MedNess Newsletter July 19, 2023

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July 19, 2023

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MedNess News Highlights this week

European Commission approves fixed-duration Columvi (glofitamab) for people with relapsed or refractory diffuse large B-cell lymphoma

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Opdivo + Chemo Shows OS & PFS Benefit for Cisplatin-Eligible Patients with Unresectable or Metastatic Urothelial Carcinoma in the Phase 3 CheckMate -901 Trial

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Drug Approvals

European Commission approves fixed-duration Columvi (glofitamab) for people with relapsed or refractory diffuse large B-cell lymphoma

"As pioneers in the development of innovative T-cell-engaging bispecific antibodies, we are delighted that we can now offer Columvi as the first approved treatment of its kind to people in Europe," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "We are confident that thanks to its off-the-shelf availability, fixed-duration regimen and durability, Columvi will positively transform the treatment experience for relapsed or refractory diffuse large B-cell lymphoma."

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Enhertu approved in China as the first HER2-directed therapy for patients with HER2-low metastatic breast cancer

Binghe Xu, MD, Director of the National Clinical Research Center for New Anticancer Drugs, Tenured Professor and Former Director, Department of Medical Oncology, Cancer Hospital Chinese Academy of Medical Sciences and Peking Union Medical College, said: "Historically, breast cancer tumours with low levels of HER2 expression have been classified as HER2-negative and have not been eligible for treatment with HER2-directed therapies. With this approval in China, based on the results of the DESTINY-Breast04 trial, clinicians will now be able to identify and potentially treat a distinct patient population based on HER2-low status."

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Drug Approvals

Regulatory news

FDA granted Fast Track Designation for REQORSA® Immunogene Therapy for patients with extensive-stage small cell lung cancer (ES-SCLC)

"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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sNDA submitted to FDA for BRUKINSA in combination with obinutuzumab as a treatment for relapsed or refractory follicular lymphoma

“Follicular lymphoma is the most common slow-growing non-Hodgkin lymphoma, but there are limited treatment options for patients whose condition has progressed after two lines of therapy. We are therefore pleased that BRUKINSA is the first Bruton’s tyrosine kinase inhibitor to demonstrate efficacy in follicular lymphoma and plan to continue worldwide regulatory submissions based on the ROSEWOOD results,” said Mehrdad Mobasher, M.D., M.P.H., Chief Medical Officer, Hematology. “Importantly, we are grateful to the people living with relapsed or refractory follicular lymphoma who chose to participate in the ROSEWOOD study.”

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Trial Results

Opdivo + Chemo Shows OS & PFS Benefit for Cisplatin-Eligible Patients with Unresectable or Metastatic Urothelial Carcinoma in the Phase 3 CheckMate -901 Trial

“Today’s news is yet another example of the power of immunotherapy combinations to transform outcomes for patients with cancer. Opdivo with cisplatin-based chemotherapy is the first immunotherapy-based combination to improve both overall survival and progression-free survivalin patients with previously untreated unresectable or metastatic urothelial carcinoma who are eligible for cisplatin-based chemotherapy, reinforcing the benefits of Opdivo-based treatments seen across a variety of genitourinary cancers, including durable survival in advanced renal cell carcinoma and a reduced risk of recurrence in resectable muscle-invasive urothelial carcinoma,” said Dana Walker, M.D., M.S.C.E., vice president, global program lead, genitourinary cancers, Bristol Myers Squibb. “We are encouraged by these positive results and remain steadfast in our commitment to bringing new solutions to patients with high unmet needs. We thank the patients, investigators and all site personnel involved in the CheckMate -901 trial.”

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Positive data update provided on best response to therapy with first complete response in GLORIA trial in GBM, bringing 50% of patients in expansion arm to complete or near-complete response

"We are very pleased to report this highly positive update from the expansion arm of our GLORIA clinical trial evaluating our lead asset NOX-A12 in combination with radiotherapy and bevacizumab in glioblastoma," said Aram Mangasarian, CEO of TME Pharma. "It is very encouraging to see one patient achieve no detectable tumor and two patients coming extremely close to complete response, achieving a reduction in tumor size of more than 99 percent. This complete response took about 12 months of therapy to achieve, underlining the importance of mature data to fully evaluate the power of NOX-A12- based therapy. Taken together with the promising picture emerging from our survival data, it is becoming clearer that NOX-A12 used in this treatment combination can provide clinically meaningful benefit over standard of care for brain cancer patients, who currently have such limited therapeutic options."

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Trial Results

Trial Status

Initiation of Randomized Controlled Part B of the DeFianCe Study of DKN-01 in Colorectal Cancer Patients Announced

"Part A of the DeFianCe study enrolled an aggressive heterogenous population of second-line CRC patients representative of the second-line population that we see in the clinic who have poor outcomes on standard of care drugs and are in need of new therapies," said Zev Wainberg, MD, Professor Medicine at UCLA and co-director of the UCLA GI Oncology Program. "Exceeding a 20% overall response rate with a high disease control rate in second-line CRC patients is a clinically meaningful efficacy signal and worthy of further exploration."

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Enrollment in Phase 1/2 Study Discontinued; Development of THE-630 in Patients with GIST Terminated

“We are disappointed that we will not be able to achieve the target exposure for pan-variant inhibition with THE-630, as we continue to believe a therapy with potent activity against all major classes of activating and resistance mutations in KIT has the potential to confer significant clinical benefit, given the unmet need in GIST,” said Tim Clackson, Ph.D., President and Chief Executive Officer of Theseus. “On behalf of the entire Theseus team, I would like to thank the patients, their caregivers, and the investigators and site staff who participated in this study. We remain committed to helping GIST patients with plans to nominate a new, highly selective pan-variant KIT inhibitor candidate for GIST in the first half of 2024. Moving forward, we are excited to have THE-349 as our next near-term clinical program, with its potential best-in-class profile as a fourth generation EGFR inhibitor appropriate for both monotherapy and combination approaches.”

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Business News

DRI Healthcare Trust Announces Acquisition of an Additional Royalty Interest in the Worldwide Sales of VONJO® (pacritinib)

“VONJO has addressed a significant unmet need in cytopenic MF patients and has seen an incredible uptake in its first year on the market,” said Behzad Khosrowshahi, Chief Executive Officer of the Trust. “We are excited to purchase a second royalty on this long duration, high-quality asset. This is the second royalty acquisition our team has completed in the past month and is a testament to our team’s ability to execute on our unique pipeline opportunities. With this transaction, DRI Healthcare has now deployed US$636 million with an additional US$59 million in potential milestone payments since our IPO. With a pipeline of over US$2.5 billion in high-quality assets, we are confident in our ability to reach our deployment target of US$850-900 million by the end of 2025 and to continue to generate value for our unitholders.”

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NANOBIOTIX Announces License Agreement for Worldwide Co-development and Commercialization of Radioenhancer NBTXR3

“As pioneers in the field of nanotherapeutics for the past 20 years, we knew that the true impact of our innovation in oncology would be in its potential to reach millions of patients around the world. For that, we needed to find the right partner, at the right time, with proven global development and commercialization capabilities,” said Laurent Levy, Nanobiotix chairman of the executive board. “We are delighted to collaborate with Janssen as we aim to improve the lives of patients with cancer around the world.”

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