

REGULATORY NEWS - 9th February 2022

[FDA investigating possible increased risk of death with lymphoma medicine Ukoniq \(umbralisib\)](#)

- The U.S. Food and Drug Administration (FDA) is investigating a possible increased risk of death with the cancer medicine Ukoniq (umbralisib) approved to treat two specific types of lymphomas, which are cancers that affect the body's immune system.
- FDA determined that initial findings from a clinical trial evaluating Ukoniq to treat a related type of cancer found a possible increased risk of death in patients taking the medicine. Because of the seriousness of this safety concern and the similarities between the two types of cancer for which this drug is approved and the type of cancer that was studied in the clinical trial, FDA is alerting patients and health care professionals that FDA is re-evaluating this risk against the benefits of Ukoniq for its approved uses.
- FDA is continuing to evaluate the results from the clinical trial called UNITY.
- FDA may also hold a future public meeting to discuss these findings and explore the continued marketing of Ukoniq.
- FDA has also suspended enrollment of new patients in other ongoing clinical trials of Ukoniq while it continues to review the UNITY findings.
- FDA will communicate the final conclusions and recommendations when it has completed the review or has more information to share.

[Marketing Authorisation Application submitted to EMA Seeking Approval of Teclistamab for the Treatment of Patients with R/R Multiple Myeloma](#)

“Despite the significant progress that has been made in the treatment of multiple myeloma, it remains an incurable cancer, with approximately half of newly diagnosed patients not reaching five-year survival and almost a third dying within one year of diagnosis,” said Edmond Chan MBChB M.D. (Res), Senior Director, EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Limited. “Today’s submission is an important step forward in our mission to improve outcomes for people living with multiple myeloma, where the need for new treatment strategies remains high.”

[U.S. FDA Approves New Label Update for CAR T-Cell Therapy Yescarta® Showing Prophylactic Steroid Use Improves Management of Cytokine Release Syndrome](#)

“These new data will enable doctors to more easily and confidently manage treatment for patients,” said Frank Neumann, MD, PhD, Kite’s Global Head of Clinical Development. “Since the first approval of Yescarta, Kite has worked closely with physicians to optimize all aspects of CAR T-cell therapy to enable as many patients as possible to have the chance to benefit from this treatment. Our responsibility includes research to expand into new diseases and earlier lines of treatment, but also continuously improving the efficacy and safety of our existing CAR T therapies.”

[Enrollment of Ph 1/2 Clinical Trial of GPS in Combination with Pembrolizumab in Advanced Metastatic Ovarian Cancer](#)

“Completion of enrollment is an important milestone as we work diligently to evaluate a much-needed therapeutic treatment option for second or third line relapsed or refractory metastatic ovarian cancer patients,” said Angelos Stergiou, MD, ScD. h.c., President and Chief Executive Officer of SELLAS. “Our ability to complete enrollment timely, especially given the challenges related to COVID, is a tremendous accomplishment. We greatly appreciate the level of commitment Merck has given to this collaboration and are deeply grateful to all patients and their families, as well as investigators and study staff involved.”

[U.S. FDA accepts sBLA for Rylaze™ \(asparaginase erwinia chrysanthemi \(recombinant\)-rywn\) Monday/Wednesday/Friday Dosing Schedule](#)

"We were pleased Rylaze, a much-needed therapeutic option, was approved under the RTOR program while the clinical trial was ongoing. Our science-led and patient-focused development program has enabled us to deliver a clinically significant advancement for patients," said Rob Iannone, M.D., M.S.C.E., executive vice president, global head of research and development of Jazz Pharmaceuticals. "With a dosing schedule of Rylaze administered 25/25/50 mg/m² on Monday/Wednesday/Friday, patients maintain a clinically meaningful level of nadir serum asparaginase activity through the entire duration of treatment. We look forward to submitting two additional regulatory applications this year to ensure as many patients as possible can have access to a reliable and high-quality supply of this important therapy, including another regulatory application to FDA to support the intravenous route of administration and an additional application in Europe later this year."