Put It on the Board, 8/17

AML drug approved with companion diagnostic

The Food and Drug Administration approved Idhifa (enasidenib) for the treatment of adult patients with relapsed or refractory acute myeloid leukemia who have a specific genetic mutation. The drug is approved for use with the RealTime IDH2 Assay, which is used to detect specific mutations in the *IDH2* gene in patients with AML.

"Idhifa is a targeted therapy that fills an unmet need for patients with relapsed or refractory AML who have an IDH2 mutation," Richard Pazdur, MD, director of the FDA's Oncology Center of Excellence and acting director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research, said in a statement. "The use of Idhifa was associated with a complete remission in some patients and a reduction in the need for both red cell and platelet transfusions."

Idhifa is an isocitrate dehydrogenase-2 inhibitor that works by blocking several enzymes that promote cell growth.

The efficacy of Idhifa was studied in a single-arm trial of 199 patients with relapsed or refractory AML who had *IDH2* mutations as detected by the RealTime IDH2 Assay. The trial measured the percentage of patients with no evidence of disease and full recovery of blood counts after treatment (complete remission, or CR), as well as patients with no evidence of disease and partial recovery of blood counts after treatment (complete remission with partial hematologic recovery, or CRh). With a minimum of six months of treatment, 19 percent of patients experienced CR for a median 8.2 months, and four percent of patients experienced CRh for a median 9.6 months. Of the 157 patients who required transfusions of blood or platelets due to AML at the start of the study, 34 percent no longer required transfusions after treatment with Idhifa.

The FDA granted the approval of Idhifa to Celgene and the approval of the RealTime IDH2 Assay to Abbott Laboratories.

[hr]

Sysmex launches XN-L hematology analyzers

Sysmex America launched its XN-L automated hematology analyzers in the United States.

The new, smaller XN-L line delivers the same clinical and operational value known in its XN-Series to lower-volume hematology laboratories, according to the company. The XN-L analyzers will be the first to feature BeyondCare Quality Monitor.

The XN-L automated hematology analyzers offer, in a compact footprint, a six-part differential including immature granulocyte analysis on each sample.

In addition, the XN-L Series offers optional software licenses for a reticulocyte channel to aid in anemia management and body fluid cell counts.

BeyondCare Quality Monitor is a web-based quality control and calibration verification management program that uses evidence-based QC targets and peer group analytics to improve error detection and minimize false rejection of control results. The managed QC and calibration program has the potential to identify shifts and trends in QC weeks sooner than traditional methods, according to Sysmex. Continuous calibration verification occurs every time the QC is analyzed as opposed to every six months. Reports are integral to the application.
[hr]

FDA clears Beckman Coulter's ClearLLab reagents

Beckman Coulter Life Sciences received FDA regulatory clearance (via the de novo process) to market its ClearLLab reagents for IVD use in the United States.

The ClearLLab reagents deliver the first preformulated IVD antibody cocktails for leukemia and lymphoma (non-Hodgkin's) immunophenotyping in the clinical laboratory.

Beckman Coulter is developing a new and advanced range of clinical flow systems to be launched over the next five years. ClearLLab is the first of this new generation of IVD systems, which the company says it is developing to address the diagnostic challenges and differing global workflow requirements of clinical laboratories.

ClearLLab provides qualitative identification of various hematolymphoid cell populations by immunophenotyping on the FC500 flow cytometer.

Mario Koksch, MD, PhD, VP and general manager of Beckman Coulter's Cytometry Business Unit, said in a statement: "Preformulated antibody combinations enable the lab to avoid the potential errors of manual antibody cocktail preparation, with the reassurance of standardized reporting to international guidelines."

ClearLLab reagents follow the 2006 Bethesda International Consensus Recommendations on the Flow Cytometric Immunophenotypic Analysis of Hematolymphoid Neoplasia. They are compatible with the World Health Organization 2016 revised classification of myeloid neoplasms and acute leukemia.

[hr]

BD releases urine culture app

BD (Becton, Dickinson and Company) announced new technology that can automatically report and release negative urine cultures.

The BD Kiestra urine culture app, together with BD BBL plated media, uses digital imaging and software algorithms to determine the amount of growth on a urine culture plate from clean caught and catheterized samples. Using the BD Kiestra ReadA compact's intelligent incubation and imaging device with high-throughput robotics to perform time series imaging, plates with no significant growth can be automatically released for disposal and the results reported to a compatible laboratory information system. Plates with significant growth automatically go into a queue for clinician analysis.

The definition of significant growth can be customized using patient demographics and lab-directed rules.

The urine culture app was validated in collaboration with the University of Ljubljana in Slovenia and the University of Heidelberg in Germany.
[hr]

Beckman Coulter Diagnostics introduces DxOne

Beckman Coulter Diagnostics has introduced its DxOne information management solutions, an integrated system of technologies and capabilities designed to ease data access and usability. The suite of next-generation technologies applies cloud-computing to provide remote-access functionality for an answers-anywhere-anytime approach to care and laboratory activities.

DxOne Inventory Manager eases inventory control functions to help labs minimize costs, ensure tight turnaround times, track trends, and reduce administrative duties through automation and electronic capabilities. DxOne Command Central helps save time by giving personnel the ability to monitor multiple instruments in real time from a single workstation. DxOne Insights streamlines workflow and efficiency by connecting instruments throughout a laboratory network.[hr]