NEWS IN BRIEF

Antibiotic R&D gets a dose of funding

The Innovative Medicines Initiative (IMI) has launched a €223 million (US$280 million) New Drugs 4 Bad Bugs (ND4BB) programme to spur the development of antibiotics.

The lowdown: Citing an increasing risk of antibacterial resistance and a lack of progress in the development of new antibiotics, the IMI has launched a call for proposals for its ND4BB programme, which is aimed at encouraging industry and academic activity in the antibiotic space. The IMI is contributing €109 million to the programme, and five pharma partners (AstraZeneca, Basilea, GlaxoSmithKline (GSK), Johnson & Johnson (J&J) and Sanofi) are pitching in a further €114 million as in-kind contributions. Funders may provide further backing to the project at later stages, and the IMI anticipates that the programme could use up to €600 million over the next 7 years.

ND4BB marks the first attempt by the IMI to directly fund clinical trial work. The programme includes a commitment to back the development of GSK's peptide deformylase inhibitor GSK1322322 — in a Phase III trial in community-acquired bacterial pneumonia and in a Phase IIb trial in acute bacterial skin and skin structure infections — in part in the hopes of improving clinical trial design and infrastructure. The programme could also fund the development of two AstraZeneca drugs, and back-up GSK compounds, depending on the results of these and other ongoing trials.

The programme also aims to foster collaborative exchange of data and regulatory experiences between companies, and to build and train networks of researchers. A fraction of the budget is earmarked for preclinical research, including projects that could improve the community's understanding of antimicrobial resistance and bacterial cell penetration, efflux and permeability. Full details of the first call for proposals for ND4BB are available online (see the IMI website), and submissions are due by 9 July 2012.

FDA on track with first-half approvals

The US Food and Drug Administration (FDA) approved 12 new drugs and biologics in the first half of the year.

The lowdown: The agency's Center for Drug Evaluation and Research (CDER) has already approved several novel drugs this year (TABLE 1).

First-in-class approvals include Genentech's Hedgehog inhibitor vismodegib for basal cell carcinoma, and Vertex's ivacaftor — a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator that is the first cystic fibrosis drug to address the mechanism of the disease rather than the symptoms. Protalix's taliglucerase alfa, an enzyme replacement therapy for Gaucher's disease, meanwhile received the first approval for a drug that is made in a plant cell system. Regulatory approval decisions were pending for several candidates — including Bristol-Myers Squibb/Pfizer's anticoagulant apixaban, Arena's anti-obesity drug lorcaserin and Sanofi's teriflunomide for multiple sclerosis — as *Nature Reviews Drug Discovery* went to press.

Last year the FDA approved 30 new drugs, in line with an average of 29.5 per year since 1993, the first full year in which the Prescription Drug User Fee Act (PDUFA) was in place. A recent 5-year outlook for the industry forecasts that the agency will approve, on average, 30–35 new drugs per year until 2016 (*Nature Rev. Drug Discov.* **11**, 435–436; 2012). An FDA official has said that the agency is anticipating that drug developers will file over 20 approval applications for cancer drugs this year.

Table 1 | **New drugs approved by the FDA in the first half of 2012**

Drug name	Lead company	Indication
Glucarpidase*	BTG International	Toxic plasma concentrations of methotrexate
Ingenol mebutate	Leo Pharma	Actinic keratosis
Axitinib	Pfizer	Advanced renal cell carcinoma
Vismodegib	Genentech	Metastatic or locally advanced basal cell carcinoma
Ivacaftor	Vertex	Cystic fibrosis
Tafluprost	Merck	Elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension
Lucinactant	Discovery Laboratories	Prevention of respiratory distress syndrome
Peginesatide	Affymax	Anaemia due to chronic kidney disease
Florbetapir F18	Avid	Agent to estimate amyloid-β neuritic plaque density as Alzheimer's disease diagnostic
Avanafil	Vivus	Erectile dysfunction
Taliglucerase alfa	Protalix	Gaucher's disease
Pertuzumab*	Genentech	HER2-positive metastatic breast cancer

*These drugs were approved as biologics license applications.

SGLT2, take two?

Interest in antidiabetic sodium-dependent glucose co-transporter 2 (SGLT2) inhibitors has picked up again.

The lowdown: Earlier this year, the FDA rejected AstraZeneca's and Bristol-Myers Squibb's SGLT2 inhibitor dapagliflozin, a potential first-in-class drug for diabetes, probably owing in part to concerns that it could increase the risk of cancer. New Phase III data and filing activity around Johnson & Johnson's SGLT2 inhibitor canagliflozin are now renewing interest in the class of drugs, which act by blocking renal glucose reabsorption and thereby increasing glucose secretion via urine (*Nature Rev. Drug Discov.* **10**, 645–646; 2011). J&J presented top-line data from five trials at the American Diabetes Association (ADA) annual meeting in Philadelphia, including one trial in which canagliflozin plus metformin and sulfonylurea beat sitagliptin plus metformin and sulfonylurea in terms of reducing haemoglobin A1c (HBA1c) levels, and another in which it beat glimepiride. The company did not disclose cancer incidence data in these trials. J&J filed the drug for US approval at the end of May.

Dapagliflozin's future in the United States, meanwhile, remains unclear. AstraZeneca and Bristol-Myers Squibb released new Phase III data on dapagliflozin at the ADA meeting showing that the drug in combination with sitagliptin reduces HbA1c levels versus placebo plus sitagliptin, but they did not release cancer incidence data from this trial. The Committee for Medicinal Products for Human Use (CHMP) gave the drug the green light for use in the European Union in April.