MedNess Newsletter May 18, 2023

From MedNess <newsletter@medness.org>

Para sarah@medness.org

Fecha jueves, 18 de mayo de 2023 a las 19:42

MedNess

bite-size biopharma and medtech news

May 18, 2023

Subscribe here

Read this newsletter online

MedNess News Highlights this week

European Commission approves Tibsovo® (ivosidenib tablets) in IDH1-mutated Acute Myeloid Leukemia and IDH1-mutated Cholangiocarcinoma

Read the post

NMPA Breakthrough Designation for IBI351 (KRASG12C Inhibitor) as Monotherapy for Previously Treated Advanced Colorectal Carcinoma

Read the post

New Results from Ph 2 Trial Confirm Benefit of Trilaciclib in Reducing Adverse Events Related to an ADC

Read the post

First Patient Dosed in Ph I Trial Evaluating TG6050, a Novel IL-12-Armed Oncolytic Virus Administered Intravenously, in NSCLC

Read the post

Gilead Strengthens Early Pipeline In Oncology And Inflammation Through The Acquisition Of XinThera

Read the post

Drug Approvals

The China NMPA Approves TYVYT® + Bevacizumab + Chemotherapy in Patients with EGFR-mutated nsqNSCLC who Progressed after EGFR-TKI Therapy

The principal investigator of the ORIENT-31 Study, Prof. Shun Lu from the Oncology Department of Shanghai Chest Hospital, stated, "Different from the western population, about half of the Chinese patients with NSCLC have EGFR mutations. EGFR-TKI targeted therapy is the first line treatment choice in NSCLC patients with EGFR sensitive mutation. However, almost all patients will eventually develop TKI-resistance and progression of disease and there are no good treatment options for EGFR-TKI failed NSCLC population. The ORIENT-31 study is globally the first prospective, randomized and double-blind Phase 3 study that demonstrated that PD-1 inhibitor ± bevacizumab combined with chemotherapy can significantly prolong PFS in EGFR-mutant non-squamous NSCLC population who have failed EGFR-TKI treatment. In addition, compared with standard platinum-based chemotherapy, sintilimab and bevacizumab combined with chemotherapy improved the ORR and DOR, showing survival benefit trend as well as improvement in quality of life. The approval of this indication brings a new treatment option for EGFR-mutated non-squamous NSCLC patients who have failed EGFR-TKI treatment, benefiting more Chinese patients."

Read more...

European Commission approves Tibsovo® (ivosidenib tablets) in IDH1-mutated Acute Myeloid Leukemia and IDH1-mutated Cholangiocarcinoma

"The prognosis for patients diagnosed with acute myeloid leukemia or cholangiocarcinoma has historically been poor with very limited treatment options. With today's approval by the European Commission, Tibsovo® is now the first targeted IDH1 inhibitor approved in Europe. This further affirms our unparalleled scientific leadership in harnessing the IDH mutation and commitment to finding new therapeutic solutions for patients with difficult and hard-to-treat cancers," said Arnaud Lallouette, M.D., Executive Vice President, Global Medical & Patient Affairs at Servier.

Read more...

More news on
Drug Approvals

Regulatory news

NMPA Breakthrough Designation for IBI351 (KRASG12C Inhibitor) as Monotherapy for Previously Treated Advanced Colorectal Carcinoma

"We are glad to see the NMPA grants another Breakthrough Therapy Designation based on the preliminary results of IBI351 monotherapy in advanced colorectal carcinoma." said Dr. Hui Zhou, Senior Vice President of Innovent. "The prognosis of advanced colorectal carcinoma patients with KRASG12C mutation is worse than KRAS wild type patients with limited therapeutic options. Currently, there are no approved drugs targeting KRASG12C available on the market in China. The preliminary data of IBI351 monotherapy has shown outstanding efficacy and favorable safety in previously treated advanced colorectal carcinoma. We look forward to obtaining more data from the ongoing clinical trials, and further validating the clinical benefits of IBI351 as monotherapy or combination therapy in patients with advanced colorectal carcinoma."

Read more...

Type A Meeting scheduled with the U.S. FDA to Review Proposed Study Design for a Second Ph 3 Study Evaluating HyBryte™ in the Treatment of CTCL

"Responding to FDA feedback, Soligenix has submitted a confirmatory Phase 3 draft study protocol retaining the key aspects of the first Phase 3 trial," stated Christopher J. Schaber, PhD, President and Chief Executive Officer of Soligenix. "We look forward to discussing the protocol in detail with FDA. We intend to provide a further update once we have received the minutes from the meeting or when we have more clarity on next steps, which we anticipate having by or before the end of June."

Read more...

More news on
Regulatory News

Trial Results

New Results from Ph 2 Trial Confirm Benefit of Trilaciclib in Reducing Adverse Events Related to an ADC

"These preliminary results continue to show the consistent benefit of trilaciclib when administered prior to sacituzumab, relative to the previously published single agent safety profile of this ADC, including greater than 50 percent reductions in the incidence of events including neutropenia, anemia, and diarrhea," said Raj Malik, M.D., Chief Medical Officer at G1 Therapeutics. "It is too early to determine the efficacy of trilaciclib prior to sacituzumab in this patient population. However, early indications suggest a higher response rate in patients with PD-L1 positive tumors, which commonly have an immune inflamed tumor microenvironment and are thus more likely to respond early to immunotherapies. Given that this trial includes a heavily pretreated patient population, we are enthusiastic about these data to date. We will continue to monitor efficacy to assess the potential of trilaciclib to improve overall survival – by protecting the immune system and stimulating long term immune surveillance – when combined with additional treatment regimens beyond gemcitabine/carboplatin for patients with TNBC. We look forward to these overall survival data in the first quarter of 2024."

Read more...

OS results from Elahere's Ph 3 MIRASOL trial announced

"We are honored that MIRASOL has been selected as a late-breaker presentation at ASCO, and pleased that we will be able to share the results from the trial so quickly after they became available," said Anna Berkenblit, MD, Senior Vice President and Chief Medical Officer of ImmunoGen. "Having demonstrated a statistically significant and clinically meaningful improvement in overall survival compared to investigator's choice of single-agent chemotherapy, I believe ELAHERE has the potential to be practice changing in FRα-positive, platinum-resistant ovarian cancer."

Read more...

More news on
Trial Results

Trial Status

First Patient Dosed in Ph I Trial Evaluating TG6050, a Novel IL-12-Armed Oncolytic Virus Administered Intravenously, in NSCLC

"We are pleased to initiate this first-in-human trial of TG6050 administered intravenously in patients with recurrent/metastatic advanced non-small cell lung cancer in great need for effective new therapeutic options," said Dr. Maud Brandely, MD, PhD, Chief Medical Officer of Transgene. "Intravenous administration of TG6050 aims at significantly enhance the therapeutic potential of this promising oncolytic virus as it allows a targeted approach to many internal cancer lesions and metastases inaccessible by intratumoral injection. With its multiple mechanisms of action – including oncolysis, the induction of an immune response together with high intra-tumoral concentrations of IL-12 and anti-CTLA4 antibody – and its ability to be administered intravenously, TG6050 has several competitive advantages. We look forward to progressing this trial and delivering clinical results for this promising new oncolytic virus."

Read more...

First Patient Treated in Ph 3 HARMONi Clinical Trial Evaluating Ivonescimab (SMT112)

"Advanced or metastatic non-small cell lung cancer is such a devastating diagnosis for patients," said Ian Anderson, M.D., Medical Oncologist at Providence Medical Foundation, who treated the first patient in HARMONi. "While we are making great strides as a medical community to improve the quality and duration of patients' lives, there remains significant room for improvement in the treatment options available for these patients. In particular, for patients with an EGFR-mutated tumor whose tumor has progressed after their initial TKI therapy, there are limited options. We are particularly excited to evaluate the potential of ivonescimab in the HARMONi study to make a meaningful impact on the lives of these patients facing this difficult disease."

Read more...

More news on
Trial Statuses

Business News

Gilead Strengthens Early Pipeline In Oncology And Inflammation Through The Acquisition Of XinThera

“Gilead and XinThera share similar missions to discover new therapies to treat cancer and inflammatory diseases, which drive our determination to unlock the body’s ability to better respond to these diseases,” said Chris LeMasters, who served as XinThera CEO. “We are eager to join Gilead and together explore the potential of our precision medicines as critical components of the next generation of therapies targeting diseases with high unmet need.”

Read more...

Bayer and Bicycle Therapeutics Enter Strategic Collaboration for Development of Novel Targeted Radionuclide Therapies in Oncology

“At Bayer, we enter strategic collaborations to expand our access to innovation,” said Christian Rommel, Ph.D., Global Head of Research and Development and Member of the Executive Committee, Pharmaceuticals Division, Bayer. “With Bicycle’s proprietary peptide-based technology, we continue to strengthen our oncology development pipeline by adding next-generation targeted radiotherapeutics to address high unmet medical needs of cancer patients.”

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.