MedNess Newsletter May 10, 2023

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Fecha miércoles, 10 de mayo de 2023 a las 18:08

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MedNess News Highlights this week

EU approves Breyanzi (lisocabtagene maraleucel) for Relapsed or Refractory Large B-cell Lymphoma After One Prior Therapy

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Drug Approvals

EU approves Breyanzi (lisocabtagene maraleucel) for Relapsed or Refractory Large B-cell Lymphoma After One Prior Therapy

"With Breyanzi, people in Europe living with relapsed or refractory DLBCL now have a differentiated CAR T cell therapy option earlier in the treatment paradigm that provides long-term clinical benefit," said Anne Kerber, senior vice president, head of Cell Therapy Development, Bristol Myers Squibb. "This marks the approval of our third indication in Europe for our CAR T cell therapy portfolio, underscoring our continued drive to deliver the promise of cell therapy with curative potential for more patients."

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BRUKINSA approved for first-line treatment for CLL/ SLL and WM in China

"CLL/SLL and WM patients are predominantly populated in the elderly, and there are increasing needs for improved efficacy and safety in CLL/SLL and WM treatments," said Professor Ma Jun, Director of the Harbin Institute of Hematology & Oncology, Chief Supervisor of Supervisory Committee at the Chinese Society of Clinical Oncology. "BRUKINSA has been recommended as the preferred regimen of multiple subtypes of lymphoma in both national and international guidelinesi,ii,iii,iv,v. With these important approvals, BRUKINSA now becomes the only approved new-generation BTK inhibitor in China for the first-line treatment of adult CLL/SLL and WM patients, bringing healthcare providers in China with a new standard of care for their patients."

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Drug Approvals

Regulatory news

CHMP recommends EU approval of Roche's fixed-duration Columvi (glofitamab) for people with R/R DLBCL

"New therapeutic options that are readily and broadly available are urgently needed for people with relapsing diffuse large B-cell lymphoma, which can become fatal without immediate treatment," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "The CHMP's recommendation for Columvi brings us closer to providing a new, fixed-duration therapy for people with diffuse large B-cell lymphoma that induces early and long-lasting responses."

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POINT Biopharma Announce FDA Grants Fast Track Designation for 177Lu-PNT2002 for the Treatment of mCRPC

“Fast track designation by the FDA is an important milestone and recognizes the potential for 177Lu-PNT2002 to address the significant unmet need for mCRPC patients,” said Jean-Claude Provost, M.D., Chief Medical Officer at Lantheus. “We are encouraged by the FDA’s decision as it reflects the need for FDA approved and widely available treatments for these patients. This designation will allow us to work closely with the FDA, along with our partner POINT, to quickly advance 177Lu-PNT2002, with the potential to make a meaningful difference for patients who require new treatment options.”

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Trial Results

ELAHERE® Demonstrates OS Benefit in the Ph 3 MIRASOL Trial in Patients with FRα-Positive Platinum-Resistant Ovarian Cancer

“I believe the data from the confirmatory MIRASOL trial are practice-changing. They demonstrate ELAHERE’s superiority to chemotherapy based on all efficacy endpoints, in particular overall survival, and build on the clinical benefit of ELAHERE previously reported in the SORAYA trial,” said Kathleen Moore, Associate Director of Clinical Research and Director of the Oklahoma TSET/Sarah Cannon Phase I Program, Professor of the Section of Gynecologic Oncology at The University of Oklahoma and MIRASOL Principal Investigator. “Last year’s accelerated approval of ELAHERE was a paradigm-shifting development in the treatment landscape for this disease and I am confident that, with the MIRASOL data, ELAHERE has the potential to become the new standard of care for patients with FRα-positive, platinum-resistant ovarian cancer. FRα status is a ‘must know’ for all ovarian cancer patients and, for those with platinum-resistant disease who test positive, I believe ELAHERE should be their first treatment option.”

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Updated Results from ORIENT-31 Study of Sintilimab + Chemo +/- Bevacizumab in Patients with EGFR-TKI failed EGFR-mutated nsqNSCLC announced

Dr. Hui Zhou, Senior Vice President of Innovent, stated, "the ORIENT-31 study is the first Phase 3 study that met primary endpoints in the world evaluating efficacy of PD-1 inhibitor and chemotherapy with or without bevacizumab in patients with EGFR mutated non-squamous NSCLC that progressed on prior EGFR-TKI therapy. The results of first and second interim analysis were published in the Lancet Oncology and the Lancet Respiratory Medicine, respectively. That represents the international academia's recognition of high quality, innovative clinical trial conducted by investigators in China, and is also a milestone marking Innovent's solid and outstanding capabilities in new drug development. Meanwhile, we look forward to the approval of sintilimab in combination with bevacizumab and chemotherapy based on the results of the ORIENT-31 study can bring new hope to patients with EGFR mutated non-squamous NSCLC that progressed on prior EGFR-TKI therapy. Innovent endeavors to advance innovative drug development targeting unmet medical needs, to bring more effective and affordable treatment options to patients in China and the world."

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Trial Results

Trial Status

First Patient Dosed in Ph 1/2 Clinical Trial of STX-478, Its Mutant-Selective PI3Kα Inhibitor for the Treatment of Breast Cancer and Other Solid Tumors

"We are excited to begin clinical evaluation of STX-478, our mutant-selective PI3Kα inhibitor with a potentially best-in-class profile, for the treatment of HR+/HER2- breast cancer and a wide array of other solid tumors," said Axel Hoos, M.D., Ph.D, Chief Executive Officer of Scorpion. "The initiation of this clinical trial in just three years after our company was founded is an important validation of our Precision Oncology 2.0 strategy. The quality of the compound and the rapid progression of this program from target selection to clinical development demonstrate the expertise of our scientific team, the technical capabilities of our discovery platform, and their combined ability to create potentially transformational therapies."

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Business News

Zai Lab Announces Strategic Partnership and Global License Agreement with MediLink Therapeutics for a Next Gen ADC Program in Oncology

"We are excited to collaborate with MediLink on this program. We will leverage our capabilities to advance the global development of YL212," said Rafael G. Amado, M.D., President, Head of Global Oncology Research and Development at Zai Lab. "This collaboration demonstrates our continued focus on developing cancer therapies including ADC drugs, further enriching our global oncology pipeline. It also complements our existing strong lung cancer portfolio. YL212 is advancing rapidly to the clinical stage, and we look forward to testing this compound in patients with limited therapeutic options."

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Eterna Therapeutics Acquires Allogeneic Immuno-Oncology Platform from Exacis Biotherapeutics

Gregory Fiore, M.D., President and CEO of Exacis, and member of Eterna's Board of Directors, commented, "Exacis was started with the goals of improving patient outcomes and experiences as well as increasing access to life-saving treatments. Today's announcement marks a key milestone on the path to achieving these goals. The Eterna Board and leadership are committed to and have been working toward these same goals, and we believe that this acquisition provides Eterna with the tools required to develop next-generation therapies targeting indications of high unmet need, including blood cancers and solid tumors."

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