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FDA grants Fast Track Designation for Anti-LILRB4 Myeloid Checkpoint Inhibitor IO-202 for the Treatment of R/R AML

“We are pleased that the FDA has granted IO-202 Fast Track designation in recognition of its potential to improve outcomes for people with relapsed or refractory AML,” said Paul Woodard, Ph.D., chief medical officer of Immune-Onc. “We look forward to working closely with the FDA to accelerate the clinical development of IO-202, which is currently being evaluated as a monotherapy and in combination with other agents in a Phase 1 dose escalation and expansion trial in patients with AML with monocytic differentiation and in chronic myelomonocytic leukemia (CMML).”

FDA Accepts for Priority Review sBLA for Breyanzi (lisocabtagene maraleucel) as a Second-Line Therapy for Relapsed or Refractory Large B-cell Lymphoma

“Breyanzi as a differentiated CD19-directed CAR T cell therapyhas already proven to be an important treatment option for patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy and nowhas the potential to be a new standard of care for patients after failure of first-line therapy, offering significantly improved outcomes beyond the current mainstay of care,” said Anne Kerber, senior vice president, Cell Therapy Development, Bristol Myers Squibb. “This acceptance from the FDA brings us one step closer to delivering a practice-changing treatment for primary refractory or relapsed large B-cell lymphoma, making Breyanzi available to more patients in need, and underscores the advancements we’re making in cell therapy research to transform the lives of patients with difficult-to-treat blood cancers, including lymphoma.”

FDA Accepts NDA for Adagrasib as Treatment of Previously Treated KRASG12C-Mutated Non-Small Cell Lung Cancer

"The acceptance of our NDA for adagrasib is a significant step forward in Mirati's ongoing efforts to advance innovative, differentiated treatment options for patients with KRASG12C cancers," said Charles Baum, M.D., Ph.D., president, founder and head of research and development, Mirati Therapeutics, Inc. "We look forward to working with the FDA during their review of our application and potentially provide a novel option for patients with non-small cell lung cancer."