dostarlimab, and antibodies directed at TIM3 and LAG3. –Elie Dolgin ■

**New Endpoints, Programs Used for Drug Approvals**

The FDA approved 59 new drugs in 2018—a record number. Of that total, 17 are novel cancer agents, two of which were greenlighted with nontraditional data, according to a report released by the agency’s Center for Drug Evaluation and Research (CDER; available at www.fda.gov).

The document “emphasizes some of the many innovative ways we were able to evaluate safety and efficacy for these new therapies,” CDER Director Janet Woodcock, MD, writes in the introduction.

Take apalutamide (Erleada; Janssen), for example. This antiandrogen, used to treat nonmetastatic castration-resistant prostate cancer, is the first drug approved based on metastasis-free survival instead of a traditional clinical trial endpoint, such as overall survival or progression-free survival.

In addition, the FDA approved lutetium Lu 177 dotatate (Lutathera; Advanced Accelerator Applications), a radioactive drug for gastroenteropancreatic neuroendocrine tumors, a group of rare cancers with few treatments. The approval was based on safety and efficacy data from an expanded access program through which patients can receive experimental drugs when no approved therapy is available. “This use of data represents an innovative way to . . . approve a needed therapy,” the report explains.

Five biosimilars related to cancer treatment hit the market in 2018 as well, the highest annual tally to date. “As patents and exclusivity protections for biologics expire in the United States, we can expect many more biosimilars to be submitted for approval,” Woodcock writes. “More products on the market means greater competition that can lead to increased access to therapies and lower costs to patients.” –Suzanne Rose ■

**BY THE NUMBERS**

**NCI Budget Breakdown, FY 2018**

- Research: cancer biology, 15.3%
- Resource development, 13.9%
- Cancer prevention and control, 5.7%
- Program management and support, 10%
- Research: treatment, 22.8%
- Research: detection and diagnosis, 10%
- Research: cancer causation, 22.3%

For fiscal year (FY) 2018, which ended on September 30, the total NCI budget was approximately $5.928 billion, including $496 million for the 21st Century Cures Act, $300 million of which was earmarked for the Beau Biden Cancer Moonshot (https://www.cancer.gov/about-nci/budget/fact-book). The agency allocated 70.4% of its budget to research. Funds for resource development were mostly devoted to cancer centers.

For more news on cancer research, visit Cancer Discovery online at http://cancerdiscovery.aacrjournals.org/CDNews.
CANCER DISCOVERY

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