

cytotoxic T-cell activation and other aspects of anticancer immunity, both inside the tumors and out. Trial participants who benefited from FMT also experienced upticks in the number of bacterial taxa previously linked with responses to anti-PD-1 therapy in observational studies, but the change in microbial abundance was statistically significant only in the U.S. study.

“The transplant induced a major and persistent change in the microbiota,” says Giorgio Trinchieri, MD, chief of the NCI’s Laboratory of Integrative Cancer Immunology, who co-lead the U.S. study. The two trials together, he adds, provide “the first proof of concept that you can actually treat the patients [with FMT] and change their response to therapy.”

Still, he adds, “I don’t think the future will be fecal transplant.”

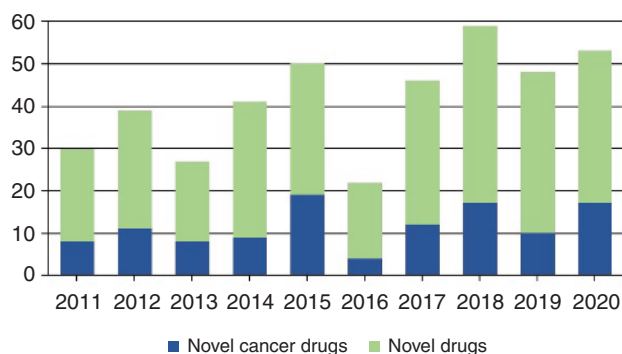
Instead, many researchers anticipate that rationally designed cocktails of bacteria—or even single lab-grown strains—will supplant stool samples as the microbial products of choice to pair with checkpoint inhibitors.

“A cultivated consortium has an enormous number of advantages over donor fecal material in terms of safety, reproducibility, scalability, and tunability,” says Bryan Coburn, MD, PhD, of Toronto General Hospital Research Institute in Canada (*N Engl J Med* 2019;381:2043–50).

Coburn and his collaborators are evaluating one such defined formulation of bacteria from NuBiyota. Other microbial mixtures from Seres Therapeutics and Vedanta Biosciences are also in clinical development. —*Elie Dolgin* ■

BY THE NUMBERS

Novel drugs approved by the FDA, 2011–2020



In 2020, the FDA approved 17 novel drugs for cancer, meaning agents with active ingredients not previously greenlighted in the United States and not new indications or combinations of approved drugs (see <http://www.fda.gov/>). The agency also OK’d the chimeric antigen receptor T-cell therapy brexucabtagene autoleucel (Tecartus; Gilead) for mantle cell lymphoma. Despite concerns that the COVID-19 pandemic would hinder the FDA’s work, the agency almost matched its high watermark for novel cancer agents approved in a single year. In addition, the agency authorized the use of several cancer therapeutics for new indications. For example, avelumab (Bavencio; EMD Serono), approved for Merkel cell carcinoma in 2017, can now be used for urothelial carcinoma, and olaparib (Lynparza; AstraZeneca), greenlighted in 2014 for ovarian cancer, can now be prescribed for prostate cancer.

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

NOTED

Amgen announced it will acquire Five Prime Therapeutics for \$1.9 billion.

Amgen will gain Five Prime’s anti-FGFR2b agent bemarituzumab (FPA144), which is in clinical testing for patients with *FGFR2b*-mutant advanced gastric cancer. In the phase II FLIGHT trial, bemarituzumab plus chemotherapy led to longer overall survival (OS) and progression-free survival (PFS) than chemotherapy alone.

The FDA approved the VEGF tyrosine kinase inhibitor tivozanib (Fotivda; AVEO Oncology) for patients with relapsed/refractory advanced renal cell carcinoma who have already received at least two therapies. The approval was based on the phase III TIVO-3 trial, in which the agent extended median PFS by 1.7 months and median OS by 2.8 months compared with sorafenib.

Blinatumomab (Blincyto; Amgen) may be effective in children with high-risk relapsed B-cell acute lymphoblastic leukemia (*JAMA* 2020;325:843–54). In a phase III trial, 31% of patients treated with the CD3/CD19-targeted bispecific antibody experienced relapse, developed a second malignancy, or died after a median of 22.4 months, compared with 57% of those who received consolidation chemotherapy.

Following a review of recent research, **the U.S. Preventive Services Task Force released a final guideline that expands the criteria for lung cancer screening** (*JAMA* 2021;325:962–70). The recommendation calls for screening adults ages 50 to 80 who have a 20 pack-year smoking history and who currently smoke or have quit within the past 15 years. Previously, the agency recommended that screening start at age 55 for people with a 30 pack-year smoking history.

Socioeconomically disadvantaged patients enrolled in cancer clinical trials may fare worse than more affluent people, despite receiving high-quality care during the trials (*J Clin Oncol* 2021 Mar 17 [Epub ahead of print]). Researchers analyzed data from 41,109 patients with cancer enrolled in 55 phase II and III trials between 1985 and 2012. They found that patients from the poorest neighborhoods had a 28% increased risk of death compared with those from the wealthiest areas.