August Oncology News Roundup

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Blue Matter Consulting is tracking oncology market trends on a daily basis, and looks back each month to highlight the newsworthy events shaping our current and future oncology market landscape.

Highly Anticipated Approval Granted for Novartis' CAR-T Therapy

The first CAR-T therapy, tisagenlecleucel (Kymriah) has officially been approved for use in heavily pretreated pediatric patients with b-cell ALL. There had been immense speculation regarding the cost of therapy, but Novartis ultimately set a price point on the very low end of market expectations, at $475k for the single-dose infusion. Given the extreme complexity of CAR-T therapy preparation and administration, the drug will be available in just twenty treatment centers at launch, with plans to expand to 32 centers by the end of the year.

Wave of FDA Approvals for Acute Leukemia Therapies

In addition to the monumental CAR-T approval for pediatric ALL, the month of August also included a wave of FDA approvals for various forms of acute leukemia. First, the FDA approved Idhifa as the only available therapy to treat patients with IDH2+ relapsed/refractory AML. Next came the approval for Vyxeos in newly diagnosed AML, where the fixed-combination treatment demonstrated clear improvement over the standard 7+3 regimen. And most recently, Pfizer's Besponsa was approved to treat adults with pretreated b-cell precursor ALL.

Gilead Sciences Acquires Kite Pharma for $11.9 Billion

After years of speculation regarding their next high-profile acquisition, Gilead Sciences agreed to acquire Kite Pharma in anticipation for market approval of its lead CAR-T asset (axi-cel). Axi-cel is expected to gain approval for refractory aggressive forms of non-Hodgkin lymphoma within the next month, while additional CAR candidates remain in trials for hematologic and solid tumors. Gilead will once again set the price for a paradigm-shifting therapy with curative potential, although in contrast with Sovaldi, an initial price point has already been set in the CAR-T space.

Additional Highlights

- Opdivo gained an indication expansion for refractory MSI-H CRC, while narrowly missing its PFS endpoint in the CheckMate-214 study in RCC.
- Lynparza was granted a significant indication expansion for maintenance therapy in ovarian cancer patients, regardless of germline BRCA mutation status.
- The FDA delayed its decision on a BLA for Mylan's Herceptin biosimilar by 3-months, extending the deadline out to early-December.