MedNess Newsletter June 14, 2023

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FDA Approves FoundationOne®LiquidCDx as a Companion Diagnostic for BRAFTOVI + Cetuximab combo to Identify Patients With BRAF V600E Alterations in mCRC

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sBLA accepted for priority review for Jemperli + chemo For The Treatment of dMMR/MSI-H Primary Advanced Or Recurrent Endometrial Cancer

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First Patient Dosed in Phase 1/2 Study of ROR1 targeting autologous CAR T, ONCT-808, in patients with relapsed or refractory aggressive B-cell lymphoma

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Bristol Myers Squibb Receives U.S. FDA Approval of New State-of-the-Art Cell Therapy Manufacturing Facility in Devens, Massachusetts

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Drug Approvals

FDA Approves FoundationOne®LiquidCDx as a Companion Diagnostic for BRAFTOVI + Cetuximab combo to Identify Patients With BRAF V600E Alterations in mCRC

"Companion diagnostics are high-quality, well-validated genomic tests that provide critical information to help oncologists make informed treatment decisions for their patients," said Mia Levy, MD, PhD, chief medical officer at Foundation Medicine. "This new companion diagnostic indication for FoundationOne Liquid CDx provides oncologists with an important, non-invasive genomic testing option for metastatic patients with this difficult to treat condition."

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Drug Approvals

Regulatory news

sBLA accepted for priority review for Jemperli + chemo For The Treatment of dMMR/MSI-H Primary Advanced Or Recurrent Endometrial Cancer

Hesham Abdullah, Senior Vice President, Global Head of Oncology Development, GSK said: "We are excited about this initial filing for this potential new indication for dostarlimab in the patient population that demonstrated the strongest treatment effect in the phase III RUBY trial. Long-term outcomes for patients with primary advanced or recurrent endometrial cancer remain poor, and there is an urgent need to evolve the current standard of care, which is platinum-based chemotherapy. We look forward to working with the FDA and other health authorities as they review this application."

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FDA Accepts Application for KEYTRUDA Plus Chemotherapy as Treatment for Advanced or Unresectable Biliary Tract Cancer

“Most biliary tract cancers go undetected until an advanced stage, at which point many patients are ineligible for surgery and have few treatment options,” said Dr. Scot Ebbinghaus, vice president, global clinical development, Merck Research Laboratories. “We look forward to working with the FDA to bring a new option to patients with advanced or unresectable biliary tract cancer that may help them live longer.”

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Trial Results

mRNA-4157 (V940) + KEYTRUDA Combination Demonstrated a Statistically Significant DMFS Improvement in Patients with High-Risk Stage III/IV Melanoma Following Complete Resection Versus KEYTRUDA

“We are excited to be sharing these results with the oncology community and thrilled to see such an exceptional result in distant melanoma recurrence or death. Patients who experience metastases at distant sites typically have worse survival outcomes and a poor prognosis, thus these results showing a reduction in the risk of distant recurrence underscore the potential of neoantigen therapy,” said Kyle Holen, M.D., Moderna’s Senior Vice President and Head of Development, Therapeutics and Oncology. “These results add to the emerging picture of how individualized neoantigen therapy may advance melanoma treatment and the promise it may hold for other types of cancer. Together with Merck, we are rapidly advancing our efforts to move this forward for patients.”

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Enhertu demonstrated clinically meaningful and durable responses in patients across multiple HER2-expressing advanced solid tumours

Funda Meric-Bernstam, MD, Chair of the Department of Investigational Cancer Therapeutics at The University of Texas MD Anderson Cancer Center, US and principal investigator for the trial, said: "The DESTINY-PanTumor02 data showed encouraging and durable response rates across a broad range of HER2-expressing solid tumours where there are currently no approved HER2-targeted treatments. Based on these results, Enhertu has the potential to benefit specific patients with HER2-expressing advanced disease who currently have limited options and may face a poor prognosis."

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Trial Results

Trial Status

First Patient Dosed in Phase 1/2 Study of ROR1 targeting autologous CAR T, ONCT-808, in patients with relapsed or refractory aggressive B-cell lymphoma

"We are excited to announce the first patient, who had failed previous CD19 CAR T therapy, has been treated with ONCT-808," said James Breitmeyer, M.D., Ph.D., Oncternal's President and CEO. "We believe ONCT-808 has the potential to produce robust and durable responses for patients suffering from aggressive lymphoma. It builds on our extensive clinical experience with zilovertamab, as well as that with zilovertamab vedotin, an antibody drug conjugate, which has shown that ROR1 can be targeted without unwanted off-tumor, on-target activity. We particularly appreciate that this first patient is under the care of Dr. Michael Wang, Endowed Professor in the Department of Lymphoma & Myeloma at the MD Anderson Cancer Center in Houston, Texas."

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Trial Statuses

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Business News

Samsung Biologics and Pfizer announce strategic collaboration for long-term manufacturing of biosimilars portfolio

“We are pleased to extend the strategic collaboration with Pfizer as we share and support their strong vision to bring innovative solutions for patients around the globe,” said John Rim, President and CEO of Samsung Biologics. “This new meaningful partnership comes just as our Plant 4 is fully completed early this month as we had previously committed and are on the move for future expansion into our second campus in order to provide our clients with even more flexible and advanced manufacturing technology.”

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Bristol Myers Squibb Receives U.S. FDA Approval of New State-of-the-Art Cell Therapy Manufacturing Facility in Devens, Massachusetts

“The Devens facility integrates the latest state-of-the-art technology in the industry with top talent in the Boston area that will take us into the next phase of our cell therapy journey,” said Karin Shanahan, executive vice president, Global Product Development & Supply, Bristol Myers Squibb. “We are working diligently to increase our product capacity through new sites like Devens and by implementing innovative manufacturing solutions that help patients in need.”

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