MedNess Newsletter July 12, 2023

From MedNess <newsletter@medness.org>

Para sarah@medness.org

Fecha miércoles, 12 de julio de 2023 a las 17:41

MedNess

bite-size biopharma and medtech news

July 12, 2023

Subscribe here

Read this newsletter online

MedNess News Highlights this week

NMPA Approves FUCASO, the First Fully-human BCMA CAR-T Therapy, for the Treatment of Relapsed or Refractory Multiple Myeloma in China

Read the post

Paxalisib Receives Fast Track Designation From FDA For Treatment Of Solid Tumor Brain Mets Harboring PI3K Pathway Mutations In Combination With Radiation Therapy

Read the post

New Positive Interim Ph 3 Data Demonstrating RenovoGem™ Delays Cancer Progression by Eight Months in Locally Advanced Pancreatic Cancer Announced

Read the post

FDA Removes Partial Clinical Hold on TakeAim Leukemia Study RP2D Established at 300 mg BID

Read the post

Caribou Biosciences Announces $25 Million Equity Investment from Pfizer

Read the post

Drug Approvals

NMPA Approves FUCASO, the First Fully-human BCMA CAR-T Therapy, for the Treatment of Relapsed or Refractory Multiple Myeloma in China

Dr. Hui Zhou, Senior Vice President of Innovent Biologics, stated, "Multiple myeloma is a common hematology malignant disease with high incidence rate, and relapse and refractory are almost inevitable after current treatments. There's an urgent unmet need of a treatment with well-tolerated and long persistence for RRMM patients in China. FUCASO®, as an innovative fully-human BCMA-directed T cell therapy, has demonstrated robust and long-lasting efficacy and outstanding safety in long-term follow-up data from the registrational clinical study, which underscores its potential to be a pioneering treatment option for patients with RRMM. We are very pleased with the approval of FUCASO® and hope it could benefit RRMM patients as the first approved BCMA CAR-T therapy in China."

Read more...

European Commission Grants Conditional Marketing Authorization for LYTGOBI Tablets for the Treatment of Adults With Cholangiocarcinoma

“Today is an important day for current and future patients with CCA as well as the healthcare providers who treat them,” said Peter Foertig, MD, Vice President, Medical Affairs, Taiho Oncology Europe. “LYTGOBI is an oral molecularly targeted medication that may provide clinically meaningful outcomes for patients undergoing treatment for CCA.”

Read more...

More news on
Drug Approvals

Regulatory news

Paxalisib Receives Fast Track Designation From FDA For Treatment Of Solid Tumor Brain Mets Harboring PI3K Pathway Mutations In Combination With Radiation Therapy

“Brain metastases are rapidly emerging as a key pillar of paxalisib’s clinical development,” said Dr. John Friend, Chief Executive Officer of Kazia. “We have seen a high level of interest from clinicians in the emerging data from this patient population, and it is exciting to now have that interest complemented by FDA’s award of Fast Track Designation. With important data read-outs expected in adult and childhood brain cancer during CY2023, we will be working with investigators and advisors to drive forward our research in brain metastases also.”

Read more...

FDA Grants Priority Review for Zolbetuximab Biologics License Application

“Astellas is committed to bringing innovative therapies to patients with hard-to-treat cancers, including gastric cancer. While rare in the U.S., gastric cancer can be deadly when diagnosed in the late stages,” said Moitreyee Chatterjee-Kishore, PhD, MBA, Senior Vice President and Head of Immuno-Oncology Development, Astellas. “The FDA’s acceptance of the Biologics License Application filing and Priority Review designation for zolbetuximab confirms the urgent therapeutic need and brings us one step closer to delivering on this commitment to patients, families and caregivers.”

Read more...

More news on
Regulatory News

Trial Results

New Positive Interim Ph 3 Data Demonstrating RenovoGem™ Delays Cancer Progression by Eight Months in Locally Advanced Pancreatic Cancer Announced

“Clinical practice has been waiting decades for a meaningful advancement in the standard of care for pancreatic cancer treatment, with less toxicity and better outcomes. The new data from the TIGeR-PaC interim results support that RenovoGem has the potential to more than double progression-free survival compared to systemic chemotherapy alone in this difficult-to-treat cancer, which demonstrates support for a new treatment standard,” said Michael J. Pishvaian, M.D., Ph.D., PI of the TIGeR-PaC study. “This data has the potential to be a paradigm-shifting treatment for patients at risk of cancer progression, including those who have limited well-tolerated options.”

Read more...

Datopotamab Deruxtecan Met Dual Primary Endpoint Of PFS In Patients With Advanced NSCLC in TROPION-Lung01 Phase 3 Trial

Susan Galbraith, Executive Vice President, Oncology R&D, AstraZeneca, said: "With TROPION-Lung01, we met the dual primary endpoint of progression-free survival, challenging the entrenched standard of care in a previously treated and unselected patient population that has long deserved an alternative to chemotherapy. These first Phase III trial results from the datopotamab deruxtecan clinical programme provide compelling evidence for the potential role this TROP2-directed antibody drug conjugate can play in treating patients with lung cancer."

Read more...

More news on
Trial Results

Trial Status

FDA Removes Partial Clinical Hold on TakeAim Leukemia Study RP2D Established at 300 mg BID

"We are pleased to announce that FDA has removed the partial clinical hold on the TakeAim Leukemia study and that we are proceeding with 300 mg BID as our RP2D. We are working with our clinical sites to enroll targeted patients with AML (patients with a FLT3 or spliceosome mutation who have received ≤ 2 prior lines of treatment). We also plan to initiate a front-line combination study of emavusertib with azacitidine and venetoclax. We believe emavusertib has the potential to be the cornerstone agent in the treatment of hematological malignancies." said James Dentzer, President and Chief Executive Officer of Curis. "In 2024, we expect to have updated data from the TakeAim Leukemia monotherapy study, clarification of a monotherapy registrational study design, and initial data from an azacitidine and venetoclax combination study."

Read more...

More news on
Trial Statuses

Business News

Caribou Biosciences Announces $25 Million Equity Investment from Pfizer

“We believe Pfizer’s investment in Caribou highlights the potential of our clinical programs and we are excited to establish this partnership with one of the world’s premier biopharmaceutical companies,” said Rachel Haurwitz, PhD, Caribou’s president and chief executive officer. “We are actively advancing our allogeneic CAR-T cell therapy pipeline and look forward to providing updates from all of our programs over the next six months, including 6-month dose escalation data from our ANTLER Phase 1 clinical trial for CB-010, dose escalation updates on our CaMMouflage Phase 1 clinical trial for CB-011, and submission of an investigational new drug application for CB-012.”

Read more...

F-star Announces Strategic Collaboration and Licence Agreement with Takeda to Discover and Develop Next-Generation Multi-Specific Antibodies

Neil Brewis, Ph.D., Head of F-star Therapeutics and Chief Scientific Officer said: “We are delighted to expand our relationship with Takeda who shares our vision of developing pioneering multi-specific immunotherapies so more people with cancer can live longer with improved lives. This strategic collaboration leverages the capabilities of both companies by combining F-star’s clinically validated Fcab™ and mAb² ™ platforms with Takeda’s unique understanding of the immune system and its ability to progress drugs to the clinic.”

Read more...

More Business
News

Editor's Desk

Richa Tewari, Managing Director and Contributing Author, Onco-This-Week

Shalini Roy Choudhury, Managing Editor

Anusha Jayaraman, Managing Editor

Siftjit Kaur, Social Media Manager

Himanshi Agarwal, Social Media Manager

Rueben Das, MedNess Neuro

Disclaimer

The editors take care to share authentic information. In case of any discrepancies please write to **newsletter@medness.org**
The sponsors do not have any influence on the nature or kind of the news/analysis reported in MedNess. The views and opinions expressed in this article are those of the authors and do not necessarily reflect the official policy or position of MedNess. Examples of analysis performed within this article are only examples. They should not be utilized in real-world analytic products as they are based only on very limited and dated open source information. Assumptions made within the analysis are not reflective of the position of anyone volunteering or working for MedNess. This blog is strictly for news and information. It does not provide medical advice, diagnosis or treatment nor investment suggestions. This content is not intended to be a substitute for professional medical advice, diagnosis, or treatment. Always seek the advice of your physician or another qualified health provider with any questions you may have regarding a medical condition. Never disregard professional medical advice or delay in seeking it because of something you have read on this website.
MedNess is a part of STEMPeers® which is a 501(c)(3) organization registered in PA as PhD Career Support Group. The organization helps create a growing network of STEM scientists that is involved in peer to peer mentoring and support.