MedNess Newsletter February 22, 2023

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MedNess News Highlights this week

US FDA grants regular approval for Jemperli for the treatment of patients with recurrent or advanced mismatch repair-deficient endometrial cancer

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FDA grants Fast Track designation for KIN-3248 for the treatment of patients with metastatic cholangiocarcinoma

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Positive Final OS Results of Ph 3 JUPITER-02 Trial of Toripalimab as Treatment for Recurrent or mNPC announced

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Trilaciclib Ph 3 PRESERVE 1 trial in CRC patients to discontinue after absence of efficacy signals in early data

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Fusion Pharmaceuticals To Acquire Ph 2 Program For 225Ac-PSMA I&T, A Radiopharmaceutical Targeting mCRPC

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Drug Approvals

US FDA grants regular approval for Jemperli for the treatment of patients with recurrent or advanced mismatch repair-deficient endometrial cancer

Hesham Abdullah, Senior Vice President, Global Head of Oncology Development, GSK, said: "This US regulatory action confirms our confidence in Jemperli as an important treatment option for patients with dMMR recurrent or advanced endometrial cancer. We continue to unlock the potential of Jemperli as the backbone for our immuno-oncology development programmes to address the unmet needs of patients, including earlier lines of endometrial cancer and other solid tumours."

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Drug Approvals

Regulatory news

FDA grants Fast Track designation for KIN-3248 for the treatment of patients with metastatic cholangiocarcinoma

"U.S. Food and Drug Administration (FDA) has granted Fast Track designation for Kinnate's investigational pan-FGFR inhibitor, KIN-3248, for the treatment of patients with unresectable, locally advanced or metastatic cholangiocarcinoma (CCA) harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other alterations, who have received at least one prior systemic therapy."

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Regulatory update provided on the clinical development plan of Tedopi® in Ph 3 in monotherapy in advanced or mNSCLC after checkpoint inhibitor failure

Nicolas Poirier, Chief Executive Officer of OSE Immunotherapeutics, comments: "We are pleased with the positive outcomes from the US Food & Drug Administration (FDA) Type C Meeting following the supportive European Medicines Agency (EMA) advice, as we are actively preparing a confirmatory phase 3 trial to support the regulatory registration of Tedopi®. Leveraging on the positive data on efficacy, safety and quality of life from the initial phase 3 randomized trial in third line post-chemotherapy followed by an immune checkpoint inhibitor (ICI), we are committed in advancing the clinical development for Tedopi® as a potential new standard of care in monotherapy in second line for advanced or metastatic lung cancer patients in secondary resistance to ICI now used in first line. No therapeutic options have yet been approved to date in this patient population with high unmet medical needs."

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Trial Results

Positive Final OS Results of Ph 3 JUPITER-02 Trial of Toripalimab as Treatment for Recurrent or mNPC

announced

“In the pivotal JUPITER-02 trial, toripalimab has demonstrated a statistically significant and clinically meaningful overall survival benefit for patients with advanced NPC, an aggressive head and neck tumor with no current FDA-approved treatment options,” said Rosh Dias, M.D., Coherus’ Chief Medical Officer. “These mature overall survival data continue to demonstrate the benefit of toripalimab in the treatment of NPC patients, further building upon the data published in Nature Medicine and presented at the 2021 plenary session at the ASCO annual meeting, and clearly show that toripalimab has the potential to become the new standard-of-care for NPC patients, once approved. We look forward to sharing these data with the oncology community at an upcoming medical meeting.”

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Trodelvy® Demonstrates Positive Efficacy Treating Both Platinum-Ineligible And Rapidly Progressing, Post-Platinum Metastatic Urothelial Cancer

“The TROPHY-U-01 data show consistent benefit of Trodelvy across multiple types of metastatic urothelial cancer, including the most difficult-to-treat and, often times, frail patients where treatment options are still scarce,” said Bill Grossman, MD, PhD, Senior Vice President, Therapeutic Area Head, Gilead Oncology. “Trodelvy has the potential to become a cornerstone treatment in metastatic urothelial cancer, and we are excited about the expected results from the ongoing Phase 3 TROPiCS-04 study that may serve to convert our U.S. accelerated approval to full approval for Trodelvy to treat patients with locally advanced or metastatic urothelial cancer following a platinum-containing chemotherapy and PD-1/PD-L1 inhibitor.”

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Trial Results

Trial Status

Trilaciclib Ph 3 PRESERVE 1 trial in CRC patients to discontinue after absence of efficacy signals in early data

“PRESERVE 1 is the first clinical evaluation of trilaciclib in a 5-FU-based chemotherapeutic backbone,” said Raj Malik, M.D., G1 Therapeutics’ Chief Medical Officer. “This study reaffirms that trilaciclib is a highly effective drug for myeloprotection that all but eliminated neutropenia as a concern for patients with CRC in the trial, which helps inform our ongoing combination studies with other highly myelotoxic regimens like ADCs. Unfortunately, despite the robust myeloprotection and improved tolerability, early survival indicators, including the observed overall response rate in this trial, favor patients receiving placebo. These results in PRESERVE 1 are inconsistent with what we’ve observed in other tumors with different chemotherapy backbones. As a result of these topline results, we have made the decision to terminate this study. While we are disappointed, we are grateful for the patients, clinical investigators and their office staff, our partner Simcere, and the G1 team—all of whom contributed to the conduct of this trial.”

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Ph 3 Study of Uproleselan in R/R AML to continue to Originally Planned Final Analysis Following Interim Analysis by Independent Data Monitoring Committee

“We thank the independent DMC for its recommendation and are strongly encouraged as the blinded pooled survival data continues to show patients living longer than historical benchmarks. Going forward, survival duration for new events in the study will be greater than 14 months since the last patient was randomized, giving us confidence in the potential for uproleselan to improve outcomes for people living with R/R AML,” said Harout Semerjian, Chief Executive Officer of GlycoMimetics. “We are proud to be advancing a novel treatment with significant potential to address the urgent unmet medical need in this acute leukemia, and we look forward to continuing the study to the originally planned final overall survival analysis, now expected within the first half of 2024.”

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Trial Statuses

Business News

Fusion Pharmaceuticals To Acquire Ph 2 Program For 225Ac-PSMA I&T, A Radiopharmaceutical Targeting

mCRPC

“We are pleased to announce this acquisition, which adds an ongoing Phase 2 program for a validated cancer target to our pipeline of innovative TATs,” commented Fusion Chief Executive Officer John Valliant, Ph.D. “From our inception, Fusion has recognized the potential opportunity for actinium-based therapies to address unmet needs in cancer given the power and potency of alpha radiation. We believe that with Fusion’s TAT development expertise, and early investments that provide us with our actinium supply advantage, we are uniquely positioned to be first-to-market with an actinium-based PSMA agent.”

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Cullinan Oncology enters into an exclusive license with Harbour BioMed for the development and commercial rights of HBM7008 (CLN-418) in the U.S.

“We are pleased to bring CLN-418, a potential first-in-class, clinical-stage bispecific immune activator, into our diversified portfolio. We believe the best approach to conditional activation of 4-1BB is by targeting B7H4, a tumor associated antigen that is highly expressed across multiple cancers and minimally overlaps with PD-L1 expression. CLN-418 is a strong strategic fit for Cullinan, building on our expertise with bispecifics, and placing us at the forefront of bispecific antibody development in solid tumors. Importantly, this transaction adds another clinical-stage asset to our portfolio, and with it, we are on track to have potentially six clinical stage assets in our pipeline by the end of 2023,” said Nadim Ahmed, Chief Executive Officer of Cullinan Oncology. “This transaction is consistent with our goal to strategically deploy capital to expand and advance our pipeline, and the financial terms of the agreement allow us to maintain a multi-year cash runway to fund our ongoing development efforts and deliver data from multiple clinical programs. Harbour BioMed is a global clinical-stage biotech company with experienced therapeutic innovation capabilities and a network of partnerships, and we look forward to realizing the full potential of this exciting program.”

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