MedNess Newsletter February 1, 2023

From MedNess <newsletter@medness.org>

Para sarah@medness.org

Fecha miércoles, 1 de febrero de 2023 a las 14:28

MedNess

bite-size biopharma and medtech news

February 1, 2023

Subscribe here

Read this newsletter online

MedNess News Highlights this week

FDA Accelerated Approval of TUKYSA® (tucatinib) in Combination with Trastuzumab for People with Previously Treated RAS WT, HER2-Positive mCRC

Read the post

Fast Track Designation from the FDA for Tamibarotene for the Treatment of Higher-Risk Myelodysplastic Syndrome

Read the post

TRANSCEND CLL 004 Trial of Breyanzi® (lisocabtagene maraleucel) Met Primary Endpoint of Complete Response Rate in R/R CLL Patients

Read the post

KEYNOTE-991 Trial Evaluating KEYTRUDA® Plus Enzalutamide and Androgen Deprivation Therapy in Patients With mHSPC to Stop for Futility

Read the post

Teon Therapeutics Announces Clinical Trial Collaboration With Merck to Evaluate TT-81 in Combination with KEYTRUDA

Read the post

Drug Approvals

FDA Accelerated Approval of TUKYSA® (tucatinib) in Combination with Trastuzumab for People with Previously Treated RAS WT, HER2-Positive mCRC

"Historically, patients with HER2-positive metastatic colorectal cancer who have progressed following frontline therapy have had poor outcomes," said John Strickler, M.D., associate professor of medicine, Duke University Medical Center, and lead investigator for the MOUNTAINEER trial. "The FDA approval of a chemotherapy-free combination regimen that specifically targets HER2 is great news for these patients."

Read more...

FDA Approves KEYTRUDA® as Adjuvant Treatment Following Surgical Resection and Platinum-Based Chemotherapy for Patients With Stage IB, II, or IIIA NSCLC

“While there have been many advances for patients with metastatic disease, surgery remains the typical treatment for people with stage IB, II and IIIA non-small cell lung cancer. Unfortunately, many of these patients who undergo surgery still see their disease return,” said Roy S. Herbst, M.D., Ph.D., deputy director and chief of medical oncology, Yale Cancer Center and Smilow Cancer Hospital and ensign professor of medicine (medical oncology) and professor of pharmacology, Yale School of Medicine. “Today’s approval for KEYTRUDA offers a new, important immunotherapy treatment option for stage IB (T2a ≥4 cm), II, or IIIA patients with non-small cell lung cancer following surgery and adjuvant chemotherapy. This provides, for the first time, an adjuvant immunotherapy treatment option for non-small cell lung cancer patients with stage IB disease and regardless of PD-L1 expression.”

Read more...

More news on
Drug Approvals

Regulatory news

Fast Track Designation from the FDA for Tamibarotene for the Treatment of Higher-Risk Myelodysplastic Syndrome

“Receipt of Fast Track designation for tamibarotene underscores both the potential of tamibarotene and the unmet need for HR-MDS patients, who have a poor prognosis due to the progressive nature of the disease,” said David A. Roth, M.D., Chief Medical Officer of Syros Pharmaceuticals. “No new therapies beyond hypomethylating agents have been approved since 2006, and approximately half of all patients diagnosed with HR-MDS patients ultimately progress to AML. We are grateful for the opportunity to potentially expedite the delivery of tamibarotene as a new standard of care for this population.”

Read more...

IND cleared for SC291, a Hypoimmune-modified, CD19-targeted Allogeneic CAR T Therapy for Patients with B-Cell Malignancies

“The clearance of our SC291 IND is an important milestone, putting us closer to our goal of making an important medicine for patients with B-cell lymphomas and leukemias,” said Steve Harr, Sana’s President and CEO. “We look forward to

understanding the safety, potency, and persistence of these cells in patients, and we are optimistic that SC291 can become an important medicine for patients with these difficult cancers. Furthermore, this platform forms the backbone for additional development of CAR T cells targeting CD22, BCMA, and beyond. We expect initial clinical data from the SC291 study later this year and believe insights from this study will better inform our opportunities across the broader platform, both for CAR T cells and for programs outside of cancer such as our pancreatic islet cell therapy for patients with type 1 diabetes."

Read more...

More news on
Regulatory News

Trial Results

TRANSCEND CLL 004 Trial of Breyanzi® (lisocabtagene maraleucel) Met Primary Endpoint of Complete Response Rate in R/R CLL Patients

"CLL is an incurable disease with complex biology and immune dysregulation that has made the development of T cell-based therapies that provide deep remission very challenging," said Anne Kerber, senior vice president, head of Cell Therapy Development, Bristol Myers Squibb. "In a population that has limited options, the TRANSCEND CLL 004 study represents the first multicenter trial evaluating a CAR T cell therapy in heavily pre-treated patients with relapsed or refractory CLL or SLL, with results showing the potential of Breyanzi as a personalized one-time treatment approach for patients with this difficult-to-treat disease."

Read more...

Ph 3 CARTITUDE-4 Study of CARVYKTI® (cilta-cel) meets Primary Endpoint in Patients with Relapsed and Refractory Multiple Myeloma

“The CARTITUDE-4 study represents the first Phase 3 program in our comprehensive clinical development strategy for CARVYKTI, and further demonstrates our commitment to advance the treatment of patients with relapsed/refractory multiple myeloma,” said Jordan Schecter, M.D., Vice President, Clinical Development Cellular Therapy Program, Janssen Research & Development, LLC. “We look forward to the presentation of the data from the CARTITUDE-4 study at a future medical meeting.”

Read more...

More news on
Trial Results

Trial Status

KEYNOTE-991 Trial Evaluating KEYTRUDA® Plus Enzalutamide and Androgen Deprivation Therapy in Patients With mHSPC to Stop for Futility

“There is a significant unmet need for patients with advanced prostate cancer, and the outcome of this study is an important reminder that this disease remains very difficult to treat,” said Dr. Scot Ebbinghaus, vice president, clinical research, Merck Research Laboratories. “We are grateful to the patients and investigators for their participation in this study, and we will continue to advance our clinical development program to evaluate KEYTRUDA-based combinations and novel candidates for patients with prostate cancer.”

Read more...

Ongoing MGTA-117 Ph 1/2 Dose-Escalation Clinical Trial in R/R AML and MDS paused

Read more...

More news on
Trial Statuses

Business News

Teon Therapeutics Announces Clinical Trial Collaboration With Merck to Evaluate TT-81 in Combination with KEYTRUDA

"We are fortunate to have the opportunity to collaborate with Merck for this Phase 1/2 trial. The collaboration of the combination arm of our TT-816 clinical trial represents an important advancement in our comprehensive development program and further supports our mission to invent new hope for patients by potentially providing meaningful treatments to those with few remaining alternatives," said Serge Messerlian, Chief Executive Officer of Teon Therapeutics. "In addition to its great potential as a monotherapy, by blocking both the PD-1 and CB2 pathways, we believe that TT-816 in combination with KEYTRUDA may have an additive benefit in 'hot' tumors and synergistic effect in 'cold' tumors that may result in improved outcomes for more patients. Results of our preclinical studies indicate that TT-816 has unique mechanisms of action that enhance both T cell and NK cell antitumor immunity, prevent broad-based T cell exhaustion, synergize antitumor effects with current immune checkpoint inhibitor therapies, and directly promote T cell infiltration into solid tumors."

Read more...

Takeda To Acquire Exclusive Worldwide (ex-China) License of HUTCHMED's Fruquintinib

"Fruquintinib has the potential to change the treatment landscape for patients with refractory metastatic CRC who are in need of additional treatment options. We look forward to utilizing our development and commercial capabilities to expand the potential of this innovative medicine to patients beyond China," said Teresa Bitetti, President of the Global Oncology Business Unit at Takeda. "We have a strong track record of working with companies that share our focus on bringing transformative medicines to patients around the globe who need them. Working with HUTCHMED will enable us to expand our oncology portfolio, bringing us one step closer to achieving our aspiration to cure cancer."

Read more...

More Business News

Editor's Desk

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

Shalini Roy Choudhury, Managing Editor

Shivasankari Gomathinayagam, Contributing Author, MedNess Vaccines

Siftjit Kaur, Social Media Manager

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.