MedNess Newsletter July 5, 2023

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MedNess

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MedNess News Highlights this week

U.S. FDA grants Fast Track Designation to REQORSA® in Combination with Tecentriq® for the Treatment of Small Cell Lung Cancer

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Imfinzi + Imjudo demonstrated sustained OS benefit in advanced liver cancer with an unprecedented one in four patients alive at four years in HIMALAYA Ph 3 trial

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First patient dosed in Ph 2 MATISSE study in combination with durvalumab and chemotherapy in treatment-naïve patients with resectable early stage NSCLC

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FDA clears Roche’s Elecsys CSF diagnosis assays for Alzheimer’s disease

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Mestag Therapeutics and VIB enter into an exclusive partnership in oncology

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Regulatory news

U.S. FDA grants Fast Track Designation to REQORSA® in Combination with Tecentriq® for the Treatment of Small Cell Lung Cancer

“We are very pleased to receive a third Fast Track Designation from the FDA for REQORSA, this time for patients with ES-SCLC in combination with the checkpoint inhibitor Tecentriq,” said Rodney Varner, President, Chairman and Chief Executive Officer at Genprex. “This is another exciting achievement in our REQORSA development program, which further validates REQORSA’s potential not only in NSCLC but also in SCLC. We look forward to accelerating the clinical development of REQORSA, and potentially providing a new treatment option for patients with SCLC.”

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Zenocutuzumab granted Breakthrough Therapy Designation by US FDA for the treatment of NRG1+ pancreatic cancer

“We believe the compelling clinical data for Zeno in NRG1+ cancer, and Breakthrough Therapy Designation, provide the opportunity to further engage with the FDA to expedite the review of a potential BLA submission,” said Bill Lundberg, M.D., President, Chief Executive Officer of Merus. “Additionally, our intention to partner Zeno is a reflection of our strategy to carefully balance value creation with capital allocation requirements across our portfolio.”

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Regulatory News

Trial Results

Imfinzi + Imjudo demonstrated sustained OS benefit in advanced liver cancer with an unprecedented one in four patients alive at four years in HIMALAYA Ph 3 trial

Bruno Sangro, MD, PhD, Director of the Liver Unit and Professor of Internal Medicine at Clínica Universidad de Navarra, Pamplona, Spain and a lead investigator in the trial, said: “Historically, only seven per cent of patients with advanced liver cancer have survived five years, making the HIMALAYA long-term survival data especially meaningful. One in four patients treated with the STRIDE regimen were still alive at four years, reinforcing this novel regimen as a standard of care in this setting.”

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Datopotamab deruxtecan met dual primary endpoint of PFS in patients with advanced NSCLC in TROPION-Lung01 Phase III trial

Susan Galbraith, Executive Vice President, Oncology R&D, AstraZeneca, said: "With TROPION-Lung01, we met the dual primary endpoint of progression-free survival, challenging the entrenched standard of care in a previously treated and unselected patient population that has long deserved an alternative to chemotherapy. These first Phase III trial results from the datopotamab deruxtecan clinical programme provide compelling evidence for the potential role this TROP2-directed antibody drug conjugate can play in treating patients with lung cancer."

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Trial Results

Trial Status

First patient dosed in Ph 2 MATISSE study in combination with durvalumab and chemotherapy in treatment-naïve patients with resectable early stage NSCLC

Joyson Karakunnel, MD, MSc, FACP, Chief Medical Officer at Innate Pharma "We are pleased to announce the dosing of a first patient in this Phase 2 study conducted in collaboration with our partner AstraZeneca. The study aims to assess the potential of combining our IPH5201 drug candidate with durvalumab as neoadjuvant treatment with chemotherapy and adjuvant treatment in patients affected by resectable, early stage non-small cell lung cancer. If this combination shows relevant anti-tumor activity while remaining well tolerated, as observed in the previous Phase 1 study, it will be a major step in the development of IPH5201 in this indication."

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Phase 3 Study of Tifcemalimab plus Toripalimab for Treatment of Limited-stage Small Cell Lung Cancer initiated

“In recent years, immune-oncology (I-O) therapy has made rapid advancements, particularly in the field of lung cancer, where it has emerged as the standard of care for first-line treatment of advanced NSCLC,” said Dr. Jianjun ZOU, the Global Research and Development President of Junshi Biosciences. “Regarding more aggressive SCLC, however, the progress in I-O therapy has been relatively slow. To date, no immune checkpoint inhibitor has received approval for the treatment of LS-SCLC. Tifcemalimab is Junshi Biosciences’ first independently developed ‘first-in-class’ product, and it bears the potential to be combined with our cornerstone antibody, toripalimab, and enhance patient response to I-O therapy, increase the number of patients who can benefit from I-O therapy, and introduce new breakthroughs in the treatment of LS-SCLC patients!”

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Trial Statuses

FDA clears Roche’s Elecsys CSF diagnosis assays for Alzheimer’s disease

Roche’s Elecsys beta-Amyloid (1-42) CSF II (Abeta42) and Elecsys Total-Tau CSF (tTau) assays received FDA’s 510(k) clearance (also called pre-market notification) for early and accurate diagnosis of Alzheimer’s disease (AD). This assay pair measures the ratio of two biomarkers of ADviz., tau (tTau) and beta-amyloid (Abeta42). It will hit the market in Q4 of 2023 and is the second pair of Elecsys AD CSF assays from Roche for AD diagnosis. In 2022, FDA 510(k) cleared Elecsys beta-Amyloid (1-42) CSF II (Abeta42) and Elecsys Phospho-Tau (181P) CSF (pTau181) assays and are already available for use. This combination measures the ratio of phosphorylated Tau-181 (pTau181) and beta-amyloid (Abeta42). Elecsys AD CSF assays are registered in 46 countries, including the European Union. AD is a form of dementia characterized by aggregates of beta amyloid plaques and neurofibrillary tangles of tau protein. Accurate diagnosis of AD can take years. The only FDA-cleared methods to determine beta amyloid pathology are CSF tests and PET scan imaging. Elecsys AD CSF assays are consistent with amyloid PET scan imaging and anticipated to be more affordable and accessible routine option to detect both amyloid and tau biomarkers from one draw with no exposure to radiation. Success rate of accurately diagnose AD clinically is only 70-80%. While not confirmatory, these assays will serve as additional tests on top of clinical diagnostic evaluations for early detection of AD improving medical decisions.

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Business News

Mestag Therapeutics and VIB enter into an exclusive partnership in oncology

Susan Hill, PhD, Chief Executive Officer of Mestag Therapeutics, said, “We are delighted to partner with VIB, one of the premier research institutes in Europe and a leader in nanobody technology and cancer biology. This agreement further strengthens Mestag’s first-in-class pipeline and targets an exciting new area of fibroblast-immune cancer biology.”

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K36 Therapeutics Announces $70 Million Series B Financing to Fund Clinical Proof of Concept of KTX-1001 for Treatment of Multiple Myeloma Patients with Genetic Translocation (4;14)

“We are committed to developing KTX-1001 for t(4;14) multiple myeloma patients, a large patient population with chronic disease who are relatively unresponsive to existing and emerging therapeutics,” said Terry Connolly, Ph.D., Chief Executive Officer of K36 Therapeutics. “We welcome our new investors who bring extensive expertise in cancer drug development as well as company building, and we are proud of the continued commitment from of our existing investors. This financing comes at a key time for K36 as we look forward to establishing KTX-1001 clinical proof of concept in multiple dosing regimens and demonstrating the expanded opportunity for KTX-1001 in additional hematologic and solid tumor malignancies.”

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