Daniel F. Hayes, MD, the clinical director of the Breast Oncology Program at the University of Michigan Comprehensive Cancer Center in Ann Arbor, will begin a 1-year term as president of the American Society of Clinical Oncology (ASCO) at its 2016 Annual Meeting in Chicago, IL, on June 6. He has a long history of conducting clinical and translational breast cancer research related to drug development and the clinical utility of biomarkers. He has been principally responsible for the introduction and adoption of several circulating tumor markers, including CA15-3, which identifies the protein MUC1, and for the characterization of circulating tumor cells.

Paul A. Bunn Jr., MD, a professor of medicine and the James Dudley Endowed Professor of Lung Cancer at the University of Colorado (UC) School of Medicine in Aurora, will receive the Kamofsky Memorial Award on June 4 at the ASCO meeting. The award pays tribute to his outstanding contributions to cancer research, such as identifying novel diagnostics and treatment strategies for lung cancer, and to treatment, by striving to improve outcomes for patients with the disease. Currently, Bunn is the principal investigator of the SPORRE in Lung Cancer grant at UC, which supports translational research.

Also at the ASCO meeting, William G. Kaelin, Jr., MD, a professor of medicine at Dana-Farber Cancer Institute and Harvard Medical School, and a senior physician at Brigham and Women’s Hospital, all in Boston, MA, will receive the Science of Oncology Award on June 5. Kaelin studies the functions of proteins encoded by specific tumor-suppressor genes. He led fundamental studies on the VHL protein, work that was instrumental in the approval of five VEGF inhibitors for the treatment of metastatic renal cell carcinoma, as well as two mTOR inhibitors, which indirectly block VEGF.

**Venetoclax Approved for CLL**

The FDA has greenlighted venetoclax (Venclexta; AbbVie/Genentech) under its accelerated approval program for patients with chronic lymphocytic leukemia (CLL) who lack part of chromosome 17 and are refractory to standard treatment. A companion diagnostic to detect the 17p deletion in patients’ peripheral blood—the Vysis CLL FISH probe kit (Abbott Molecular)—has also received the agency’s go-ahead.

Venetoclax “is the fourth transformative CLL drug approved in the last 3 years, which is phenomenal,” says John Byrd, MD, of The Ohio State University in Columbus. The other drugs are obinutuzumab (Gazyva; Genentech), idelalisib (Zydelig; Gilead Sciences), and ibritinib (Imbruvica; Pharmacyclics/Janssen).

Up to 10% of patients newly diagnosed with CLL have the 17p deletion, which also occurs in 30% to 50% of patients with relapsed or refractory disease. They respond poorly to standard chemotherapy and immunotherapy and have a dismal prognosis. By binding to and inhibiting the antiapoptotic protein BCL2, which is overexpressed in CLL, venetoclax triggers the tumor cells to self-destruct.

The FDA’s decision was based on a phase II study, led by Stephan Stilgenbauer, MD, of the University of Ulm in Germany, which enrolled 106 patients with treatment-resistant CLL, all harboring the 17p deletion. At the American Society of Hematology’s annual meeting last December, Stilgenbauer reported that the overall response rate to venetoclax was 79.4%, with eight patients experiencing complete remissions and 84.7% maintaining their response at 12 months. Minimal residual disease—small numbers of leukemic cells that remain in patients even during remission, a major cause of relapse—was undetectable in more than 20% of responders.

Venetoclax has an acceptable safety profile, with the main side effects being neutropenia and upper respiratory tract infections. Tumor lysis syndrome—metabolic abnormalities that can occur when dying cells release their contents into the bloodstream—is another risk; to mitigate it, a stepwise dosing schedule is recommended. During the phase II study, “even at 5% of the target dose, we were already seeing tumor-cell destruction, which highlights venetoclax’s dramatic efficacy,” Stilgenbauer says.

Full approval for venetoclax is contingent upon a randomized phase III study assessing end points such as median progression-free and overall survival. Meanwhile, with multiple CLL therapies now available, finding the most effective combinations is the logical next step. “We want to induce deep remissions, so after defined treatment periods, patients can come off treatment and enjoy long intervals of life without CLL,” Byrd explains.

“We’ve reached the point where getting rid of chemotherapy is plausible” for the majority of people diagnosed with this disease, Byrd adds. “We can move on to targeted agents, which is really exciting for patients, their families, and all of us who care for them.”

—Alissa Poh

**Biden Calls for Realigning Research Incentives**

In New Orleans, LA, the American Association for Cancer Research Annual Meeting 2016 closed on a high note on April 20 with a speech delivered by Vice President Joe Biden and his wife, Dr. Jill Biden, who introduced him. Since being tasked with leading the National Cancer Moonshot in January, Joe Biden has been on “a listening tour” at cancer centers around the country, soliciting ideas on what’s needed to move ahead with his initiative “to eliminate cancer as we know it.”

“We had access to the best doctors in the world when our Beau was diagnosed, and the more we talked to them, the more we understood that we’re on the cusp of a real inflection point in the fight against cancer,” Biden said, reflecting on his son’s treatment for stage IV glioblastoma. He added that “silencing this disease may be the one subject where there is absolute, unlimited bipartisan support.” Global leaders are equally keen to participate, he added, noting that Israel has offered demographic data...
Venetoclax Approved for CLL


**Updated version**  
Access the most recent version of this article at: 
doi:10.1158/2159-8290.CD-NB2016-054

**E-mail alerts**  
Sign up to receive free email-alerts related to this article or journal.

**Reprints and Subscriptions**  
To order reprints of this article or to subscribe to the journal, contact the AACR Publications Department at pubs@aacr.org.

**Permissions**  
To request permission to re-use all or part of this article, use this link [http://cancerdiscovery.aacrjournals.org/content/6/6/564.2](http://cancerdiscovery.aacrjournals.org/content/6/6/564.2). Click on "Request Permissions" which will take you to the Copyright Clearance Center's (CCC) Rightslink site.