Numerous companies are pursuing other anti-inflammatory targets in psoriasis as well, including the development of inhibitors of various cytokines and the Janus kinases (**Table 1**), which makes Otezla's future positioning hard to predict. In addition to psoriatic arthritis, Celgene has filed for FDA approval for Otezla in moderate to severe psoriasis. But even assuming FDA go-ahead for treating that additional market, generalizing Otezla's results to other T cell–mediated chronic autoimmune diseases is problematic. "Psoriasis is the odd one out," says Kingston Mills of Trinity College in Dublin. "It's easy to do a trial in psoriasis so drug companies start there first." For example, every interleukin (IL)-17– or IL-23–targeted drug that has been tested has worked in psoriasis, he says, but that has not been the case for more heterogeneous diseases like rheumatoid arthritis or Crohn's disease.

The tremendous success of TNFα inhibitors certainly influenced the Otezla development program. Knowing that TNFα inhibitors work in psoriasis and related diseases like psoriatic arthritis, irritable bowel disease and rheumatoid arthritis "definitely had an impact on where we thought [Otezla] might be clinically useful," Schafer says. Celgene is actively testing Otezla in Behcet's disease (a rare inflammatory disorder of the blood vessels) and ankylosing spondylitis (an inflammation causing spinal vertebrae to fuse) but has stopped development in acne and atopic dermatitis. It is also evaluating phase 2 results in rheumatoid arthritis. A second PDE4 inhibitor, CC-11050, is being studied in lupus through Celgene Global Health, a subsidiary with interests in making drugs for the developing world. But CC-11050 is not being tested in any of the diseases where Otezla is being investigated, Schafer says.

Revenue estimates for Otezla are just under $100 million for 2014. The drug was approved with no 'black box' safety warning on the label or instructions for monitoring infections or lymphoma. Otezla is priced at $22,500 per year wholesale acquisition cost (before discounts or rebates)—substantially below the $30,000–40,000 for the biologics. "We believe this is a good pricing strategy to target the much bigger, but likely more price-sensitive, prebiologic patient population and because payers will be keen to better adopt a 'cheaper' drug," says Michael Yee of RBC Capital Markets in San Francisco. Psoriatic arthritis is also a "high-churn" market, he says, with an average of two therapy switches a year, including 50% of patients on biologics, who switch back to older disease-modifying drugs like methotrexate or cyclosporin.

**Mark Ratner** *Boca Raton, Florida*

# IN their words

**"One of the wonderful things about a process like GET [genomes, environments, traits] labs is instead of asking single-trait, single-gene questions, we can say, 'Let's look at everything we can collect about breast biology'."** Abigail Wark, a research fellow at Harvard University, is studying genomic variation controlling areola size as part of Harvard's Personal Genomics Project. (*The New York Times,* 28 April 2014)

The Scripps Research Institute

**"There are a lot of people concerned about synthetic biology because it deals with life, and those concerns are completely justified. Society needs to understand what it is and make rational decisions about what it wants."** Floyd Romesberg, whose team at Scripps Research Institute in La Jolla, California, created an organism with a pair of unnatural DNA bases. (*The Guardian* 7 May 2014)

Corrected after print 18 June 2014.

**Corrections**

In the news analysis "Myriad diversifies, fights rearguard action on patents" (*Nat. Biotechnol.* **32**, 211, 2014), Crescendo Bioscience's diagnostic test Vectra DA was incorrectly described as testing for 25 biomarkers associated with rheumatoid arthritis. The correct number is 12. The error has been corrected in the HTML and PDF versions of the article.

In the news analysis "Illumina claims $1,000 genome win" (*Nat. Biotechnol.* **32**, 115, 2014), the number of gigabytes in 1.8 terabases was incorrectly given as 1,800 Gb. The correct number is 18,000 Gb. The error has been corrected in the HTML and PDF versions of the article.

In the news analysis "Biocon's first-in-class anti-CD6 mAb reaches the market" (*Nat. Biotechnol.* **31**, 1062–1063, 2013), Andrew Robertson was incorrectly identified with the last name Anderson. The error has been corrected in the HTML and PDF versions of the article.

# IN brief

## AbbVie drops transparency fight

Chicago, Illinois–based AbbVie dropped a lawsuit to stop the European Medicines Agency (EMA) from releasing clinical trial data for its blockbuster drug Humira (adalimumab) to the public. AbbVie withdrew from the legal fight in April after the EMA accepted data redacted to remove commercially confidential information. Also in April, the European Parliament and the Council of the European Union adopted new regulations for European clinical trials, designed to increase transparency and standardize trials across multiple EU member states. The new legislation requires sponsors to register and apply for clinical trial permissions in a central database, and to post a summary of positive or negative results within one year from trial completion. In addition, those submitting a marketing authorization application to the EMA must post reports from clinical studies conducted in the EU—regardless of that application's success. The mandate for transparency "reinforces the legal basis for publicly releasing clinical study reports and other documents," says Fergus Sweeney, head of inspections and human pharmacovigilance at the EMA. Although lauded as a boon to public health, the transparency mandate may work against small and medium companies, says Siân Gill, a patent and trademark attorney at London-based Venner Shipley. There is increasing pressure to include proof of an invention's efficacy in patent applications, she says. But if clinical trial data must be made public before a company has proof of efficacy, this "might destroy the chance of getting patent protection," she says. Although the new EU clinical trials database will be accessible to the general public, many documents will be redacted to protect commercially confidential information and personal data, says Sweeney. The documents will be accessed through a new web portal that will replace the existing EU Clinical Trials Register and EU Clinical Trials Database (EudraCT) no sooner than May 2016. (p. 528) *Gunjan Sinha*

# IN their words

**"There are worse things than dying. What about something that makes your death worse or remaining life shorter … that is quite likely with some of these experimental drugs."** David Gorski, managing editor of *Science-Based Medicine.* (*The Coloradan,* 23 April 2014)

# Erratum: In Their Words

*Nat. Biotechnol.* **32, 507 (2014); published online 9 June 2014; corrected after print 18 June 2014**

In the version of this article initially published, a headshot of Floyd Romesberg incorrectly appeared next to a quote from Tony Wyss-Coray. The error has been corrected in the PDF version of the article.