Amgen's migraine antibody advances

Amgen moved closer towards becoming the first company to gain an approval for a monoclonal antibody therapy to prevent migraine episodes. The Thousand Oaks, California, biotech announced positive top-line phase 3 data September 28, for erenumab, which blocks the calcitonin gene-related peptide (CGRP) receptor. In phase 3 studies, erenumab reduced the number of monthly migraine days by 2.9 days compared with 1.8 days in the placebo arm, measured over 12 weeks, meeting its primary endpoint. Participants in the study, called ARISE, had been experiencing 4–14 migraine days each month. The safety profile of erenumab was similar to placebo. ARISE is the first pivotal trial of erenumab. Amgen is collaborating on the drug's development with Basel-based Novartis, which holds commercialization rights outside of the US, Canada and Japan. They are competing with several other developers of CGRP-targeting migraine drugs; Alder Biopharmaceuticals, Eli Lilly and Allergan all have candidates that bind to CGRP ligand in phase 3 (*Nat. Biotechnol.* **33**, 676, 2015). In June, Amgen also announced positive phase 2 results using erenumab to treat chronic migraine, a market comprising about 10% of migraine patients. Amgen may seek approval in one or more migraine indications in early 2018, says Leerink Swann analyst Geoffrey Porges—a faster timeline than for its competitors, who have yet to report phase 3 data. But analysts generally do not expect to see much difference in efficacy between these drugs. They will more likely be differentiated based on dosing format and/or frequency and tolerability versus current treatments, Porges and other Leerink analysts said in a note this past summer.

"In this sorry saga, those convinced that there are looming limits did not apply demography and statistics to test hypotheses about lifespan limits—instead they exploited rhetoric, deficient methods and pretty graphics to attempt to prove their gut feelings." James Vaupel, the director of the Max Planck Institute for Demographic Research, takes issue with research published in *Nature* setting a limit to human lifespan at 115 years. (*BBC News*, 5 October 2016)

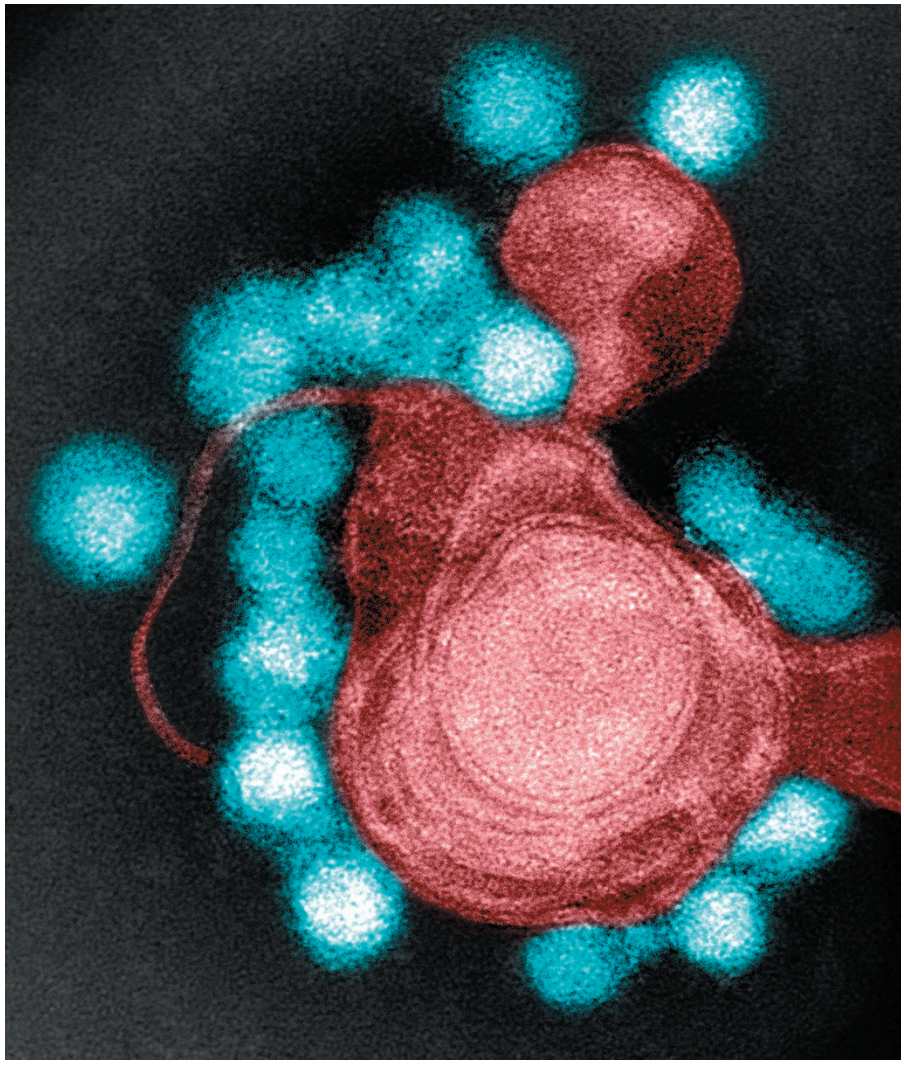
"Humanity is working hard to manufacture more survival time, with some degree of success. But we should acknowledge that a genetically determined fixed life-history strategy for our species stands in the way of radical life extension." Jay Olshansky, of the University of Chicago's School of Public Health, comments on the report that human lifespan is finite. (*Wired*, 5 October 2016)

Zika pipeline progresses

In September, the US Congress finally released $1.1 billion to fund Zika research, but not before officials at both the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention had to cannibalize other programs to get things rolling with Zika. Funding difficulties notwithstanding, work on Zika has proceeded rapidly on several fronts. At least two vaccines are in phase 1 trials, improved diagnostics are in the works, and newly identified anti-viral compounds are gearing up to enter preclinical testing.

Such rapid progress is remarkable, given that Zika came essentially out of nowhere, unlike Ebola, where a number of programs were ready for testing at the time of the most recent (deadly) outbreak (*Nat. Biotechnol.* **32**, 849–850, 2014). Previous work on related flaviviruses like dengue and chikungunya, as well as existing infrastructure for creating and testing vaccines, has helped, of course. It was a "perfect storm" of capabilities and partnerships, says Nelson Michael, of Walter Reed Army Institute of Research (WRAIR) in Bethesda, Maryland, whose group collaborated with Dan Barouch, director of the Center of Virology and Vaccine Research at Beth Israel Hospital in Boston. At the outset, WRAIR already had a concentration in flavivirus experts, with work on yellow fever dating back to the 1890s, while Barouch's group, with expertise stemming from work on HIV vaccines, had the infrastructure to design and test immunogens. "What most groups take four years to do, we did in 180 days." he says.

Although the Zika, a mosquito-borne flavivirus, has been around since the 1940s, it wasn't until late 2015 that the problems with fetal development in pregnant women infected with the virus emerged in the Americas. This captured the attention of researchers like Hengli



Science Source

Zika virus (blue), isolated from a microcephaly case in Brazil, viewed with an electron microscope.