MedNess Newsletter March 1, 2023

From MedNess <newsletter@medness.org>

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MedNess

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March 1, 2023

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MedNess News Highlights this week

Imfinzi plus Imjudo approved in the EU for patients with 1L HCC and mNSCLC based on significant survival benefits in HIMALAYA and POSEIDON Ph 3 trials

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Drug Approvals

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Bruno Sangro, MD, PhD, Director of the Liver Unit and Professor of Internal Medicine at Clínica Universidad de Navarra, and a lead investigator in the HIMALAYA Phase III trial, said: "This approval in Europe is welcome news for eligible patients with advanced liver cancer, who face a poor prognosis and are in need of well-tolerated treatments that can meaningfully extend overall survival. In HIMALAYA, an estimated 31% of patients treated with this novel combination of tremelimumab with durvalumab were alive at three years, while only 20% of patients treated with sorafenib were still alive at the same duration of follow-up."

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NMPA grants Tislelizumab + chemo approval for 1L use in advanced gastric or gastroesophageal junction adenocarcinoma with high PD-L1 expression

“Advanced gastric cancer remains a significant cause of cancer-related mortality in China and we are pleased that tislelizumab plus chemotherapy demonstrated a meaningful survival benefit for patients whose tumors express PD-L1 in the RATIONALE 305 study,” said Lai Wang, Ph.D., Global Head of R&D at BeiGene. “We are grateful to the patients, investigators, and experts from across the world who took part in the RATIONALE 305 trial and look forward to bringing another immunotherapy-based treatment option to patients in China.”

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Regulatory news

Elranatamab Receives FDA and EMA Filing Acceptance with Submissions based on favorable MagnetisMM-3 trial results in patients with R/R multiple myeloma

“Today, multiple myeloma is a fatal hematologic malignancy, with a median survival of just over five years. As an off-the-shelf treatment, BCMA bispecific antibodies are heralding a new treatment paradigm that can greatly impact the lives of people with this disease.” said Chris Boshoff, M.D., Ph.D., Chief Development Officer, Oncology and Rare Disease, Pfizer Global Product Development. “We believe that elranatamab, if approved, has the potential to become the next standard of care for multiple myeloma given its favorable clinical results and convenient subcutaneous route of administration. We look forward to working with the FDA and EMA to bring this new innovative medicine to patients globally.”

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mRNA-4157/V940 + KEYTRUDA® combo Granted Breakthrough Therapy Designation by the FDA for Adjuvant Treatment of Patients With High-Risk Melanoma Following Complete Resection

“The FDA’s Breakthrough Designation for mRNA-4157/V940 in combination with KEYTRUDA reflects the excitement that we have for the potential promise of individualized cancer treatments,” said Stephen Hoge, M.D., Moderna’s President. “mRNA-4157/V940 in combination with KEYTRUDA provided the first demonstration of efficacy for an investigational mRNA cancer treatment in a

randomized clinical trial and potentially represents a new frontier in treating melanoma and other cancers. We look forward to publishing the full data set and sharing the results at an upcoming oncology medical conference, as well as continuing discussions with health authorities. We are grateful to the FDA for this designation."

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Trial Results

Updated survival data from Ph 2 trial of Bria-IMT™ + retifanlimab combo in advanced metastatic breast cancer patients announced

"This is working, and it's working well. We had high hopes going into this clinical read-out, and the survival numbers have even exceeded our expectations. With 9 of 11 women still alive, this has a material impact for the patients and their loved ones, especially since some patients may have had only weeks or months to live prior to our treatment," stated Dr. William V. Williams, BriaCell's President and CEO. "This survival update bodes well for our upcoming pivotal trial, since the FDA has agreed to survival benefits as the primary endpoint."

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Positive Full Data Results From the Pivotal Ph 3 SIERRA Trial in Patients with Active, R/R AML announced

Dr. Sergio Giralt, Deputy Head, Division of Hematologic Malignancies, Attending Physician, Adult BMT Service at Memorial Sloan Kettering Cancer Center, stated, "The SIERRA trial results are an exciting advancement for older patients with active r/r AML and will be practice changing in how we treat these patients. I am thrilled to see a high percentage of Iomab-B patients who achieved durable remissions reaching the critical 2-year survival mark. Significant improvement in event-free survival and overall survival, with an excellent safety profile in the SIERRA trial, demonstrate the potential of Iomab-B becoming a new standard of care for active, r/r AML."

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Trial Results

Trial Status

First Patient dosed in Ph 2 Neoadjuvant Clinical Study of (Z)-Endoxifen in Premenopausal Women with ER+/ HER2- Breast Cancer

"We are excited to kick-off this important trial, a significant achievement in our development strategy," said Dr. Steven Quay, Atossa's President and Chief Executive Officer. "Approximately 78% of breast cancers are ER+ / HER2- and

premenopausal women diagnosed with this disease need more effective and tolerable treatment options; specifically new treatments that do not require ovarian function suppression. We feel (Z)-endoxifen has the potential to change the treatment paradigm for these patients."

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Business News

AstraZeneca enters license agreement with KYM Biosciences for CMG901, a Claudin-18.2 antibody drug conjugate

Puja Sapra, Senior Vice President, Biologics Engineering & Oncology Targeted Delivery, Oncology R&D, AstraZeneca, said, "We are excited by the opportunity to accelerate the development of CMG901, a potential new medicine for patients with Claudin18.2-expressing cancers. CMG901 strengthens our growing pipeline of antibody drug conjugates and supports our ambition to expand treatment options and transform outcomes for patients with gastrointestinal cancers."

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Blueprint Medicines to Regain Global Rights to GAVRETO® (pralsetinib) from Roche

"At Blueprint Medicines, we are dedicated to driving innovation and changing outcomes for patients with lung cancer. GAVRETO is an important treatment option for patients with RET fusion-positive lung cancer and other RET-altered cancers, and we are committed to ensuring that patients being treated with GAVRETO in the commercial and clinical trial settings continue to have access," said Kate Haviland, Chief Executive Officer of Blueprint Medicines. "Over the next year, we will work alongside Roche to transition the GAVRETO program. In parallel, Blueprint will determine the optimal path forward to bring GAVRETO to patients in a way that maximizes its impact and value. As we do this, we will remain focused on our 2023 goals, with our highest priorities being the anticipated U.S. launch of AYVAKIT® (avapritinib) in indolent systemic mastocytosis and the ongoing advancement of our pipeline of investigational medicines."

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