MedNess Newsletter June 7, 2023

From MedNess <newsletter@medness.org>

Para sarah@medness.org

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MedNess

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MedNess News Highlights this week

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Drug Approvals

Lynparza + abiraterone approved in the US for the treatment of BRCA-mutated mCRPC

Andrew Armstrong, MD, ScM, of the Duke Cancer Institute, Durham, North Carolina, US, and an investigator in the trial, said: “Preventing or delaying radiographic progression or death is an important clinical endpoint in assessing cancer treatment and is very important to patients, their caregivers and their families. The PROpel results showed the Lynparza combination demonstrated a notable clinically meaningful benefit that should rapidly be considered as the standard of care treatment for patients with BRCA-mutated metastatic castration-resistant prostate cancer.”

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Regulatory news

FDA Accepts for Priority Review Repotrectinib's Application for the Treatment of Patients with Locally Advanced or Metastatic ROS1-Positive NSCLC

"Patients with ROS1-positive non-small cell lung cancer face a rare disease with a significant unmet medical need given the limited durability of benefit and emergence of resistance to approved therapies," said Jonathan Cheng, M.D., senior vice president and head of oncology development, Bristol Myers Squibb. "The FDA's acceptance of this application marks an exciting milestone on our journey to bring this next-generation tyrosine kinase inhibitor to patients. If approved, this would represent a potential best-in-class option for TKI-naïve patients and a potential first-in-class option for patients with ROS1-positive NSCLC who have been previously treated with TKI, and for whom there are currently no approved targeted therapies available. We are eager to continue working closely with the FDA on the review of this precision medicine, which has shown unprecedented level of durability of responses and robust intracranial responses in patients with ROS1-positive NSCLC."

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Strategic Update provided on AFM24 Development Plan

"We believe that AFM24 can be an important addition to the treatment armamentarium for addressing EGFR mutant tumors as the early anti-tumor effects support further evaluation in a combination setting with the goal of achieving meaningful patient benefit. That is why we are adding an EGFR mutant NSCLC cohort to our ongoing phase 1/2 study in combination with Roche's PD-L1 checkpoint inhibitor atezolizumab," said Dr. Andreas Harstrick, Chief Medical Officer at Affimed. "Our broad AFM24 program aimed at identifying the right therapeutic settings and indications, and we believe that the data generated to date allow us to build the right path forward to maximize patient benefit."

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Trial Results

Positive Lead-In Data from Ongoing Ph 3 PEAK Trial of Bezuclastinib + Sunitinib in Patients with Gastrointestinal Stromal Tumors (GIST) announced

"These data reinforce our belief that the combination of bezuclastinib and sunitinib has the potential to become a new treatment option for second-line GIST patients," said Andrew Robbins, President, and Chief Executive Officer at Cogent Biosciences. "We are pleased to demonstrate in a robust clinical dataset that the addition of bezuclastinib to sunitinib does not appear to change the frequency or severity of adverse events associated with sunitinib monotherapy. In addition, we are encouraged by the performance of this combination in second-line GIST patients, the population we are currently enrolling in the Phase 3 PEAK clinical trial, with a disease control rate of 100% and 4 out of 7 patients now on treatment for more than 10 cycles."

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Lynparza + Imfinzi reduced risk of disease progression or death by 37% vs. chemo + Avastin in ovarian cancer patients without tumour BRCA mutations in the DUO-O Ph 3 trial

Professor Philipp Harter, Director, Department of Gynaecology and Gynaecologic Oncology, Evangelische Kliniken Essen-Mitte, Germany, and principal investigator for the trial, said: "The primary aim of first-line treatment of patients with advanced ovarian cancer is long-term control over the disease, but still too many patients progress quickly and face poor clinical outcomes today. Data from the DUO-O trial interim progression-free survival analysis provide evidence for further improvement with olaparib and durvalumab combination versus chemotherapy and bevacizumab alone in patients without tumour BRCA mutations."

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More news on
Trial Results

Trial Status

Phase 2/3 Pivotal Study REFRaME-O1 to be initiated in Ovarian cancer patients

Anne Borgman, M.D., Sutro's Chief Medical Officer said, "On the heels of these positive results, we are thrilled that REFRaME, our pivotal Phase 2/3 trial, is officially underway. From the clinical and nonclinical data gathered, we maintain our positive outlook that luvelta could potentially serve multiple additional indications where patients express FolRα."

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More news on
Trial Statuses

Business News

Impact Therapeutics Entered into Global Partnership with Eikon Therapeutics to Develop and Commercialize PARP1 Selective Inhibitors

"We are delighted to establish the global partnership with Eikon, whose leadership team has a well-documented track record of developing some of the world's most therapeutically meaningful and commercially successful oncology medicines." said Sui Xiong Cai, Ph.D., Chief Executive Officer of IMPACT Therapeutics. "As a company committed to develop innovative medicines globally, based on our deep understanding of synthetic lethality, we believe this partnership will allow us to accelerate the development of our PARP1 selective inhibitor program combining Impact and Eikon's scientific, clinical, regulatory expertise and financial resources. We look forward to working with Eikon in bringing new cancer medicines to patients in China and across the globe."

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C4 Therapeutics and Betta Pharmaceuticals Announce Exclusive Licensing Agreement for the Development and Commercialization in Greater China of CFT8919

"We are excited to partner with Betta to develop CFT8919, an orally bioavailable allosteric EGFR L858R degrader, with the potential to treat NSCLC patients with EGFR L858R mutations in Greater China and beyond," said Andrew Hirsch, president and chief executive officer of C4 Therapeutics. "With their strong track record of developing and commercializing NSCLC therapies in China, we believe Betta is the ideal partner to advance CFT8919 clinical development in a region where there is a high prevalence of lung cancer patients with the EGFR L858R mutation."

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