Gilead wades into epigenetics

Gilead Sciences snapped up Danish epigenetics specialist EpiTherapeutics for $65 million in May. The acquisition is a sign that the Foster City, California–based giant is interested in small-molecule epigenetic regulators as potentially first-in-class cancer therapeutics. The deal gives Gilead access to a pipeline of preclinical oncology candidates developed by Kristian Helin, professor at Biotech Research and Innovation Centre at the University of Copenhagen, and EpiTherapeutics co-founder. The biotech's programs are focused on regulating transcription in cancer by targeting histone demethylases and methyltransferases. In 2010, EpiTherapeutics forged a deal with Abbott Laboratories, and in 2014 raised $25 million in a series A round from investors Novo Seeds, Lundbeckfond Emerge, Merck Serono Ventures, Pharmaceuticals Astellas Venture and SEED Capital. Gilead has not released further details about the acquisition.

Rivals unite in biosimilars push

A group of 11 companies banded together in May to launch the Biosimilars Forum to educate and advocate for public policies and practices that encourage access, awareness and adoption of biosimilars. The nonprofit group's founding members are Actavis, Amgen, Boehringer Ingelheim, Coherus BioSciences, the EMD Serono division of Merck KGaA, Hospira, Merck & Co., Pfizer, Samsung Bioepis (a joint venture between Samsung and Biogen), Novartis' Sandoz unit and Teva Pharmaceutical. Some of the founders have been adversaries on a slew of biosimilar-related issues, most recently Amgen and Sandoz (*Nat. Biotechnol.* **33**, 435, 2015). Now with the Forum, the joint focus is on education, access, the regulatory environment, reimbursement and legal affairs relating to biosimilars. The Forum's first offering is an educational handbook, *The Next Frontier for Improved Access to Medicines: Biosimilars and Interchangeable Biologic Products*.

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"It was very startling. To say this is a lot of people is an understatement." Leslie Biesecker, chief of the medical genomics and metabolic genetics branch at the National Human Genome Research Institute, commenting on a finding by NIH researchers that in the genomes of 1,000 healthy volunteers, more about 100 had mutations that should predispose them to a genetic disorder. Previously it was thought only 0.02% of the population was so afflicted. (*The Washington Post*, ”

Migraine mAbs crowd into late-stage trials

The migraine field was abuzz in May as companies developing calcitonin-gene-related peptide (CGRP) inhibitors pushed neck and neck into phase 3. At the Congress of the International Headache Society meeting in Valencia, Spain, Alder, Amgen and Teva all reported encouraging phase 2 data from trials of their respective monoclonal antibody (mAb) drugs; Eli Lilly published positive phase 2 results last fall. That all four are similarly effective and without serious side effects confirms the strategy of inhibiting CGRP using antibodies is solid. "This is not a one-hit fluke," says John Latham, CSO at Bothell, Washington–based Alder.

The rival companies (**Table 1**) will be squaring up for a slice of a market estimated at $3.3 billion market, possibly large enough to encompass all players. About 10% of people worldwide experience periodic migraines and 1.7–4% of the global adult population suffers from disabling migraines 15 or more days a month, according to the World Health Organization. If any of the mAbs sails through phase 3, it would become the first therapy developed specifically to treat or prevent migraine in 50 years, says Lawrence Newman, president of the American Headache Society. "Patients are eager for alternatives."

Migraine is characterized by attacks of intense head pain that typically last from 4–72 hours—some suffer from frequent attacks lasting 15 days or longer. Standard care includes drugs repurposed for migraine, such as, anti-seizure medications, drugs from the triptan class of selective serotonin receptor agonists and Botox injections; triptans constrict blood vessels causing side effects that limit their use. Moreover, data suggest that up to 80% of patients who start on a drug prophylactically discontinue it within a year, says Rob Lenz, lead developer of the drug at Amgen, "and about half of them discontinue it within the first week." The reasons are varied but include fear of side effects.

Blocking CGRP emerged over 15 years ago as a possible migraine treatment strategy. CGRP, the result of alternative mRNA splicing of the calcitonin gene, is a neuromodulator produced at high concentrations in almost all organs of the body including the central and peripheral nervous system. CGRP is elevated during migraine attacks and sensitizes glutaminergic synapses, causing pain. The mAb drugs work by inhibiting migraine pain transmission at the trigeminal ganglion outside the blood-brain barrier, but do not cross it.

So far, studies using anti-CGRP mAb have yielded encouraging results. At the recent headache conference, Thousand Oaks, California–based Amgen and Petach Tikva, Israel–based Teva presented phase 2 results; Alder presented six-month follow-up data. In Amgen's 483-patient trial, only the highest dose of the AMG334 mAb given as a monthly subcutaneous injection reduced

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