COVER STORY

GVHD management improves, but questions remain about risk stratification, prophylaxis

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The FDA approval of ibrutinib for adults with chronic graft-versus-host disease may herald a practice-changing breakthrough in the management of this posttransplant complication.

GVHD causes a cross-section of complications — from infections to debilitating tissue injury that can cause irreversible fibrosis — that have made it a daunting challenge following hematopoietic stem cell transplant. Although the approval of one drug will not eliminate all these challenges, there is hope the agent will provide a step on the road to long-term GVHD management.

"For a long time, there were no new drugs for GVHD, at least in part because pharmaceutical companies were reluctant to get involved," **James L.M. Ferrara MD, DSc,** Ward-Coleman chair in cancer medicine; director of Hematologic Malignancies Translational Research Center at Tisch Cancer Institute; and professor of medicine, hematology and medical oncology at Icahn School of Medicine at Mount Sinai, told *HemOnc Today*. "One very smart senior VP of a pharma company said the problem is that GVHD is where new drugs go to die."

Still, the tide may be changing with increased understanding of GVHD biology, and with encouraging data emerging on JAK and histone deacetylase inhibitors.

"However, there are a couple of big questions that we'll need to answer with these drugs," Ferrara said. "One is whether we'll be able to get a complete response, and another is whether we'll be able to get patients off steroids, which decimate the immune system."

Beyond treatment, researchers also are working to prevent GVHD by identifying novel biomarkers for stratifying patients. The gut microbiome and donor type and source are

other areas of active investigation.

HemOnc Today spoke with HSCT experts about the long-term complications associated with GVHD, the impact of the ibrutinib (Imbruvica; Pharmacyclics, Janssen) approval, ongoing research to better understand and treat acute and chronic GVHD, and headway being made into GVHD prophylaxis.

Impact of GVHD

Although HSCT can provide long-term survival for some patients with hematologic malignancies, the procedure poses a substantial risk for GVHD.

Following allogeneic HSCT, GVHD develops when the donor's immune cells attack the patient's normal cells.

Acute GVHD — which typically occurs soon after transplant — can range from mild to severe, and can be life-threatening if not controlled.

Chronic GVHD can occur 3 months to up to 2 years after transplant. Although chronic GVHD is more common among patients who experienced acute GVHD, patients can experience both, either or neither type of GVHD.

Incidence of acute GVHD ranges from 26% to 50% among recipients of matched sibling donor grafts, and from 42% to 75% among recipients of matched unrelated donor grafts. Chronic GVHD can affect around 30% of recipients of fully matched transplants to 60% to 70% of recipients of mismatched transplants.

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