Subgroup Analysis from Phase 3 Clinical Trial Supports Efficacy of Maribavir Over Conventional Therapies in Transplant Recipients With Cytomegalovirus Infection (Refractory, With or Without Resistance) | 1

[ad_1]

**Business Wire India**

– More Than Three Times as Many Transplant Recipients With Confirmed Resistant Cytomegalovirus (CMV) Infection at Baseline Receiving the Investigational Drug Maribavir Achieved CMV Viremia Clearance Compared to Conventional Antiviral Therapies, Building on Previously Presented Results Supporting the Efficacy of Maribavir

– Transplant Recipients Receiving Maribavir Experienced Lower Rates of Treatment-Related Neutropenia and Acute Kidney Injury Compared to Conventional Antiviral Therapies

– Takeda Continues to Investigate Maribavir for the First-Line Treatment of CMV in Hematopoietic Cell Transplant Recipients in an Ongoing Phase 3 Clinical Trial

Takeda Pharmaceutical Company Limited (TSE:4502/NYSE:TAK) (“Takeda”) today during the Presidential Symposium at the 47th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT) announced the results from a subgroup analysis of the Phase 3 TAK-620-303 (SOLSTICE) trial, for the investigational drug TAK-620 (maribavir), which supported the efficacy results from the overall randomized population. More than three times as many (62.8%; 76/121) transplant recipients with confirmed genotypic resistant CMV infection at baseline treated with maribavir achieved confirmed CMV viremia clearance at Study Week 8 (end of treatment phase) compared to those treated with conventional antiviral therapies (20.3%, 14/69) (investigator assigned treatment; IAT consists of one or a combination of ganciclovir, valganciclovir, foscarnet or cidofovir) (adjusted difference [95% CI]: 44.1% [31.3, 56.9]).

Findings from the overall trial population showed the study met its primary endpoint, demonstrating that maribavir was superior to conventional antiviral therapies in CMV viremia clearance at Study Week 8. Specifically, 55.7% (131/235) of transplant recipients with refractory, with or without resistance (R/R), CMV infection/disease treated with maribavir achieved confirmed CMV viremia clearance as compared to 23.9% (28/117) of those on conventional antiviral therapies (adjusted difference [95% CI]: 32.8%, [22.8, 42.7]; p<0.001).
“Transplant recipients with CMV infections resistant to conventional antiviral therapies are some of the hardest to treat. Current treatment options are limited, and hematologist-oncologists have to engage in a careful balance of viral clearance and side effect management,” said Dr. Rafael Duarte, Hospital Universitario Puerta de Hierro, Madrid. “We believe these data are important as they build on previously presented results supporting the potential of maribavir, which, if approved, could transform the management of CMV in these patients.”

Transplant recipients receiving maribavir exhibited lower incidence of treatment-related toxicities common with conventional antiviral therapies. Those receiving maribavir experienced lower rates of treatment-related neutropenia vs. valganciclovir/ganciclovir (1.7% [4/234] vs. 25% [14/56]) and acute kidney injury vs. foscarnet (1.7% [4/234] vs. 19.1% [9/47]). Incidence of any treatment-emergent adverse events (TEAEs) was 97.4% (228/234) for maribavir and 91.4% (106/116) for the conventional therapy group. The most common TEAEs in the maribavir group were dysgeusia (35.9%, 84/234), nausea (8.5%, 20/234) and vomiting (7.7%, 18/234). Incidence of TEAEs leading to study drug discontinuation was 13.2% (31/234) in the maribavir group and 31.9% (37/116) in the conventional therapy group. Two treatment-related serious TEAEs led to death (1 patient per treatment group).

“Current CMV management is associated with difficult tradeoffs, including management of toxicities and viremia clearance,” said Obi Umeh, MD, Vice President and Maribavir Global Program Leader, Takeda. “As we continue our research of maribavir, an oral antiviral compound, across patient populations, we are committed to addressing this unmet need so physicians potentially have an additional treatment option.”

About CMV

CMV is a beta herpesvirus that commonly infects humans; serologic evidence of prior infection can be found in 40%-100% of various adult populations. CMV typically resides latent and asymptomatic in the body but may reactivate during periods of
Subgroup Analysis from Phase 3 Clinical Trial Supports Efficacy of Maribavir Over Conventional Therapies in Transplant Recipients With Cytomegalovirus Infection (Refractory, With or Without Resistance) | 3

Immunosuppression. Serious disease may occur in individuals with compromised immune systems, which includes patients who receive immunosuppressants associated with various types of transplants including hematopoietic cell transplant (HCT) or solid organ transplant (SOT).[^1] Out of the estimated 200,000 adult transplants per year, CMV is one of the most common viral infections experienced by transplant recipients, with an estimated incidence rate between 16-56% in SOT recipients and 30-70% in HCT recipients.^[5-10]

In transplant recipients, reactivation of CMV can lead to serious consequences including loss of the transplanted organ and, in extreme cases, can be fatal.^[11-12] Existing therapies to treat posttransplant CMV infections may demonstrate toxicities that require dose adjustments or may fail to adequately suppress viral replication.^[13-15] Additionally, existing therapies may require or prolong hospitalization due to administration.^[13-14]

**About Maribavir**

Maribavir, an orally bioavailable anti-CMV compound, is the only antiviral agent presently in Phase 3 development for the treatment of post-transplant patients with CMV in SOT or HCT. Maribavir is an investigational treatment that has not been approved for use by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) or any other regulatory authorities. Maribavir is the only CMV antiviral drug that targets and inhibits the UL97 protein kinase and its natural substrates.^[16-19]

Maribavir has been granted Orphan Drug Designation by the European Commission as a treatment of CMV disease in patients with impaired cell mediated immunity and by the FDA for treatment of clinically significant CMV viremia and disease in at-risk patients. Orphan status is granted to certain investigational medicines intended for the treatment or prevention of a rare, life-threatening disease. The FDA has also granted maribavir Breakthrough Therapy Designation as a treatment for CMV infection and disease in transplant patients resistant or refractory to prior therapy. Breakthrough Therapy Designation expedites the development and review of investigational treatments for serious conditions with preliminary clinical evidence indicating that the drug may demonstrate
substantial improvement over available therapy. These designations do not guarantee that the EMA or FDA will approve maribavir for the treatment of CMV infections in transplant patients, and the timing of any such approval is uncertain.

About Takeda’s SOLSTICE Trial

The TAK-620-303 (SOLSTICE) trial (NCT02931539) is a multicenter, randomized, open-label, active-controlled trial comparing treatment with either maribavir or investigator assigned treatment, IAT, (conventional antiviral therapy) in hematopoietic cell transplant and solid organ transplant recipients with CMV infection refractory, with or without resistance, to one or a combination of the conventional antiviral therapies: ganciclovir, valganciclovir, foscarnet or cidofovir. Patients underwent a 2-week screening period, followed by randomization 2:1 to maribavir (n=235) (400 mg) or IAT (n=117) for an 8-week treatment period, plus 12 weeks of follow-up.

The trial’s primary endpoint was defined as the proportion of patients who achieved confirmed CMV viremia clearance (plasma CMV DNA <137 IU/mL in two consecutive tests ≥5 days apart at central laboratory) compared to IAT at the end of Study Week 8. The key secondary endpoint was defined as achievement of CMV viremia clearance and symptom control at end of Study Week 8, maintained through Study Week 16.

About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited (TSE: 4502/NYSE: TAK) is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetic and Hematology, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. We are focusing on developing highly innovative medicines that contribute to making a difference in people’s lives by
advancing the frontier of new treatment options and leveraging our enhanced collaborative R&D engine and capabilities to create a robust, modality-diverse pipeline. Our employees are committed to improving quality of life for patients and to working with our partners in health care in approximately 80 countries. For more information, visit https://www.takeda.com.

Important Notice

For the purposes of this notice, “press release” means this document, any oral presentation, any question and answer session and any written or oral material discussed or distributed by Takeda Pharmaceutical Company Limited (“Takeda”) regarding this release. This press release (including any oral briefing and any question-and-answer in connection with it) is not intended to, and does not constitute, represent or form part of any offer, invitation or solicitation of any offer to purchase, otherwise acquire, subscribe for, exchange, sell or otherwise dispose of, any securities or the solicitation of any vote or approval in any jurisdiction. No shares or other securities are being offered to the public by means of this press release. No offering of securities shall be made in the United States except pursuant to registration under the U.S. Securities Act of 1933, as amended, or an exemption therefrom. This press release is being given (together with any further information which may be provided to the recipient) on the condition that it is for use by the recipient for information purposes only (and not for the evaluation of any investment, acquisition, disposal or any other transaction). Any failure to comply with these restrictions may constitute a violation of applicable securities laws.

The companies in which Takeda directly and indirectly owns investments are separate entities. In this press release, “Takeda” is sometimes used for convenience where references are made to Takeda and its subsidiaries in general. Likewise, the words “we”, “us” and “our” are also used to refer to subsidiaries in general or to those who work for them. These expressions are also used where no useful purpose is served by identifying the particular company or companies.
Subgroup Analysis from Phase 3 Clinical Trial Supports Efficacy of Maribavir Over Conventional Therapies in Transplant Recipients With Cytomegalovirus Infection (Refractory, With or Without Resistance) | 6

Forward-Looking Statements

This press release and any materials distributed in connection with this press release may contain forward-looking statements, beliefs or opinions regarding Takeda’s future business, future position and results of operations, including estimates, forecasts, targets and plans for Takeda. Without limitation, forward-looking statements often include words such as “targets”, “plans”, “believes”, “hopes”, “continues”, “expects”, “aims”, “intends”, “ensures”, “will”, “may”, “should”, “would”, “could” “anticipates”, “estimates”, “projects” or similar expressions or the negative thereof. These forward-looking statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those expressed or implied by the forward-looking statements: the economic circumstances surrounding Takeda’s global business, including general economic conditions in Japan and the United States; competitive pressures and developments; changes to applicable laws and regulations, including global health care reforms; challenges inherent in new product development, including uncertainty of clinical success and decisions of regulatory authorities and the timing thereof; uncertainty of commercial success for new and existing products; manufacturing difficulties or delays; fluctuations in interest and currency exchange rates; claims or concerns regarding the safety or efficacy of marketed products or product candidates; the impact of health crises, like the novel coronavirus pandemic, on Takeda and its customers and suppliers, including foreign governments in countries in which Takeda operates, or on other facets of its business; the timing and impact of post-merger integration efforts with acquired companies; the ability to divest assets that are not core to Takeda’s operations and the timing of any such divestment(s); and other factors identified in Takeda’s most recent Annual Report on Form 20-F and Takeda’s other reports filed with the U.S. Securities and Exchange Commission, available on Takeda’s website at: https://www.takeda.com/investors/reports/sec-filings/ or at www.sec.gov. Takeda does not undertake to update any of the forward-looking statements contained in this press release or any other forward-looking statements it may make, except as required by law or stock exchange rule. Past performance is not an indicator of future results and the results or statements of Takeda in this press release may not be indicative of, and are not an estimate, forecast, guarantee or projection of Takeda’s future results.

The difference in proportion of responders between treatment groups was obtained using Cochran-Mantel-Haenszel (CMH) weighted average across all strata and tested using
Subgroup Analysis from Phase 3 Clinical Trial Supports Efficacy of Maribavir Over Conventional Therapies in Transplant Recipients With Cytomegalovirus Infection (Refractory, With or Without Resistance) | 7

stratum-adjusted CMH method, with transplant type and baseline plasma CMV DNA concentration as two stratification factors
† Refractory defined as documented failure to achieve >1 log10 decrease in CMV DNA level in whole blood or plasma after a 14 day or longer treatment period with IV ganciclovir/oral valganciclovir, IV foscarnet, or IV cidofovir
‡ Resistant defined as refractory CMV and documentation of >1 CMV genetic mutations associated with resistance to ganciclovir, valganciclovir, foscarnet, and/or cidofovir

Subgroup Analysis from Phase 3 Clinical Trial Supports Efficacy of Maribavir Over Conventional Therapies in Transplant Recipients With Cytomegalovirus Infection (Refractory, With or Without Resistance) | 8

2018;7:1-16.

View source version on businesswire.com:

[ad_2]

Source link
Subgroup Analysis from Phase 3 Clinical Trial Supports Efficacy of Maribavir Over Conventional Therapies in Transplant Recipients With Cytomegalovirus Infection (Refractory, With or Without Resistance) | 9

Share this:

- [Click to share on Twitter](#) (Opens in new window)
- [Click to share on Facebook](#) (Opens in new window)
- [Click to share on LinkedIn](#) (Opens in new window)
- [Click to share on Skype](#) (Opens in new window)
- [Click to share on WhatsApp](#) (Opens in new window)
- [Click to share on Telegram](#) (Opens in new window)