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Plants used to produce insulin

Clinical trials now taking place

Source could meet diabetic demand

By Clive Cookson, Science Editor

The world's first clinical trial of human insulin produced in plants is under way in the UK, raising the prospect of a new source of insulin to meet rapidly growing demand from diabetics.

The trial will be an important milestone for the nascent "biopharming" industry, which aims to produce a range of human molecules in genetically engineered plants. Although several such pharmaceuticals are in development, none has yet reached the market – and insulin could be the first if the experiment is successful.

A genetically modified variety of safflower that makes high concentrations of human insulin in its seeds has been developed by SemBioSys, a Canadian biotechnology company. Safflower, a thistle-like plant

with large yellow flowers, is currently a minor source of seed oil.

The trial will reveal whether safflower-derived insulin has the same effects on blood sugar levels as commercial insulin, which is now produced mainly by cultures of genetically engineered bacteria in huge fermenters. The traditional animal sources of insulin, the pancreas of pigs and cows from slaughterhouses, have largely been phased out.

A demonstration of "bio-equivalence" will be essential to prove that the plant-

produced insulin is biologically identical to human insulin before regulators such as the European Medicines Agency and US Food and Drug Administration approve sale. Thirty healthy volunteers are taking part in the product's inaugural trial.

Following the trial, from which results will be available within six months, there will be more extensive testing with diabetic patients. The product could be on sale within four years, SemBioSys says.

It selected safflower

because it needed a species with seeds rich in oil, from which insulin could easily be extracted.

"We also chose safflower because it is a relatively obscure crop, not grown widely in Europe or North America, so we could separate our insulin-producing fields from other safflower production," says Maurice Moloney, the company's chief scientist. The insulin for clinical trials is grown in central Washington state in the US.

"The demand for insulin is increasing dramatically as demographic factors and dietary changes increase the incidence of diabetes," says Andrew Baum, SemBioSys chief executive. Independent estimates suggest that the world market for insulin could double to \$15bn (£10.3bn) a year by 2012.

The capital and operating costs of producing insulin in safflower seeds will be 70 to 80 per cent less than in bacterial fermenters, Mr Baum says. That would particularly help developing countries facing an epidemic of diabetes.



Genetically modified safflowers are rich in insulin Getty Images