (https://t.co/xBohbpJFKx)
>
> — Max-D (@MaxD56808233) March 28, 2019 (https://twitter.com/MaxD56808233/status/1111206850605862912?ref_src=twsrc%5Etfw)

"This submission marks an important step in the pursuit of potential treatments for newly diagnosed patients

living with multiple myeloma, as DARZALEX has the potential to improve clinical outcomes in combination with a standard regimen," said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Vice President, Hematologic Malignancies Disease Area Leader, Janssen Research & Development, LLC. "We look forward to working closely with the FDA during review of the submission with the goal of bringing a new treatment option to newly diagnosed patients who are transplant eligible."

Type II variation application submitted to the EMA for Daratumumab + VTD in 1L autologous stem cell transplant eligible Multiple myeloma patients based on Ph III CASSIOPEIA trial data (https://ir.genmab.com/news-releases/news-release-details/genmab-announces-european-regulatory-submission-daratumumab-3)

> Janssen Seeks Expanded Use of DARZALEX®▼ (daratumumab) Combination Therapy for Newly Diagnosed, Transplant Eligible Patients with Multiple Myeloma https://t.co/AWeTS9zy3M (https://t.co/AWeTS9zy3M) pic.twitter.com/dMOLg8H1Vo (https://t.co/dMOLg8H1Vo)
>
> — Latest News from Business Wire (@NewsFromBW) March 27, 2019 (https://twitter.com/NewsFromBW/status/1110847693612433410?ref_src=twsrc%5Etfw)

"With this submission we move another step closer to potentially expanding the DARZALEX label. This gives us hope that a new population of patients with multiple myeloma in first line may be able to gain access to DARZALEX," said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

FDA BLA Submission for [Fam-] Trastuzumab Deruxtecan (DS-8201) in HER2 Positive metastatic Breast Cancer post T-DM1 to be accelerated to H1 2019 (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006986.html)

> $AZN (https://twitter.com/search?q=%24AZN&src=ctag&ref_src=twsrc%5Etfw) and Daiichi Sankyo sign global development and commercialization collaboration for Daiichi's cancer drug Trastuzumab Deruxtecan.
> $1.35B upfront to Daiichi. $DSNKY (https://twitter.com/search?q=%24DSNKY&src=ctag&ref_src=twsrc%5Etfw)https://t.co/CqreVkNnwC (https://t.co/CqreVkNnwC)
>
> — Bio Stocks™ (@BioStocks) March 29, 2019 (https://twitter.com/BioStocks/status/1111573578301038592?ref_src=twsrc%5Etfw)

"We are pleased to confirm the acceleration of the [fam-] trastuzumab deruxtecan clinical development program for this potential indication in patients with HER2 positive metastatic breast cancer pretreated with T-DM1 ahead of schedule," said Antoine Yver, MD, MSc, Executive Vice President and Global Head, Oncology Research and Development, Daiichi Sankyo. "Simultaneously, we are committed to our aggressive development strategy evaluating the potential of [fam-] trastuzumab deruxtecan across a spectrum of HER2 expressing cancers including breast, gastric, lung and colorectal."

TRIAL RESULTS

Positive topline results announced from Ph II EV-201 trial of Enfortumab vedotin in locally advanced or metastatic urothelial cancer (http://investor.seattlegenetics.com/news-releases/news-release-details/seattle-genetics-and-astellas-announce-positive-topline-results)

> Enfortumab Vedotin Impresses In Urothelial Cancer After Chemo Immunotherapies: The antibodydrug conjugate being evaluated by Astellas and Seattle Genetics has posted remarkable positive topline results in locally advanced or...&160;&160; https://t.co/SuvUOwPy2x (https://t.co/SuvUOwPy2x)
>
> — Clinical Trials News (@ClinicalPhase) March 28, 2019 (https://twitter.com/ClinicalPhase/status/1111307595187249152?ref_src=twsrc%5Etfw)

"After progression on platinum-containing chemotherapy and a PD-1 or PD-L1 inhibitor, patients with locally advanced or metastatic urothelial cancer are left with no approved standard of care treatment options," said Steven Benner, M.D., Senior Vice President and Global Therapeutic Area Head, Oncology Development at Astellas. "These data are very encouraging, and we look forward to discussing the data with relevant health authorities."

Positive results observed in Ph II lurbinectedin monotherapy trial in relapsed SCLC patients (http://pharmamar.com/wp-content/uploads/2019/03/PR_Lurbinectedin-phase-II-results_OK.pdf)

> Lurbinectedin Monotherapy Improves ORR in Relapsed SCLC https://t.co/Y80B2aVMqK (https://t.co/Y80B2aVMqK)
>
> — Jason M. Watts (@mrjasonwatts) March 25, 2019 (https://twitter.com/mrjasonwatts/status/1110200553806725122?ref_src=twsrc%5Etfw)

Ph II trial of Lurbinectidin met its primary endpoint of ORR in relapsed SCLC patients, as per by both investigator review and IRC (Independent Review Committee) review. Results to be announced in a major medical conference.

Ph II DECIDE trial of DPX-Survivac continues to show promising data in ovarian cancer patients (https://ir.imv-inc.com/news-releases/news-release-details/initial-phase-2-data-imv-clinical-study-continues-demonstrate)

> Initial Phase 2 Data From an IMV Clinical Study Continues to Demonstrate DPX-Survivac's Prior Trend as a Potential Monotherapy Treatment for Advanced Ovarian Cancer https://t.co/GMXTddT8us (https://t.co/GMXTddT8us) pic.twitter.com/oMZFlj3N9K (https://t.co/oMZFlj3N9K)
>
> — Latest News from Business Wire (@NewsFromBW) March 26, 2019 (https://twitter.com/NewsFromBW/status/1110500547176456192?ref_src=twsrc%5Etfw)

"This initial phase 2 data confirms the earlier trends we saw in the phase 1b portion of the study," said Frederic Ors, Chief Executive Officer. "It supports the potential of DPX-Survivac as a monotherapy and the use of our patient selection strategy. We are encouraged by these early initial results and are committed to advancing this program quickly with the goal of providing an additional treatment option to patients with advanced ovarian cancer."

TRIAL STATUSES

Patient enrolment completed in Ph II innovaTV 204 trial of tisotumab vedotin in recurrent or metastatic cervical cancer patients (http://investor.seattlegenetics.com/news-releases/news-release-details/seattle-genetics-

completes-enrollment-phase-2-clinical-trial)

> "Tisotumab vedotin, a tissue factor-specific antibody-drug conjugate, was associated with manageable safety and antitumor activity in a cohort of patients with pretreated recurrent/metastatic #CervicalCancer (https://twitter.com/hashtag/CervicalCancer?src=hash&ref_src=twsrc%5Etfw)" https://t.co/Iov2MJ3Ybe (https://t.co/Iov2MJ3Ybe)
>
> — IGCS (@IGCSociety) March 29, 2019 (https://twitter.com/IGCSociety/status/1111641688093675521?ref_src=twsrc%5Etfw)

"Cervical cancer is a devastating disease with a significant need to develop improved therapies for patients with metastatic disease who have progressed after treatment," said Roger Dansey, M.D., Chief Medical Officer at Seattle Genetics. "Completing enrollment in this potentially pivotal phase 2 trial marks an important step forward in evaluating tisotumab vedotin for women with previously treated recurrent and/or metastatic cervical cancer."

Patient enrolment initiated in Ph II trial of Tesetaxel-checkpoint inhibitors combinations in mTNBC patients and in HER2neg metastatic breast cancer patients (https://ir.odonate.com/news-releases/news-release-details/odonate-therapeutics-initiates-contessa-trio)

> Odonate Therapeutics Announces Initiation of CONTESSA 2, a Phase 2 Study of Tesetaxel in Patients with Locally Advanced or Metastatic Breast Cancer Who Have Not Previously Received a Taxane https://t.co/jGVodaayqI (https://t.co/jGVodaayqI)
>
> — PharmaMKTnet (@PharmaMKTnet) March 11, 2019 (https://twitter.com/PharmaMKTnet/status/1105230724549001217?ref_src=twsrc%5Etfw)

"Taxane-IO combinations hold great promise for patients living with TNBC," said Sara Tolaney, M.D., M.P.H., Associate Director, Susan F. Smith Center for Women's Cancers, Director, Clinical Trials, Breast Oncology at Dana-Farber Cancer Institute and Principal Investigator of CONTESSA TRIO. "This study will investigate the safety and antitumor activity of tesetaxel, an orally administered taxane with a distinct tolerability and pharmacokinetic profile, in combination with three approved PD-(L)1 inhibitors. CONTESSA TRIO also will investigate tesetaxel monotherapy in elderly patients with MBC, a patient population in need of easier-to-take and better tolerated therapies."

Ph II trial of MT-3724 initiated in CD20-targeting engineered toxin bodies (ETBs) in R/R DLBCL patients (http://ir.mtem.com/news-releases/news-release-details/molecular-templates-announces-initiation-phase-ii-monotherapy)

> Molecular Templates Announces Initiation of Phase II Monotherapy Study of MT3724 in RelapsedRefractory Diffuse Large BCell Lymphoma Patients: AUSTIN Texas March 28 2019 GLOBE NEWSWIRE Molecular Templates Inc. Nasdaq MTEM a clinical stage... https://t.co/46hgAIsz5k (https://t.co/46hgAIsz5k)
>
> — Renal Cell Carcinoma (@Renal_Bio) March 28, 2019 (https://twitter.com/Renal_Bio/status/1111240653130723332?ref_src=twsrc%5Etfw)

"We have been highly encouraged by the responses observed in the Phase I/Ib study of MT-3724 in heavily

pretreated DLBCL patients," said Eric Poma, Ph.D., CEO and CSO of Molecular Templates. "This Phase II study largely replicates the Phase Ib expansion cohort, but with more clinical sites for enrollment, an independent data safety monitoring board, and independent central review for efficacy. Given the high level of unmet need in advanced DLBCL, we hope that this study will confirm that MT-3724 provides a meaningful benefit for this difficult to treat patient population."

Enrolment started in Ph I/II trial of Telaglenastat + PARP Inhibitor Talazoparib in patients with advanced or metastatic solid tumors (http://ir.calithera.com/news-releases/news-release-details/calithera-biosciences-initiates-phase-12-trial-telaglenastat?field_nir_news_date_value%5bmin%5d=)

> whytestocks: $CALA (https://twitter.com/search?q=%24CALA&src=ctag&ref_src=twsrc%5Etfw) News Article – Calithera Biosciences Initiates Phase 1/2 Trial of Telaglenastat in Combination https://t.co/XUNoFJDFjD (https://t.co/XUNoFJDFjD) pic.twitter.com/nJCrojfJRc (https://t.co/nJCrojfJRc)
>
> — IH News Desk (@IHNewsDesk) March 26, 2019 (https://twitter.com/IHNewsDesk/status/1110644734735745024?ref_src=twsrc%5Etfw)

"The initiation of this clinical trial of telaglenastat in combination with talazoparib marks the first of two clinical trials that will evaluate telaglenastat with approved Pfizer therapeutics as part of this collaboration," said Susan Molineaux, PhD, president and chief executive officer of Calithera. "We believe these new combination trials have the potential to broaden the opportunities for telaglenastat to improve patient outcomes."

Patient enrolment on track in pivotal Ph III INSPIRE trial of Rigosertib in high risk R/R MDS patients (https://investor.onconova.com/news-releases/news-release-details/onconova-achieves-over-75-percent-planned-enrollment-pivotal)

> Rigosertib May Be Effective, Safe for SCC in RDEB Patients, Study Says https://t.co/cjXABu1Eyp (https://t.co/cjXABu1Eyp)
>
> — EB Info World (@ebinfoworld) March 28, 2019 (https://twitter.com/ebinfoworld/status/1111316811952214016?ref_src=twsrc%5Etfw)

"We are pleased to have passed the 75 percent completion of enrollment milestone and are on track with our anticipated timeline for completion of accrual to the INSPIRE study in the second half of 2019," said Dr. Richard Woodman, Onconova's Chief Medical Officer and Senior Vice President of Research & Development. "Rigosertib has the potential to be the first new MDS treatment in more than 15 years for a condition afflicting an estimated 59,000 patients in the United States."

COLLABORATIONS

AstraZeneca and Daiichi Sankyo to develop and commercialize HER2-targeting ADC, Trastuzumab deruxtecan (DS-8201; [fam-] trastuzumab deruxtecan) (https://www.astrazeneca.com/media-centre/press-releases/2019/astrazeneca-and-daiichi-sankyo-enter-collaboration-for-novel-her-2-targeting-antibody-drug-conjugate.html)

AstraZeneca and #Daiichi (https://twitter.com/hashtag/Daiichi?src=hash&ref_src=twsrc%5Etfw) #Sankyo (https://twitter.com/hashtag/Sankyo?src=hash&ref_src=twsrc%5Etfw) collaborate for #antibody (https://twitter.com/hashtag/antibody?src=hash&ref_src=twsrc%5Etfw)-drug conjugate https://t.co/WViqKNhMOm (https://t.co/WViqKNhMOm) #FDI (https://twitter.com/hashtag/FDI?src=hash&ref_src=twsrc%5Etfw) pic.twitter.com/02XBGpC6uG (https://t.co/02XBGpC6uG)

— investmedical (@investmedical) March 29, 2019 (https://twitter.com/investmedical/status/1111757457230053376?ref_src=twsrc%5Etfw)

Pascal Soriot, Chief Executive Officer, said: “We believe that trastuzumab deruxtecan could become a transformative new medicine for the treatment of HER2-positive breast and gastric cancers. In addition, it has the potential to redefine breast cancer treatment as the first therapy for HER2-low expressing tumours. It also has the potential to treat other HER2-mutated or HER2-overexpressing cancers, including lung and colorectal cancers. We are proud to be working with Daiichi Sankyo, a long-term collaborator of AstraZeneca in other disease areas.”

Onco-this-Week Trivia

SNAPSHOT OF OCE REPORT 2018

The Oncology Center of Excellence of the FDA reports annually on its accomplishments and organization

2018 ONCOLOGY APPROVALS

19	32	1	2
New Molecular Entitites (NMEs)/ Original BLAs	Efficacy Supplement - New Indications	Efficacy Supplement - New Patient Population	Efficacy Supplement - Accelerated Approval Confirmatory Study

2	9	10	1
Biosimilars	505 (b)(2)s	PMA- Modification Companion Diagnostic	PMA Approval (Combination Product)

*APPROVAL NUMBERS REFLECT APPROVAL FROM CBER, CDER & CDRH

KNOW THE TERMINOLOGY

New Molecular Entities (NMEs)- Products contain active moieties that have not been approved by FDA previously, either as a single ingredient drug or as part of a combination product

Efficacy Supplement- "a supplement to an approved application proposing to make one or more related changes from among the following changes to product labeling:
(1) Add or modify an indication or claim;
(2) Revise the dose or dose regimen;
(3) Provide for a new route of administration;
(4) Make a comparative efficacy claim naming another drug product;
(5) Significantly alter the intended patient population;
(6) Change the marketing status from prescription to over-the-counter use;
(7) Provide for, or provide evidence of effectiveness necessary for, the traditional approval of a product originally approved under subpart H of part 314; or
(8) Incorporate other information based on at least one adequate and well-controlled clinical study."

Biosimilar : "(also known as follow-on biologic or subsequent entry biologic) is a biologic medical product that is almost an identical copy of an original product that is manufactured by a different company. Biosimilars are officially approved versions of original "innovator" products and can be manufactured when the original product's patent expires. Reference to the innovator product is an integral component of the approval."

505(b)(2)- "application is one for which one or more of the investigations relied upon by the applicant for approval "were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted"

Premarket approval (PMA): "is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury."

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About the Author:


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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: "The image shows a section of a developing wild type mouse mammary gland immunostained for vimentin (red), beta-catenin (green) and DNA (blue). This is an example of a control image for experiments demonstrating the functions of the Elf5 protein. See: Chakrabarti et al. 2012. Elf5 inhibits the epithelial-mesenchymal transition in mammary gland development and breast cancer metastasis by transcriptionally repressing Snail2. Nat Cell Biol 14:1212-1222." Source (http://www.cellimagelibrary.org/images/43851)

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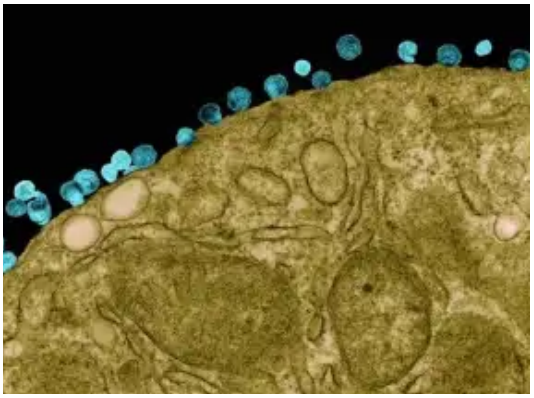

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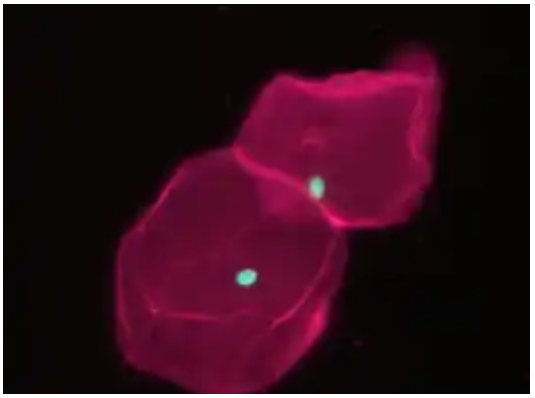

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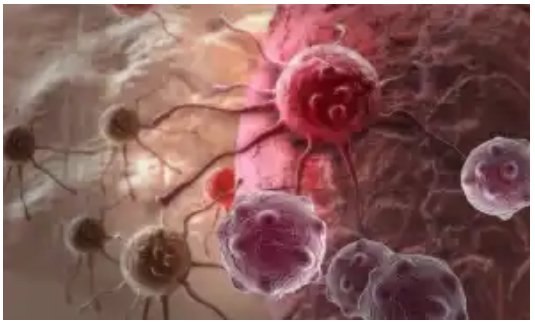

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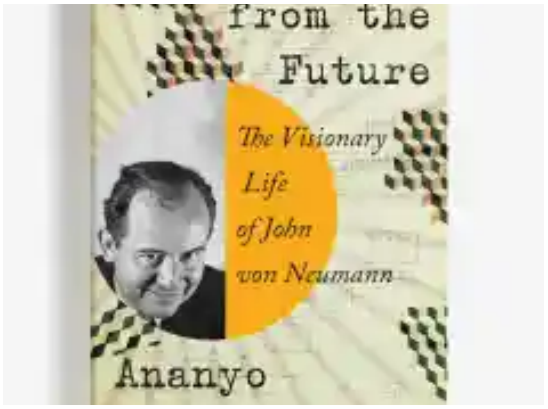

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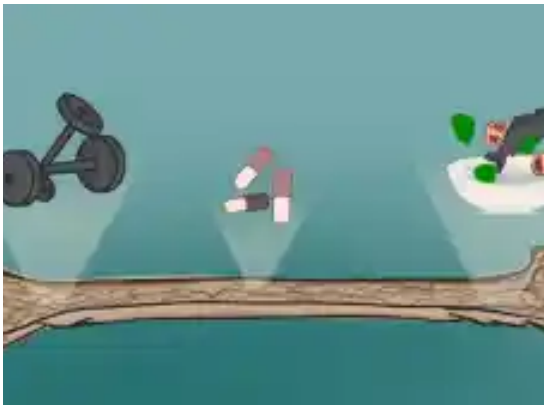

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