NOTED

- **Bristol-Myers Squibb's nivolumab achieved a 2-year survival rate of 24% among 129 heavily pretreated patients with non–small cell lung cancer** in updated results from a phase I trial presented at the 15th World Conference on Lung Cancer in Sydney, Australia, on October 29. The PD-1 immune checkpoint inhibitor is being studied in more than 25 trials.
- **The U.S. Food and Drug Administration (FDA) approved obinutuzumab (Gazyva; Genentech) for use with chlorambucil to treat patients with previously untreated chronic lymphocytic leukemia.** The drug is the first with a Breakthrough Therapy designation to receive the agency's approval.
- Additionally, **the FDA asked Ariad Pharmaceuticals of Cambridge, MA, to suspend sales and marketing of its leukemia drug Iclusig (ponatinib)** because of the risk of life-threatening blood clots and severe narrowing of blood vessels.
- In a phase III trial among more than 14,000 females ages 16 to 26, **Merck's V503 investigational human papillomavirus (HPV) vaccine prevented approximately 97% of cervical, vaginal, and vulvar precancers caused by HPV types 31, 33, 45, 52, and 58, and generated immune responses to HPV types 6, 11, 16, and 18 that were noninferior to those generated by the company's Gardasil vaccine.** The company plans to submit a Biologics License Application for V503 to the FDA this year.
- **The National Cancer Institute (NCI) released a checklist of 30 criteria for evaluating molecular tests** that will guide decisions made during NCI-supported clinical cancer trials.
- After state leaders lifted a moratorium, **the Cancer Prevention and Research Institute of Texas (CPRIT) is moving ahead with new grants.** CPRIT had awarded $836 million between 2009 and the start of the moratorium in December 2012.
- The World Health Organization's **International Agency for Research on Cancer officially classified outdoor air pollution as a group 1 carcinogen,** after an expert group concluded that there is sufficient evidence that exposure to such pollution causes lung cancer.

at the Center for Inherited Disease Research at Johns Hopkins University in Baltimore, MD. The data generated will be made public through the National Center for Biotechnology Information's database of Genotypes and Phenotypes. Other centers testing samples include Genome Quebec and the University of Cambridge in the UK. ■

NIH–FDA Effort Focuses on Tobacco Research

Tobacco science is getting an assist from the federal government. The NIH and the U.S. Food and Drug Administration (FDA) announced in September a collaborative effort establishing 14 Tobacco Centers of Regulatory Science (TCORS), almost all of which are at large universities, to investigate tobacco's effects on human health.

The two agencies awarded $53 million to the centers to fund their first year of tobacco research, which will generate evidence to inform future regulations for the marketing, manufacturing, and distribution of products derived from tobacco.

Over the next 5 years, total funding for the program could exceed $273 million, according to the NIH.

The research targets seven core research areas: diversity of tobacco products, addiction, toxicity and carcinogenicity, adverse health consequences, communications, marketing, and economics and policy.

Each center is funded to pursue a specific goal relevant to at least one of the core areas. At Yale University's TCORS in New Haven, CT, investigators will study how flavors influence addiction.

"Most kids will tell you that they started using tobacco with flavored products," says Suchitra Krishnan-Sarin, PhD, an associate professor of psychiatry who leads the Yale TCORS with Stephanie O'Malley, PhD. Flavors improve taste and ease the body's reaction, and studies connect early use of these products with later nicotine addiction and smoking.

Yale's center uses experts from many fields to understand the flavor–addiction connection. "We have projects ranging from basic molecular studies, to clinical studies on different populations, to epidemiologic studies, to studies based on the economics of tobacco use, to get at the broad question of how flavor influences addiction," says Krishnan-Sarin.

What are the roles and health implications for new tobacco-based products, such as electronic cigarettes, which are not currently regulated by the U.S. Food and Drug Administration (FDA) and haven't been evaluated for safety and effectiveness? Those are among the questions being addressed by 14 Tobacco Centers of Regulatory Science, established this year with $53 million from the FDA and NIH. Over the next 5 years, total funding could reach $273 million.

Epidemiologist Pamela Clark, PhD, at the University of Maryland, College Park, directs a TCORS that focuses on the toxicity of new and "manipulated" tobacco products, like e-cigarettes, which are not currently regulated by the FDA and haven't been evaluated for safety or effectiveness.

"There's a chance some of those products may be beneficial in helping people quit smoking," says Clark, "but most of these are marketed to get people through until they can have another cigarette."

In order to help the FDA rapidly understand these products and make regulatory decisions, "we want to be very nimble," Clark says. "As soon as a new product is put into place, we want to be able to find out what it's all about." That includes identifying the array of chemicals in the product.

In a press statement, NIH Director Francis S. Collins, MD, PhD, notes that one in five deaths can still be blamed on smoking. Partnerships like TCORS, he says, "keep us focused on reducing the burden and devastation of preventable disease caused by tobacco use." ■

For more news on cancer research, visit *Cancer Discovery* online at http://CDnews.aacrjournals.org.