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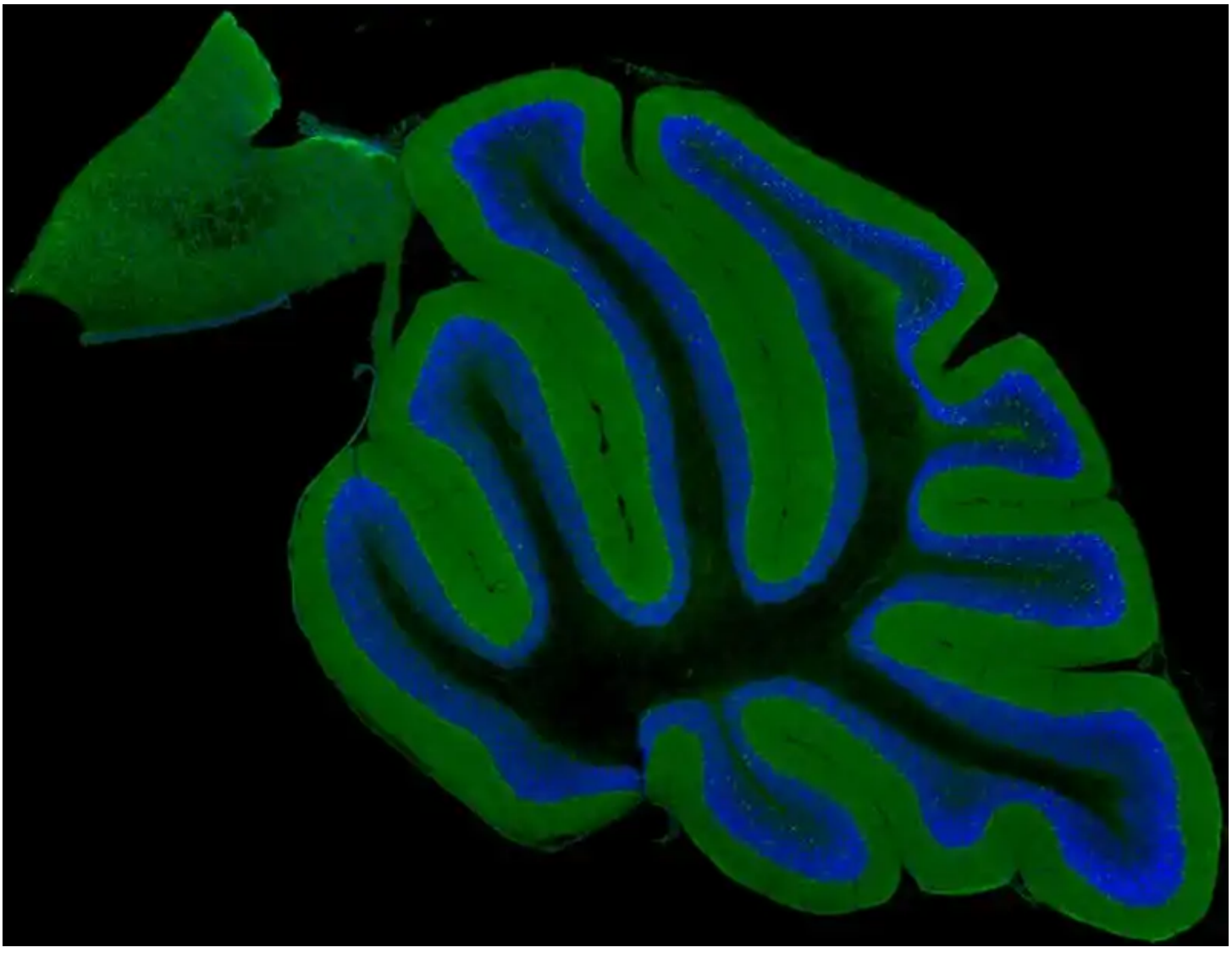
Onco-this-Week

April 14, 2019(https://sciwri.club/archives/date/2019/04/14)



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DRUG APPROVALS

Pembrolizumab monotherapy approved in 1L stage III unresectable / metastatic EGFR/ALK WT PD-L1>1% NSCLC patients based on Ph III KEYNOTE-042 data (https://investors.merck.com/news/press-release-details/2019/FDA-Approves-Expanded-Monotherapy-Label-for-Mercks-KEYTRUDA-pembrolizumab/default.aspx)

> The #FDA (https://twitter.com/hashtag/FDA?src=hash&ref_src=twsrc%5Etfw) has expanded its approval of pembrolizumab to include the first-line treatment of certain patients with stage III or metastatic #NSCLC (https://twitter.com/hashtag/NSCLC?src=hash&ref_src=twsrc%5Etfw). https://t.co/PtrYMjKnvL (https://t.co/PtrYMjKnvL) pic.twitter.com/vsfqQKj5B1 (https://t.co/vsfqQKj5B1)
>
> — Oncology Newswatch (@OncologyWatch) April 12, 2019 (https://twitter.com/OncologyWatch/status/1116774293650792448?ref_src=twsrc%5Etfw)

"The KEYNOTE-042 trial demonstrated a survival benefit with KEYTRUDA monotherapy across histologies in certain patients with stage III or metastatic non-small cell lung cancer whose tumors expressed PD-L1 in at least 1% of tumor cells," said Dr. Gilberto Lopes, associate director for global oncology at the Sylvester Comprehensive Cancer Center at the University of Miami. "As a practicing oncologist, having additional options available for patients is important in the rapidly evolving treatment landscape for lung cancer, which remains the leading

cause of cancer death in the United States."

EMA approves Olaparib in gBRCA1/2m+ HER2neg locally advanced or metastatic breast cancer based on Ph III OlympiAD trial data (https://www.astrazeneca.com/media-centre/press-releases/2019/lynparza-approved-in-eu-for-the-treatment-of-germline-brca-mutated-her2-negative-advanced-breast-cancer-10042019.html)

> #ICYMI (https://twitter.com/hashtag/ICYMI?src=hash&ref_src=twsrc%5Etfw): Olaparib has been approved in Europe for the treatment of patients with germline BRCA1/2-mutant, HER2-negative locally advanced or metastatic breast cancer based on findings from the phase III OlympiAD trial. #bcsm (https://twitter.com/hashtag/bcsm?src=hash&ref_src=twsrc%5Etfw) https://t.co/q7GCHX7Xxa (https://t.co/q7GCHX7Xxa)
>
> — OncLive.com (@OncLive) April 11, 2019 (https://twitter.com/OncLive/status/1116440821354639361?ref_src=twsrc%5Etfw)

Dave Fredrickson, Executive Vice President, Oncology, said: "With this approval, Lynparza provides patients throughout the EU with a targeted and oral chemotherapy-free treatment option for a difficult-to-treat cancer. It also reinforces the importance of testing for biomarkers including BRCA, hormone receptor and HER2 expression, helping physicians to make the most informed treatment decisions for patients."

REGULATORY NEWS

FDA clearance obtained to initiate Ph III trial of VEGFR2 inh Apatinib + PD-1 inh camrelizumab in 1L HCC patients (http://lskbiopharma.com/lsk-biopharma-and-jiangsu-hengrui-medicine-announce-fda-clearance-to-initiate-a-phase-3-clinical-trial-in-advanced-hepatocellular-carcinoma-hcc/)

> CamrelizumabSHR1210 Combined With Apatinib in the Treatment of Advanced Metastatic Colorectal Cancer: The incidence and mortality of colorectal cancer in China's cancer disease spectrum is on the rise and it is a common malignant... https://t.co/jrp75UQj9d (https://t.co/jrp75UQj9d) #GERD (https://twitter.com/hashtag/GERD?src=hash&ref_src=twsrc%5Etfw) #gastroenterology (https://twitter.com/hashtag/gastroenterology?src=hash&ref_src=twsrc%5Etfw)
>
> — BioPortfolio GERD (@GERD_Bio) April 12, 2019 (https://twitter.com/GERD_Bio/status/1116655464815587329?ref_src=twsrc%5Etfw)

"We are happy with this important regulatory milestone in our global clinical collaboration," said Dr. Sung Chul Kim, LSKB's President. "We are enthusiastic to work with Hengrui to hopefully help more HCC patients through development of this combination therapy."

"As one of the leading biopharmaceutical companies in China, Hengrui is committed to developing breakthrough medicines for patients worldwide. This milestone is another step towards our mission. We look forward to working with LSKB to jointly make a difference for HCC patients around the world," said Dr. Piaoyang Sun, Chairman of Hengrui.

BLA submitted for erythroid maturation agent Luspatercept in patients with very low to intermediate risk

MDS-associated anemia (https://ir.celgene.com/press-releases/press-release-details/2019/Celgene-Corporation-and-Acceleron-Pharma-Announce-Submission-of-Luspatercept-Biologics-License-Application-to-US-FDA/default.aspx)

> Celgene submits BLA for luspatercept in US https://t.co/9iMWeUjoBR (https://t.co/9iMWeUjoBR) pic.twitter.com/kRP9E2LEcB (https://t.co/kRP9E2LEcB)
>
> — Pharma Business Int (@PBIForum) April 10, 2019 (https://twitter.com/PBIForum/status/1115983666549645312?ref_src=twsrc%5Etfw)

"There remains a high unmet medical need for patients with MDS or beta-thalassemia who suffer from the effects of their disease-related anemia. The primary treatment option for these patients currently is chronic transfusion of red blood cells which can be associated with complications such as iron overload," said Jay Backstrom, M.D., Chief Medical Officer for Celgene. "New treatment options are urgently needed for these patients. With this submission, we look forward to working with the Agency to deliver luspatercept to patients with these serious blood diseases."

SPECIAL STATUSES

Photoimmunotherapy ASP-1929 to be designated Sakigake status in head & neck cancers based on Ph I Japan and Ph I/IIa USA trial data (https://rakuten-med.com/2019/04/08/rakuten-medicals-asp-1929-photoimmunotherapy-for-head-and-neck-cancers-to-be-designated-under-the-sakigake-designation-system-for-its-potential-innovativeness-and-effectiveness/)

> Rakuten Medical's ASP-1929 photoimmunotherapy for head and neck cancers to be designated under the Sakigake Designation System for its potential innovativeness and effectiveness https://t.co/AlmAKedbpU (https://t.co/AlmAKedbpU) pic.twitter.com/25JFv3sB05 (https://t.co/25JFv3sB05)
>
> — Stocks News Feed (@feed_stocks) April 9, 2019 (https://twitter.com/feed_stocks/status/1115408872443801600?ref_src=twsrc%5Etfw)

Based on receipt of this designation, Mickey Mikitani, chairman and CEO of Rakuten Medical said, "Every day, we receive messages from many patients waiting for this treatment. To those people, I am delighted to be able to make an announcement today that brings them hope. This is a major step forward toward delivering a new treatment for head and neck cancer patients. We are aiming to get this therapy to as many patients as possible, and as soon as possible, by rigorously following the process established by the Sakigake Designation System."

EZH1/2 dual inhibitor Valemetostat (DS-3201) receives SAKIGAKE designation in R/R PTCL patients (https://www.daiichisankyo.com/media_investors/media_relations/press_releases/detail/006996.html)

> Daiichi Sankyo's EZH1/2 dual inhibitor valemetostat gets Japanese SAKIGAKE designation to treat patients with relapsed/refractory PTCL https://t.co/Bq3MB8gqqe (https://t.co/Bq3MB8gqqe)
>
> — OMENSOL (@OMENSOL) April 10, 2019 (https://twitter.com/OMENSOL/status/1115822787116060672?ref_src=twsrc%5Etfw)

“There is a need for new and novel treatment approaches for patients with peripheral T-cell lymphoma, a group of heterogenous diseases for which relapse rates tend to be high and options beyond systemic chemotherapy are limited,” said Kaszushi Araki, Valemetostat Global Team Leader, Oncology Clinical Development Department, Oncology Function, Daiichi Sankyo. “We look forward to working closely with the Japan Ministry of Health, Labour and Welfare to optimize development of valemetostat and to potentially offer a new, first-in-class targeted therapy option for patients with various subtypes of relapsed/refractory PTCL, including those that are more common in Japan.”

TRIAL RESULTS

FAILED TRIAL: Nivolumab monotherapy or Ipilimumab combination in 1L maintenance fails to improve survival in ED SCLC in Ph III CheckMate-451 trial (https://www.esmo.org/Press-Office/Press-Releases/ELCC-Checkmate451-SCLC-Lung-Cancer-Owonikoko)

> Nivolumab/Ipilimumab Combo Misses Primary Endpoint in Phase III SCLC Trial https://t.co/5OB1n8HLPi (https://t.co/5OB1n8HLPi)
>
> — Luis Ydler (@luisfydler) February 19, 2019 (https://twitter.com/luisfydler/status/1097961306852868097?ref_src=twsrc%5Etfw)

Study author Professor Taofeek Owonikoko, Co-Chair of the Clinical and Translational Review Committee, Winship Cancer Institute of Emory University, Atlanta, US, said the finding was “a big disappointment”.

But he added: “There was some indication that compared to placebo, it took longer for the cancer to progress in patients who received either combination immunotherapy or nivolumab alone. This was not the primary endpoint of the study so we cannot make definitive conclusions, but it shows that this strategy could be promising, especially in patients who are responsive to immunotherapy. The challenge will be how to select and identify those patients since patients who began maintenance therapy sooner after completion of chemotherapy did appear to derive greater benefit.”

71% ORR observed in NTRK fusion positive mNSCLC patients; mDOR NR at mFUP of 12.9 months (https://www.bayer.us/en/newsroom/press-releases/article/?id=123298)

> Bayer Announces Results of Sub-group Analysis for Vitrakvi® (larotrectinib) in Patients with NTRK Gene Fusion-Positive Metastatic Non-small Cell Lung Cancer (NSCLC) https://t.co/sKnCdOVosO (https://t.co/sKnCdOVosO) #PRNewswire (https://twitter.com/hashtag/PRNewswire?src=hash&ref_src=twsrc%5Etfw) April 11, 2019@10:13am
>
> — Political HEDGE (@politicalHEDGE) April 12, 2019 (https://twitter.com/politicalHEDGE/status/1116563914345443333?ref_src=twsrc%5Etfw)

“The efficacy and safety of larotrectinib in patients with NSCLC reinforce the importance of identifying genomic alterations early,” said Alexander Drilon, M.D., clinical director of Early Drug Development Service at Memorial Sloan Kettering Cancer Center. “Lung cancer is the leading cause of cancer deaths in the United States and these data are important to progressing the treatment options available for these patients in order to provide appropriate care.”

“As researchers learn more about tumor genomics, new medicines that directly address the genomic abnormalities driving tumor growth become increasingly relevant for patients,” said Scott Fields, MD, Senior Vice President and Head of Oncology Development at Bayer’s Pharmaceutical Division. “These latest Vitrakvi data in NSCLC underscore the importance of genomic cancer testing in all NSCLC patients.”

TRIAL STATUSES

TRIAL STATUS: Ph I trial of STAT3 inhibitor WP1066 to be initiated in pediatric patients with R/R malignant brain tumors (https://ir.moleculin.com/press-releases/detail/127/moleculin-announces-agreement-with-emory-university-to)

> Feeling proud to have contributed to the pre-clinical #medulloblastoma (https://twitter.com/hashtag/medulloblastoma?src=hash&ref_src=twsrc%5Etfw) research i.e. heading towards Phase 1 Clinical trials in pediatric brain tumor patients. Big thanks to @EmoryUniversity (https://twitter.com/EmoryUniversity?ref_src=twsrc%5Etfw) @childrensatl (https://twitter.com/childrensatl?ref_src=twsrc%5Etfw) @AlexsLemonade (https://twitter.com/AlexsLemonade?ref_src=twsrc%5Etfw) @CUREchildcancer (https://twitter.com/CUREchildcancer?ref_src=twsrc%5Etfw) @NIH (https://twitter.com/NIH?ref_src=twsrc%5Etfw) https://t.co/iLTvfIFDVJ (https://t.co/iLTvfIFDVJ)
>
> — abhinav dey (@abhinavdey) April 13, 2019 (https://twitter.com/abhinavdey/status/1116918854503022592?ref_src=twsrc%5Etfw)

“Given the exciting data Emory University researchers presented at the recent Society for Neuro Oncology conference, we have been working closely with them to begin a trial in pediatric brain tumors,” commented Walter Klemp, Moleculin’s Chairman and CEO. “WP1066 was shown to have a significant anti-tumor effect on medulloblastoma cell lines, so there is a lot of encouragement regarding the opportunity to provide new hope for treating this rare condition. This will also give us yet another opportunity to develop human proof of concept data, bringing our total number of clinical trials to five. This clinical trial is expected to begin recruitment in the second half of this year.”

Dosing started for Ph II trial of DNA-based immunotherapy MEDI0457 + Durvalumab in multiple HPV-associated cancers (http://ir.inovio.com/news-and-media/news/press-release-details/2019/Inovio-Achieves-Third-Cancer-Indication-Milestone-for-MEDI0457-Phase-2-Development/default.aspx)

> #Inovio (https://twitter.com/hashtag/Inovio?src=hash&ref_src=twsrc%5Etfw) achieved another milestone from AstraZeneca related to dosing a patient in a Phase 2 trial evaluating MEDI0457 (formerly called INO-3112) in combination with durvalumab targeting cervical, anal, penile, and vulvar cancers associated with #HPV (https://twitter.com/hashtag/HPV?src=hash&ref_src=twsrc%5Etfw).https://t.co/8wsNFErsbc (https://t.co/8wsNFErsbc)
>
> — Doug Milford (@dougmmilford) April 8, 2019 (https://twitter.com/dougmmilford/status/1115244535385337856?ref_src=twsrc%5Etfw)

Dr. J. Joseph Kim, Inovio’s President and Chief Executive Officer, said, “This Phase 2 milestone stresses the potential breadth of MEDI0457 in treating multiple HPV-associated cancers. Inovio’s goal is to lead the HPV-treatment market from pre-cancers with its lead product VGX-3100 to cancers with MEDI0457 along with our

partner AstraZeneca."

Patient dosing initiated in 5th cohort in Ph I NHL trial of CA-4948 (IRAK4 kinase inhibitor) (http://investors.curis.com/2019-04-08-Curis-Announces-Advancement-to-the-200mg-BID-Cohort-in-the-CA-4948-Study)

> New Post: Phase 1 Trial of CA-4948 Recruiting Non-Hodgkin's Lymphoma Patients https://t.co/oya1cwq72a (https://t.co/oya1cwq72a) pic.twitter.com/TYLEuyAczn (https://t.co/TYLEuyAczn)
>
> — Lymphoma News Today (@lymphomanews) April 11, 2019 (https://twitter.com/lymphomanews/status/1116453123768365070?ref_src=twsrc%5Etfw)

"This is an important milestone in the execution of our clinical program," said James Dentzer, the Company's President and Chief Executive Officer. "Last fall, we re-organized the company to heighten focus on clinical execution and laid out an aggressive goal to advance to the 5th cohort (200mg BID) in time for a midyear 2019 release of initial data. We are pleased to announce that we have begun dosing the 5th cohort sooner than expected and we re-iterate our plan to report initial clinical data this summer."

Neon Therapeutics completes enrollment in Ph Ib NT-002 trial of NEO-PV-01 in metastatic NSCLC (https://ir.neontherapeutics.com/news-releases/news-release-details/neon-therapeutics-announces-completion-enrollment-phase-1b-nt)

> We're pleased to announce completion of enrollment in NT-002, our Phase 1b trial evaluating our personal cancer vaccine, NEO-PV-01, with Keytruda® and chemotherapy in metastatic non-small cell lung cancer. Read more: https://t.co/BwiO7bkCJg (https://t.co/BwiO7bkCJg) pic.twitter.com/c57gMKUjWm (https://t.co/c57gMKUjWm)
>
> — Neon Therapeutics (@neon_tx) April 8, 2019 (https://twitter.com/neon_tx/status/1115242034086989827?ref_src=twsrc%5Etfw)

"Our NT-002 trial has the potential to demonstrate the effect that NEO-PV-01, our personal neoantigen vaccine, may have in combination with pembrolizumab and chemotherapy, the current standard of care in first-line metastatic NSCLC. While the pembrolizumab-chemotherapy regimen has shown improved clinical outcomes in first-line NSCLC, we believe NEO-PV-01 could improve the therapeutic efficacy of this combination by directing T cells to target neoantigens expressed in each patient's tumor," said Richard Gaynor, M.D., President of Research and Development at Neon Therapeutics.

COLLABORATIONS

BioAtla and BeiGene collaborate to develop and commercialize novel conditionally active biologic CTLA-4 therapy (http://ir.beigene.com/phoenix.zhtml?c=254246&p=irol-newsArticle&ID=2393908)

NEWS: BeiGene and BioAtla form worldwide collaboration to develop and commercialize novel conditionally active biologic CTLA-4 Therapy. Read more: https://t.co/JaGq13TIpp (https://t.co/JaGq13TIpp) pic.twitter.com/fJHy53OonC (https://t.co/fJHy53OonC)

— BeiGene (@BeiGeneUSA) April 9, 2019 (https://twitter.com/BeiGeneUSA/status/1115598294451871746?ref_src=twsrc%5Etfw)

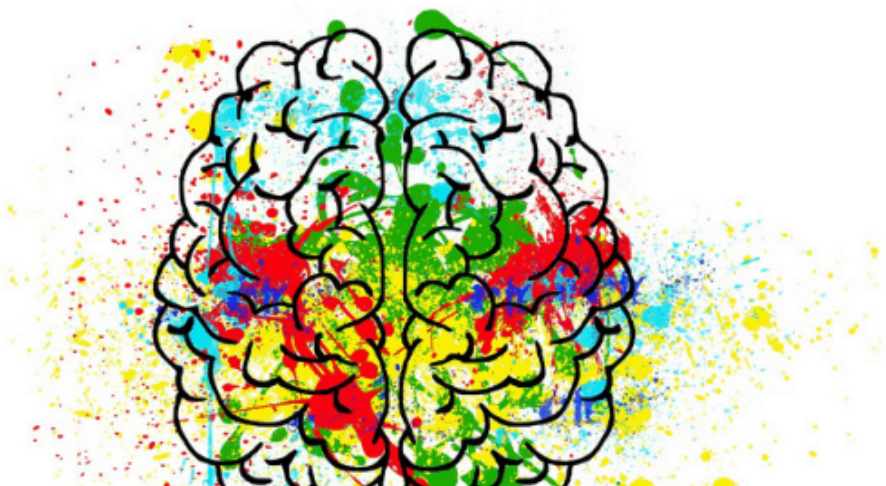
"BioAtla has developed an exciting proprietary protein discovery and expression platform to generate CABs, which in turn have been applied to BA3071, a novel, investigational CTLA-4 inhibitor that is designed to be conditionally activated in the tumor microenvironment," commented Dr. Lai Wang, Senior Vice President, Asia Pacific Clinical Development, Global Research, Clinical Operations and Biometrics, for BeiGene. "The unique nature of BA3071 provides an exciting opportunity to combine this CTLA-4 antibody with our anti-PD-1 antibody, tislelizumab. We look forward to working with BioAtla through proof-of-concept, followed by global development of this potentially unique cancer therapy as a single agent or in combination with other therapies."

Immunomedics and Janssen to promote Erdafitinib in the U.S. (https://www.immunomedics.com/our-company/news-and-events/immunomedics-announces-promotion-agreement-with-janssen-for-erdafitinib-in-the-u-s/)

Immunomedics Announces Promotion Agreement With Janssen for Erdafitinib in the U.S.: MORRIS PLAINS N.J. April 08 2019 GLOBE NEWSWIRE Immunomedics Inc. NASDAQ IMMU Immunomedics or the Company a leading biopharmaceutical company in the area of antibodydrug... https://t.co/rP7ZLj8dYO (https://t.co/rP7ZLj8dYO)

— Bio-Alliances News (@BioAlliances) April 8, 2019 (https://twitter.com/BioAlliances/status/1115247940304429057?ref_src=twsrc%5Etfw)

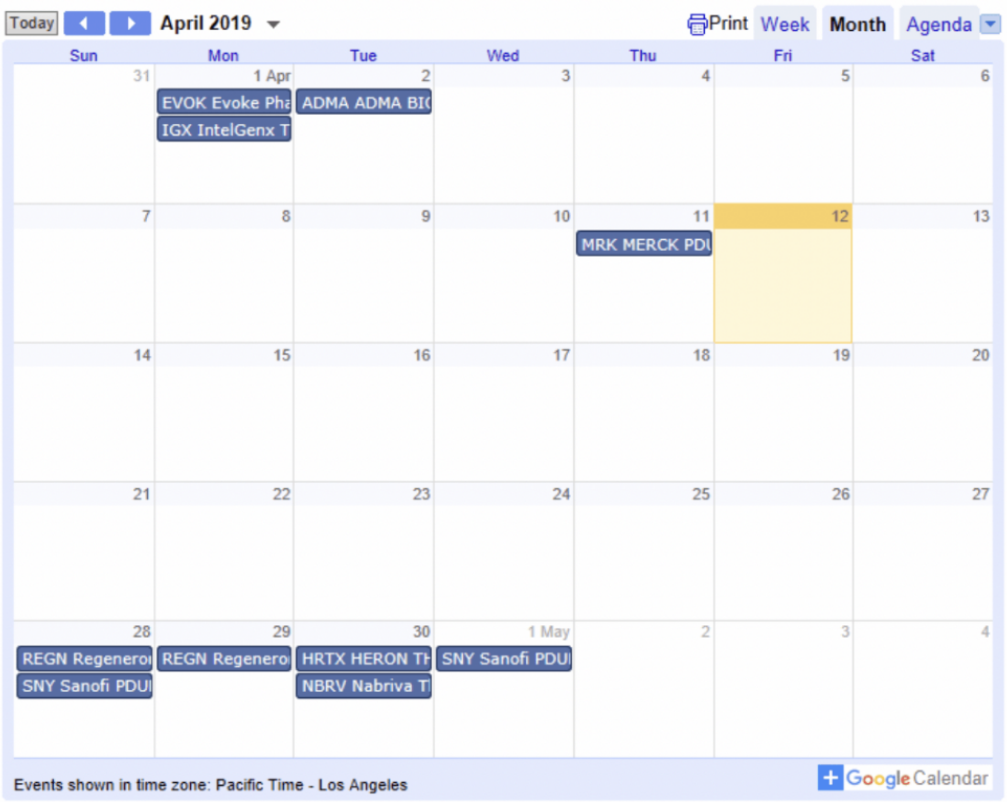
"We are delighted to be collaborating with Janssen and we look forward to working closely with the Janssen team to help promote erdafitinib," said Brendan Delaney, Chief Commercial Officer of Immunomedics. "We have built strong commercial capabilities at Immunomedics and this agreement allows us to leverage our experienced oncology sales force to educate the U.S. market on this potential new treatment option for patients with metastatic urothelial cancer upon FDA approval."



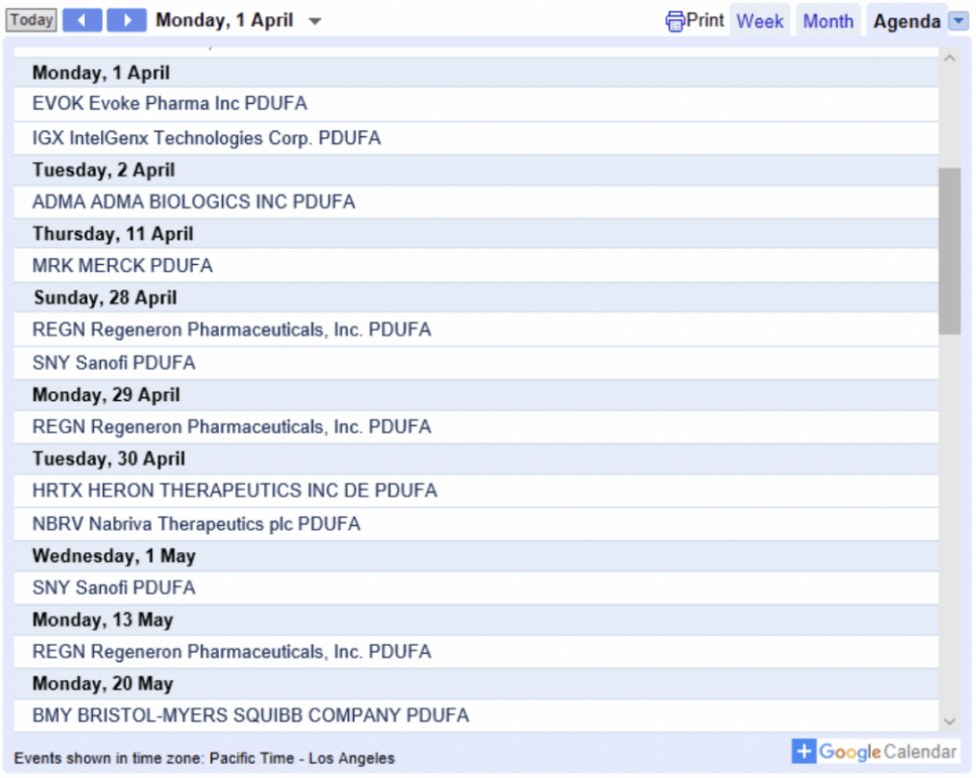
OTW Trivia

Standard FDA Calendar

- Tracks PDUFA drug approval dates and FDA advisory committee meeting dates
- Events can be tracked by week, month or as agenda
- April's events:



- Agenda view:



Source: https://www.fdatracker.com/fda-calendar/ (https://www.fdatracker.com/fda-calendar/)

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: "Image mosaic of a section through mouse cerebellum showing the distribution of alpha synuclein (green) in transgenic mouse overexpressing alpha synuclein. Section was counterstained with a nuclear stain (blue) to reveal the locations of cell somata" Source (http://cellimagelibrary.org/images/CCDB_33)

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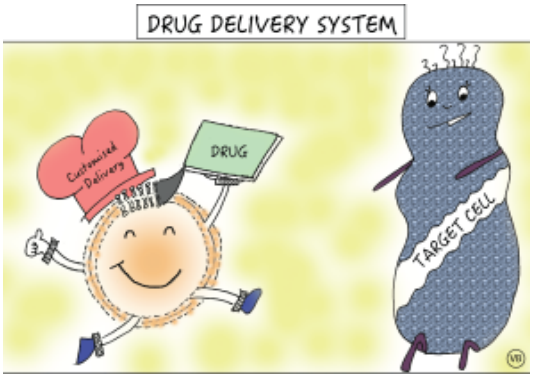

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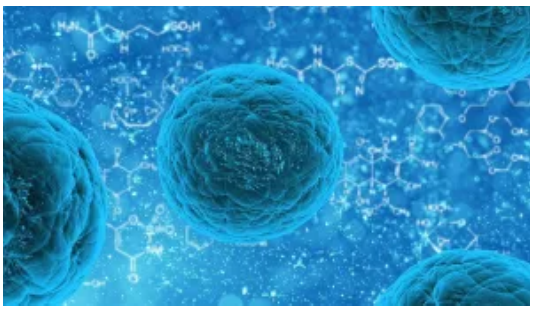

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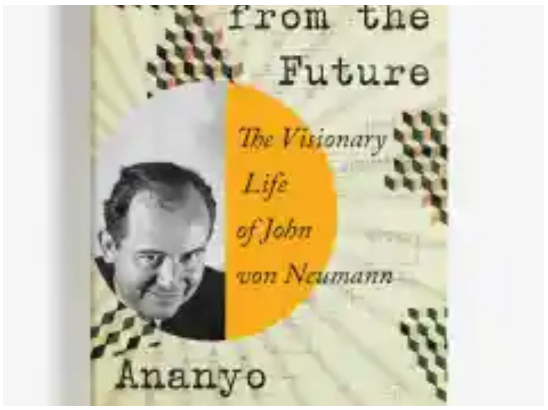

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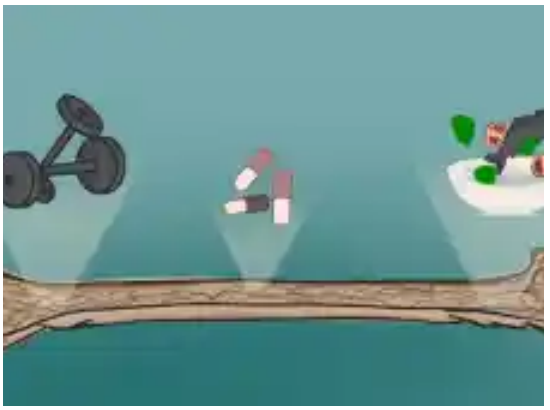

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