# NEWS IN BRIEF

## A bumper year for the FDA

As negotiations over the PDUFA V move into Congress, the FDA points to its 20 approvals in 2011 as evidence of its ability to deliver.

**The lowdown:** The US Congress is deliberating over the Prescription Drug User Fee Act V (PDUFA V) — which details how the US Food and Drug Administration (FDA) can collect fees from industry to fund the drug approval process — ahead of the expiry of PDUFA IV in October 2012. Despite concerns that the agency is too risk-averse, some recent evidence suggests otherwise. A *Health Affairs* article reported that the median positive review time for new cancer medicines was 182 days in the United States, versus 350 days in Europe (http://go.nature.com/B4M4Ob). The agency has also pointed to the 2011 approval record as evidence of value: it has already given the green light to 20 new molecular entities this year (until 14 July), compared with 21 throughout 2010. These include six first-in-class agents (marked with an * in the table).

| Drug name | Lead company | Indication |
|---|---|---|
| Ioflupane i-123 | GE Healthcare | Imaging agent for parkinsonian syndromes |
| Spinosad | ParaPRO | Head lice |
| Vilazodone | Forest laboratories | Major depressive disorder |
| Azilsartan | Takeda | Hypertension |
| Roflumilast* | Forest Laboratories | COPD exacerbations |
| Belimumab* | Human Genome Sciences | Systemic lupus erythematosus |
| Gadobutrol | Bayer | Blood–brain barrier imaging agent |
| Ipilimumab* | Bristol-Myers Squibb | Unresectable or metastatic melanoma |
| Gabapentin enacarbil | GlaxoSmithKline | Restless legs syndrome |
| Vandetanib | AstraZeneca | Medullary thyroid cancer |
| Abiraterone* | Centocor Ortho Biotech | Metastatic castration-resistant prostate cancer |
| Linagliptin | Boehringer Ingelheim | Type 2 diabetes |
| Boceprevir* | Merck & Co | HCV genotype 1 |
| Rilpivirine | Tibotec | HIV-1 |
| Telaprevir | Vertex Pharmaceuticals | HCV genotype 1 |
| Fidaxomicin | Optimer Pharmaceuticals | *Clostridium difficile*-associated diarrhoea |
| Ezogabine | Valeant Pharmaceuticals | Partial-onset seizures |
| Belatacept | Bristol-Myers Squibb | Organ rejection |
| Indacaterol | Novartis | COPD |
| Rivaroxaban* | Johnson & Johnson | Deep vein thrombosis |

COPD, chronic obstructive pulmonary disease; HCV, hepatitis C virus.

## Regulating in harmony

The FDA has outlined new plans for harmonizing its work with regulators worldwide, and is making advances to work more closely with the EMA.

**The lowdown:** The FDA unveiled its 'Pathway to Global Product Safety and Quality', a strategy that calls for the creation of coalitions of international regulators and increased data sharing. The strategy primarily focuses on enhanced collaboration over the importation of products, including drugs, but also builds on ongoing efforts to improve drug safety. The FDA added that it has increased the number of foreign drug manufacturing inspections by 27% between 2007 and 2009, and is working with its counterparts worldwide to harmonize aspects of drug regulation through the International Conference on Harmonization.

Efforts to increase collaboration between the FDA and the European Medicines Agency (EMA) have picked up since 2003, when the two agencies agreed to collaborate on regulatory issues under confidentiality arrangements. A first joint EMA–FDA report on collaboration shows that the regulators now hold around 55 ad hoc interactions per month (go.nature.com/4HlxCT). In the latest developments, they accepted the first submission — of an undisclosed Pfizer product — under the joint 'Quality By Design' drug-review pilot programme. Through this scheme, the two agencies separately assess the quality and chemistry, manufacturing and control sections of submissions, but communicate and consult with each other with the aim of creating a common list of questions for applicants and a harmonized evaluation of responses. The pilot programme is expected to run until April 2014. The two agencies have also just created a biosimilar 'cluster' to harmonize their approach to these products. This newest cluster will meet three times a year.

## Antibodies in space

Amgen, UCB and NASA have teamed up to test an anti-sclerostin antibody in outer space.

**The lowdown:** When the space shuttle Atlantis took off in July on its final voyage, it took a drug development experiment along for the ride. On board, in addition to the astronauts and gear, were 30 mice that had been treated 24 hours before launch with the experimental bone-loss drug STS-135, a sclerostin-binding antibody. Upon landing, the mice will be assessed for bone structure, composition and strength, among other factors. They will also be compared with ground-based control mice. The microgravity-induced bone loss that afflicts astronauts and space-bound mice provides a novel window in conventional indications — namely, osteoporosis — says Ted Bateman, at the University of North Carolina, Chapel Hill, USA, who is an investigator on the study. Amgen and UCB have already pushed another sclerostin-binding antibody, Amgen's AMG785, into Phase II trials for bone-related conditions, including postmenopausal osteoarthritis and fracture healing.

This is not the first time drug discovery has been carried out at the bold new frontier. Amgen has previously flown treated animals to test the effects of osteoprotegerin on bone loss and the effects of a myostatin inhibitor on muscle-wasting diseases. Other researchers are using cell culture based systems for drug discovery focused work as well, adds Bateman.