# MedNess Newsletter August 9, 2023

From MedNess <newsletter@medness.org>

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# MedNess

***bite-size biopharma and medtech news***

**August 9, 2023**

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## MedNess News Highlights this week

European Commission Approves LONSURF® (Trifluridine/tipiracil) in Combination With Bevacizumab in 3rd Line Refractory mCRC

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U.S. FDA Grants Orphan Drug Designation to ABM-1310 for the Treatment of Patients with Glioblastoma Harboring BRAF V600 Mutation

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REZILIENT3 Global First-Line Trial of Zipalertinib Launched in Patients With NSCLC Harboring EGFR Exon 20 Insertion Mutations

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# Drug Approvals

## European Commission Approves LONSURF® (Trifluridine/tipiracil) in Combination With Bevacizumab in 3rd Line Refractory mCRC

“The approval by the European Commission is supported by data from the phase 3 SUNLIGHT trial for patients suffering from an advanced colorectal cancer who have already failed two prior chemotherapy regimens. The Marketing Authorization covers the 27 countries of the European Union as well as Iceland, Northern Ireland, Liechtenstein and Norway.”

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## Jemperli (dostarlimab) + chemo approved in the US as 1L treatment for dMMR/MSI-H primary advanced or recurrent endometrial cancer

Hesham Abdullah, Senior Vice President, Global Head of Oncology Development, GSK, said: “Today’s expanded approval of Jemperli redefines the treatment landscape for patients with dMMR/MSI-H primary advanced or recurrent endometrial cancer. Until now, chemotherapy alone has been the standard of care with many patients experiencing disease progression. In the RUBY trial, Jemperli plus chemotherapy demonstrated a 71% reduction in the risk of disease progression or death versus chemotherapy in this patient population, providing a statistically significant and clinically meaningful benefit. These results and today’s approval underscore our belief in the potential for Jemperli to transform cancer treatment as a backbone immuno-oncology therapy.”

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# Regulatory news

## U.S. FDA Grants Orphan Drug Designation to ABM-1310 for the Treatment of Patients with Glioblastoma Harboring BRAF V600 Mutation

"ABM-1310 is an orally administered medicine with high BRAF-mutation selectivity, high water solubility, and high blood-brain barrier permeability. It is one of innovative drugs independently developed by ABM. ABM-1310 is in Phase I studies at multiple clinical sites in the U.S. and China for BRAF V600-mutant advanced solid tumors. The interim result from its U.S. Phase 1 study was presented in June 2023 at the American Society of Clinical Oncology (ASCO) Annual Meeting, demonstrating ABM-1310's promising anticancer activity and good safety profile in patients with advanced BRAF V600 mutant solid tumors including primary brain tumors such as GBM and other gliomas. A new Phase I clinical trial specifically targeting GBM has recently been initiated in China."

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## FDA sends CRL for LYMPHIR™ (Denileukin Diftitox) for the Treatment of Patients with R/R Cutaneous T-Cell Lymphoma

"We appreciate the FDA's expeditious review of our application. We intend to provide additional data and remain fully engaged with the FDA as we continue to work toward approval. We remain confident in the potential of LYMPHIR to become an important addition to the treatment landscape for patients with relapsed or refractory CTCL and make a meaningful difference in their lives," stated Leonard Mazur, Chairman and CEO of Citius.

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# Trial Results

## Retevmo® (selpercatinib) Demonstrated Superior PFS vs a PD-1 Inhibitor + Chemo for Adults with Newly-Diagnosed Advanced or Metastatic RET Fusion-Positive NSCLC

"The LIBRETTO-431 trial aims to answer an important question about the selection of initial treatment for people with advanced RET fusion-positive NSCLC and these results suggest Retevmo should be considered a first-line standard of care," said David Hyman, M.D., chief medical officer, Loxo@Lilly. "Additionally, this clinically meaningful achievement of improved outcomes underscores the importance of timely and comprehensive genomic testing to inform initial treatment decisions for all patients with NSCLC. The results of this study provide further confirmation that RET status – like EGFR, ALK, and others in the family of lung cancer oncogenic drivers – should be known prior to initiating therapy. We look forward to sharing these data in more detail with the oncology community."

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## FAILED TRIAL: Phase 3 AXLerate-OC Study of Batiraxcept in Platinum-Resistant Ovarian Cancer failed to meet primary endpoint of PFS improvement

"We are conducting additional analyses on the AXLerate-OC Phase 3 trial to further evaluate the results of this study and determine the best path forward with our two other planned indications in renal cell carcinoma and pancreatic cancer," said Gail McIntyre, Ph.D., DABT, Aravive's President and Chief Executive Officer. "We want to thank the patients who participated in this trial, the clinical investigators, and the Aravive team for their hard work, as we continue to pursue our goal of finding innovative cancer treatments for patients in need."

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Trial Results

# Trial Status

## REZILIENT3 Global First-Line Trial of Zipalertinib Launched in Patients With NSCLC Harboring EGFR Exon 20 Insertion Mutations

"Patients with NSCLC who have EGFR exon 20 insertion mutations are known to have poorer outcomes than those with more common EGFR mutations,1" said Volker Wacheck, MD, PhD, Senior Vice President, Clinical Development, Taiho Oncology, Inc. "Advancing care for this subset of patients with NSCLC is essential to advancing care in NSCLC overall."

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## First patient dosed in Pivotal Study of Berubicin for the Treatment of Glioblastoma Multiforme (GBM)

"Enrolling patients in an orphan disease trial is always a challenge, and that's why we are thrilled with the rate of enrollment in this potentially pivotal study. The robust interest and enthusiasm among our investigators and patients reflect the pressing need to develop treatment options for patients with GBM. Addressing this devastating disease continues to be the driving force for our team," commented John Climaco, CEO of CNS Pharmaceuticals.

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Trial Statuses

## Lily’s Donanemab poised for FDA’s approval

The positive outcome of Eli Lilly’s 18 months phase 3 randomized clinical trial on donanemab among 1736 participants with early Alzheimer disease (mild cognitive impairment/mild dementia) with amyloid and low/medium or high tau pathology was simultaneously presented and published at Alzheimer’s Association International Conference in Amsterdam and the journal JAMA respectively. Donanemab, an antibody designed to clear brain amyloid plaque, significantly slowed disease progression at 76 weeks by 35%. Lequembi, FDA’s recently approved drug, is known to reduce the progression by 27%. The uniqueness of this study was that patients were off the drug once the plaques cleared. Plaques did not reappear during the remaining period of the study, and the beneficial effects on memory and thinking persisted. Therefore unlike Leqembi, patients might not need monthly intravenous infusions of Donanemab, thereby reducing side effects and treatment cost. The duration of this benefit is, however, not known yet. Advanced cases showed less beneficial effect suggesting earlier treatment intervention is more likely to have a positive outcome. Like other amyloid modifying therapies Donanemab also resulted in amyloid-related imaging abnormalities (ARIA) in about 25% of those treated with the drug. Three participants with serious ARIA died. Among other side effects, 6% of Donanemab treated group complained of headache, nausea and confusion. While this potential drug is not a cure to Alzheimer’s disease, early intervention will slow the progression of the disease among patients. Lily has already submitted the results to FDA. By the end of this year we will know whether Donanemab receives FDA clearance.

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# Business News

## Replimune and Incyte Enter into Clinical Trial Collaboration and Supply Agreement to Evaluate RP1 and INCB99280 in Patients with Cutaneous Squamous Cell Carcinoma

"We are excited to enter into this collaboration with Incyte to explore the use of RP1 prior to surgery as we believe that our tumor-directed oncolytic immunotherapies could have a great impact in the neoadjuvant setting both in cutaneous squamous cell carcinoma (CSCC) and in other cancer types, given the high rates of complete responses we've seen to date, and data indicating RP1 is generally very well tolerated," said Robert Coffin, Chief Research and Development Officer of Replimune. "The unique potential of the RPx platform to induce a patient-specific anti-tumor immune response with an off-the-shelf treatment speaks to the practicality and broad potential utility of the approach, and exploring its use with Incyte's oral PD-L1 inhibitor has the potential to improve the patient experience further."

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## CG Oncology Announces $105 Million Oversubscribed Crossover Financing to Support Continued Advancement of Clinical-Stage Bladder Cancer Pipeline

"We are excited to welcome leading life science investors who share our vision of developing cutting-edge therapeutics addressing unmet medical needs in bladder cancer," said Arthur Kuan, Chief Executive Officer, CG Oncology. "Our lead asset, cretostimogene grenadenorepvec, continues to make significant clinical progress in bladder cancer in both monotherapy and in combination studies and we are encouraged to see our treatments get closer to being available to bladder cancer patients worldwide."

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