Bioengineered 3:5, 257–259; September/October 2012; © 2012 Landes Bioscience

Bio-Bites!

National Bioeconomy Blueprint released

The Obama Administration announced its commitment to strengthening bioscience research as a major driver of American innovation and economic growth. The National Bioeconomy Blueprint outlines steps that agencies will take to drive the bioeconomy—economic activity powered by research and innovation in the biosciences—and details ongoing efforts across the Federal government to realize this goal.

Reference

1. Maxon M, Robinson E. National Bioeconomy Blueprint Released. The White House Office of Science and Technology Policy. 2012 April 26; Available from: http://www.whitehouse.gov/blog/2012/04/26/national-bioeconomy-blueprint-released

Human drug produced in plant cells wins FDA approval

Protalix Biotherapeutics, a small biotech company in Israel, has won FDA approval for its taliglucerase alfa (named "Elelyso"), the first biological drug for human use manufactured inside modified plant cells.

Drugs that are based on large biological molecules have been produced inside genetically engineered animal cells, yeast and bacteria for more than two decades.

Since the early 1990s, some researchers have been developing plants that could act as cheaper factories for biologics.

Protalix targets a rare heritable disorder, Gaucher disease, caused by an enzyme malfunction which results in the accumulation of fat in cells and organs. Two existing drugs compensate for the enzyme deficiency, but they can cost up to $300,000 per year in the United States, furthermore, drug shortages in recent years have left some patients in need of hospital care.

Protalix's solution is to take a normal version of the human gene affected in Gaucher disease and introduce it into carrot cells. The lower production overheads will allow the company to sell Elelyso for 75% of the price of the most popular drug on the market, says David Aviezer, Protalix's president.

And there is more to come: other manufacturers have already begun or completed phase II clinical trials and hope to follow Elelyso to market (see **Table 1**).

Table 1.

Drug	Condition	Company	Platform
Locteron (interferon-α)	Hepatitis C	Biolex Therapeutics	Duckweed
H5N1 vaccine	Influenza	Medicago	Tobacco
VEN100	Antiobiotic-associated diarrhea	Ventria Bioscience	Rice
CaroRx	Dental caries	Planet Biotechnology	Tobacco

Reference

1. Maxmen A. Drug-making plant blooms: Approval of a 'biologic' manufactured in plant cells may pave the way for similar products. Nature. 2012 May 8; Available from: http://www.nature.com/news/drug-making-plant-blooms-1.10604

Europes 2014–20 funding framework approved

European science ministers have agreed on a general structure for Horizon 2020, the region's 2014–20 research funding programme (worth ~ €90 billion /US$111 billion). Eastern European countries and the European Parliament have urged measures to ensure that less-developed EU states will have a more equal share. Mechanisms to reach this goal might include twinning wealthy western universities with eastern partners. Final decisions on the new framework will be completed in 2013. Negotiations over the budget allocations to Horizon 2020's various sub-programmes will begin shortly, and the council's discussions will probably conclude in late December under the Cypriot EU presidency. Negotiations with the European Parliament begin in September/October, with all sides hoping for an early agreement.

Reference

1. Phillips L. Drug-making plant blooms: Europe science ministers approve 2014–20 funding framework: Eastern states and the European Parliament push for more even distribution of funds.. Nature. 2012 June 1; Available from: http://www.nature.com/news/europe-science-ministers-approve-2014-20-funding-framework-1.10774

Eased sterility requirements for the making of biologics

The US Food and Drug Administration has relaxed some of the rules governing how companies must test the sterility of materials used to make biologic drugs, vaccines, or diagnostics.

The FDA's detailed rules, which appeared in the Federal Register at the beginning of May and went into effect on June 4th eliminate specified sterility test methods, culture media formulae, and culture media test requirements; eliminate the specified membrane filtration procedures required for certain products; eliminate specified sterility test requirements for most bulk material; modify the repeat sterility test requirements, so that repeat tests will occur only once for each product lot; and replace storage and maintenance requirements, testing sample sizes, and test interpretations with simplified guidelines.

In short, the FDA is reacting to the evolution of testing technology with rapid and advanced impurity detection capabilities to provide "manufacturers the flexibility to take advantage of methods as they become available, provided that these methods meet certain criteria," according to the Federal Register entry.

Reference

1. Grant B. FDA Eases Sterility Requirements. The Scientist. 2012 May 16; Available from: http://the-scientist.com/2012/05/16/fda-eases-sterility-requirements/

Obesity vaccine promotes weight loss in mice

Two obesity vaccines developed by Braasch Biotech in South Dakota were shown to reduce body weight of obese mice by up to10 percent.[2] Both vaccines target somatostatin, a hormone that can promote weight gain.

The sole author on the paper, Keith Haffer, injected mice fed an obesity-inducing diet with two vaccine candidates designed to produce antibodies against somatostatin. Reducing somatostatin levels is thought to help increase the amount of two other hormones—growth hormone and insulin-like growth factor—that promote weight loss.

"Although further studies are necessary to discover the long-term implications of these vaccines, treatment of human obesity with vaccination would provide physicians with a drug- and surgical-free option against the weight epidemic," Haffer said in a press release.

Reference

1. Zielinska E. Obesity Vaccine Success. The Scientist. 2012 July 9; Available from: http://the-scientist.com/2012/07/09/obesity-vaccine-success/

2. Haffer KN. Effects of novel vaccines on weight loss in diet-induced-obese (DIO) mice. J Anim Sci Biotechnol 2012; 3:21; PMID:22958753; http://dx.doi.org/10.1186/2049-1891-3-21

Health care fraud case against GalaxoSmithKline settled for $3 billion

GlaxoSmithKline agreed to plead guilty to misdemeanor criminal charges and pay $3 billion to settle what government officials have described as the largest case of healthcare fraud in US history.

GSK targeted the antidepressant Paxil to patients under age 18 when it was approved for adults only, and it pushed the drug Wellbutrin for uses for which it was not approved, including weight loss and treatment of sexual dysfunction.

In a third instance, GSK failed to give the US Food and Drug Administration safety data about its diabetes drug Avandia.

The misconduct continued for years beginning in the late 1990s and continued, in the case of Avandia's safety data, through 2007.

The agreement to settle the charges "is unprecedented in both size and scope," said James Cole, the No. 2 official at the US Justice Department.

GSK said in a statement it would pay the fines through existing cash resources.

Chief Executive Officer Andrew Witty said the misconduct originated "in a different era for the company" and will not be tolerated. "I want to express our regret and reiterate that we have learnt from the mistakes that were made," he said in a written statement.

The GSK settlement surpasses what had been the largest criminal case involving a drugmaker in US history. In 2009, Pfizer Inc agreed to pay $2.3 billion to settle allegations it improperly marketed 13 drugs.

The case is US v GlaxoSmithKline LLC, US District Court for the District of Massachusetts, No. 12-cr-10206.

Reference

1. Ingram D. 4-GalaxoSmithKline settles healthcare fraud case for $3 bln. Reuters. 2012 July 3; Available from: http://in.reuters.com/article/2012/07/02/glaxo-settlement-idINL2E8I24J620120702

Human Genome Sciences to be bought by GSK

GlaxoSmithKline is expected to announce a deal to buy Human Genome Sciences for about $2.8 billion, ending a three-month hostile pursuit of the US biotech company.

Biotechnology companies are in increasing demand as Big Pharma companies seek new products to replace older medicines that are going off patent in the biggest wave of drug patent expiries in history.

The acquisition will secure GSK full rights to Benlysta, a recently-launched drug for lupus, a disease of the immune system, and other experimental medicines for diabetes and heart disease.

There have been a spate of acquisitions of biotech companies this year as large pharmaceutical companies seek to rebuild their pipelines.

Most recently, Bristol-Myers Squibb agreed to buy diabetes specialist Amylin Pharmaceuticals by sharing the $7 billion cost of the deal with AstraZeneca.

Reference

1. Kim S, Hirschler B. GSK set for Human Genome takeover - sources. Reuters. 2012 July 16; Available from: http://uk.reuters.com/article/2012/07/16/uk-gsk-human-genome-idUKBRE86F00O20120716