MedNess Newsletter February 8, 2023

From MedNess <newsletter@medness.org>

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MedNess

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February 8, 2023

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MedNess News Highlights this week

FDA Approves Jaypirca™ (pirtobrutinib) for Adult Patients with R/R Mantle Cell Lymphoma After at Least Two Lines of Systemic Therapy, Including a BTK Inhibitor

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FDA Orphan Drug Designation for ezurpimtrostat to treat HCC

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Combination with Pembrolizumab in 1L mNSCLC Patients

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Drug Approvals

FDA Approves Jaypirca™ (pirtobrutinib) for Adult Patients with R/R Mantle Cell Lymphoma After at Least Two Lines of Systemic Therapy, Including a BTK Inhibitor

"The approval of Jaypirca represents an important advance for patients with relapsed or refractory MCL, who currently have limited options and historically have had a poor prognosis following discontinuation of treatment with a covalent BTK inhibitor," said Michael Wang, M.D., Puddin Clarke Endowed Professor of Lymphoma and Myeloma at The University of Texas MD Anderson Cancer Center. "These data indicate that Jaypirca can provide efficacy in patients previously treated with a covalent BTK inhibitor, potentially extending the time patients may benefit from BTK inhibition therapy. Jaypirca offers a new approach to targeting the BTK pathway following treatment with a covalent BTK inhibitor and has the potential to meaningfully impact the treatment paradigm for relapsed and refractory MCL patients."

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U.S. FDA Approves Trodelvy In Pre-Treated HR+/HER2- Metastatic Breast Cancer

“Despite decades of advances, people living with pre-treated HR+/HER2- metastatic breast cancer need new treatment options. Nearly all people with this type of breast cancer will eventually develop resistance to endocrine-based therapies and progress on available chemotherapies,” said Hope S. Rugo, MD, Professor of Medicine and Director, Breast Oncology and Clinical Trials Education at the UCSF Helen Diller Family Comprehensive Cancer Center, U.S. and principal investigator of the TROPiCS-02 study. “This approval is significant for the breast cancer community. We have had limited options to offer patients after endocrine-based therapy and chemotherapy, and to see a clinically meaningful survival benefit of more than three months with a quality of life benefit for these women is exceptional.”

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Regulatory news

FDA Orphan Drug Designation for ezurpimtrostat to treat HCC

“FDA Orphan Drug Designation is a significant milestone for both Genoscience and for our product, ezurpimtrostat. It recognizes that our treatment has the potential to improve the lives of individuals living with HCC,” said Professor Philippe Halfon, CEO of Genoscience Pharma. “We have recently launched our phase 2b clinical trial using ezurpimtrostat in conjunction with the standard atezolizumab/bevacizumab treatment. We are looking forward to sharing the intermediate results in 2024.”

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FDA Approval of IND Application for EP0042 for AML Patients Announced

Dr Rajan Jethwa, Chief Executive Officer & Founder of Ellipses, commented “This FDA approval of EP0042’s Investigational New Drug application allows us to open additional trial sites in the world’s foremost pharmaceutical market. This will help us in achieving our strategic goal of bringing potential new treatment

options to patients in need at unprecedented speed, whilst also allowing us to engage with key industry and academic partners. The data we presented in December at ASH, one of the leading conferences in our sector, demonstrated the potential of EP0042, and as a team we are now focused on doing all we can to progress this potential towards reality."

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Regulatory News

Trial Results

NRG-GY018 Study Demonstrates Significantly Improved PFS Outcomes for Women with Endometrial Cancer with the Addition of Pembrolizumab to Chemotherapy

"Patients with advanced stage or recurrent endometrial cancer, the most common type of gynecologic cancer in the U.S., face a poor prognosis with limited treatment options. This is particularly notable in patients who progress after prior platinum-based adjuvant therapy with disease not amenable to curative surgery or radiation," stated Ramez Eskander, MD, of the University of California San Diego Moores Cancer Center and the Principal Investigator of the NRG-GY018 trial. "In this study, pembrolizumab in combination with carboplatin and paclitaxel resulted in a statistically significant and clinically meaningful improvement in PFS in both the dMMR and pMMR study populations.We look forward to presenting these exciting findings at an upcoming scientific congress."

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KEYTRUDA + Chemo Met Primary Endpoint of PFS as First-Line Therapy for Advanced or Recurrent Endometrial Carcinoma

"Patients with advanced stage or recurrent endometrial cancer, the most common type of gynecologic cancer in the U.S., face a poor prognosis with limited treatment options. This is particularly notable in patients who progress after prior platinum-based adjuvant therapy with disease not amenable to curative surgery or radiation," said Dr. Ramez Eskander, principal investigator and gynecologic oncologist, University of California, San Diego. "In this study, pembrolizumab in combination with carboplatin and paclitaxel resulted in a statistically significant and clinically meaningful improvement in progression-

free survival in both the dMMR and pMMR study populations. We look forward to presenting these exciting findings at an upcoming scientific congress."

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Trial Results

Trial Status

TROPION-Lung07 Ph 3 Trial Initiated to Evaluate Datopotamab Deruxtecan in Combination with Pembrolizumab in 1L mNSCLC Patients

"Metastatic non-squamous non-small cell lung cancer remains a challenge because the majority of patients experience disease progression following their initial treatment, underscoring the need for more effective treatment optionsin the first-line setting," said Mark Rutstein, MD, Global Head, Oncology Clinical Development, Daiichi Sankyo. "The TROPION-Lung07 trial will assess the potential of the combination of datopotamab deruxtecan and pembrolizumab with and without chemotherapy, to evaluate whether this combination may be a more effective standard treatment option than the current standard of care for patients in the first-line setting."

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First Patient Dosed in NMIBC Substudy of the LUMINOS-103 Basket Trial Evaluating Lerapolturev Monotherapy

"We know that NMIBC tissue expresses the poliovirus receptor, CD155 and is responsive to immunotherapy, providing the rationale for intravesicular lerapolturev for patients with low to intermediate risk BCG-naïve NMIBC," said W. Garrett Nichols, MD, MS, Chief Medical Officer at Istari Oncology. "Approximately 60,000 patients with low to intermediate risk NIMBC are identified each year in the US alone; these patients could benefit from a well-tolerated immunotherapy such as lerapolturev as a replacement for repeat resections and intravesicular chemotherapy."

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Trial Statuses

Business News

Kite And Arcellx Close Agreement To Co-Develop And Co-Commercialize Late-Stage Clinical CART-DdBCMA In Multiple Myeloma

Currently being investigated in a Phase 2 pivotal trial, CART-ddBCMA is Arcellx's T-cell therapy utilizing the company's novel synthetic binder, the D-Domain. Kite and Arcellx will jointly advance and commercialize the CART-ddBCMA asset in the U.S., and Kite will commercialize the product outside the U.S.

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CARsgen Announces Collaboration Agreement to Evaluate AB011 in Combination with Atezolizumab to Treat Gastric Cancer

"We are glad to work with Roche, a global leader in oncology, to explore the potential of AB011 in combination with atezolizumab and chemotherapy for the treatment of gastric cancer," said Dr. Zonghai Li, Founder, Chairman of the Board, Chief Executive Officer, and Chief Scientific Officer of CARsgen, "Gastric cancer is one of the most common cancer types worldwide and the treatment options for gastric cancer patients are still very limited. CLDN18.2 is a promising therapeutic target for the treatment of CLDN18.2 positive solid tumors, including gastric cancer, pancreatic cancer, etc. Since 2014, CARsgen team has developed several innovative medicines against CLDN18.2 in the pipeline including CAR T-cell therapies and AB011. AB011 is an important asset in the CLDN18.2 franchise of CARsgen and is the first monoclonal antibody against CLDN18.2 that received IND clearance in China. Through this collaboration, we are excited to evaluate the combination of AB011 and atezolizumab which can potentially bring greater clinical benefits to gastric cancer patients."

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