White House unveils National Microbiome Initiative

The White House Office of Science and Technology Policy (OSTP) launched on May 13 an initiative to investigate the Earth's microorganisms—in the human body and across different ecosystems. The National Microbiome Initiative (NMI) aims to generate knowledge from microbial systems in an attempt to impact healthcare, agriculture, environmental science and industrial processes. The effort launched with more than $121 million of funding from federal agencies over the next two years, and $400 million in total cash and in-kind contributions from 100 companies, foundations and academic institutions. Among these, the Bill and Melinda Gates Foundation of Seattle committed $100 million over the next four years to study how the gut microbiome affects malnutrition and stunting, whether the gut microbiome can be manipulated using bacteriophages to treat infections instead of antibiotics, and whether components of the soil microbiome can be used to mitigate crop pests that affect sub-Saharan Africa.

The OSTP's drive has accelerated many efforts already in the planning stages. For example, One Codex, a microbial genomics company based in San Francisco, will now develop a public portal for microbiome data to improve researchers' understanding of mixed microbial communities. "The OSTP has catalyzed action," says company founder and CEO Nick Greenfield.

Platform technologies and interdisciplinary collaborations are essential to advance microbiome research to the point of commercialization. "Researchers have found some intriguing correlations between things like the soil microbiome and plant growth, gut microbiome and obesity, and so forth, but we don't have the tools to show cause and effect," according to Jeff Miller, director of the California NanoSystems Institute (CNSI) at the University of California, Los Angeles. To this end, CNSI will launch a new Center for Nano-Microbiome Convergence to bring together microbiome researchers with engineers and physical scientists who can create tools and techniques, such as methods for imaging bacteria over time or technologies to identify what role certain species of bacteria play within a community of microbes.

Government funds include $23 million from the US Department of Agriculture, $20 million from the National Institutes of Health and $10 million from the Department of Energy. But the full funding proposed by the White House still needs to be approved as part of the government's fiscal year 2017 budget, and this represents a potential hurdle because budget fights between President Barack Obama and the Senate and House of Representatives have been the norm throughout his presidency.

Aaron Bouchie

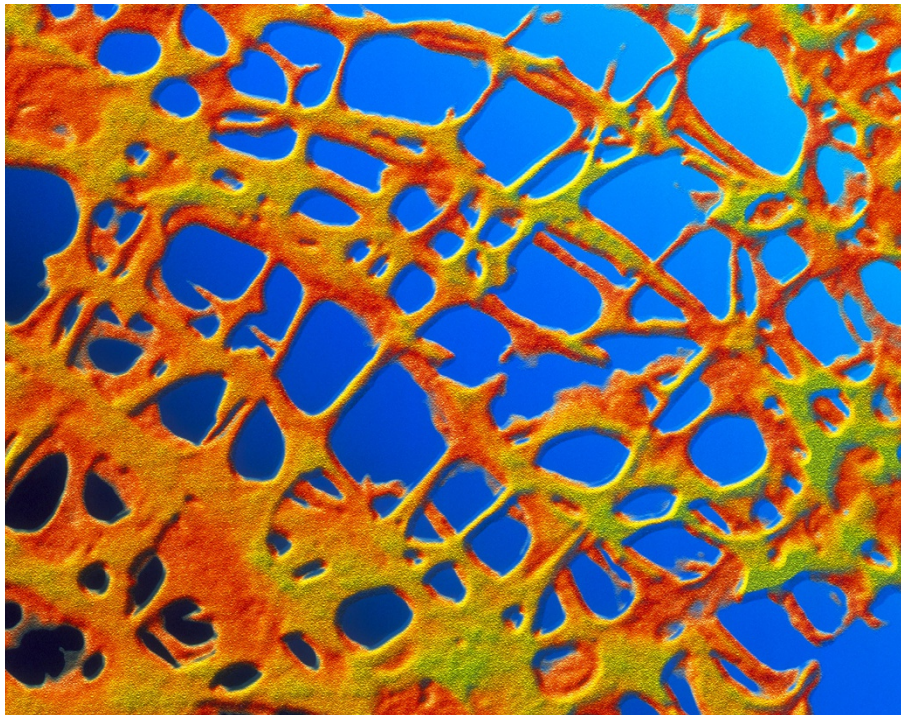
Amgen/UCB build on bone franchise with anti-sclerostin antibody

Amgen and collaborators UCB Pharma have said their investigational osteoporosis agent romosozumab met its main goal in late-stage trials. At ENDO 2016, the Endocrine Society's annual meeting in Boston, the companies released data from phase 3 trials with romosozumab, a humanized monoclonal antibody that inhibits sclerostin. Results from 10,000 postmenopausal women with osteoporosis show that romosozumab promotes bone formation, increasing bone-mineral density measured at the hip and spine, and topping results obtained with Eli Lilly's parathyroid hormone replacement therapy Forteo (teriparatide). But whether Amgen/UCB anti-sclerostin agent romosozumab might change standard-of-care treatment for osteoporosis will depend on long-term data on the drug's ability to improve fracture healing.

The phase 3 "STRUCTURE" trial with romosozumab reported a 2.6% improvement in hip bone mass density over 12 months, compared with a 0.6% loss with Forteo. The enhanced bone formation is clinically meaningful, says Taher Mahmud, consultant rheumatologist at the Maidstone and Tunbridge Wells NHS Trust, UK. The estimated hip strength also improved with romosozumab over 12 months, whereas it decreased with Forteo. Although positive, "these results do need to be viewed carefully," notes Richard Eastell, professor of bone metabolism, head of the academic unit of bone metabolism, director of the Mellanby Centre for bone research, at Northern General Hospital, University of Sheffield in UK, [who attended the meeting in Boston. "We don't know what the relationship is between changes in bone strength in response to anabolic therapy and the risk of hip fracture," Eastell points out.

Osteoporosis and its associated fracture risk is one of the major health burdens in our aging population. In healthy people, the skeleton is constantly being remodelled, balancing bone building by osteoblasts and bone resorption by osteoclasts. In postmenopausal women bone loss accelerates due to the absence of estrogen. Excessive bone resorption leads to low bone mineral density and the deterioration of bone microarchitecture, resulting in bone loss and an increase in fracture risks. Boosting new bone formation is essential in treating osteoporotic fractures, and sclerostin, an inhibitor of osteoblast activity made by osteoclasts, is an attractive therapeutic target.

Most existing drugs to treat osteoporosis target osteoclasts, preventing resorption. This is the case for the widely used bisphosphonates that induce apoptosis in osteoclasts, and for



Alfred Pasieka / Science Source

Osteoporotic bone is brittle and tends to fracture easily.