Tests underway for new HIV drug farmed from GM tobacco plants

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A clinical trial of a potential Human Immunodeficiency Virus (HIV) drug farmed from genetically modified (GM) tobacco plants has at long last got underway in the United Kingdom. The beginning of the trial follows several years of regulatory negotiations, and is being carried out by the EU-funded PHARMA-PLANTA ('Recombinant Pharmaceuticals from Plants for Human Health') consortium, an international group of 28 academic institutions and 4 small companies.

The antiviral preventative P2G12 antibody drug that has been synthesised by GM tobacco plants is being tested on a small number of women in the United Kingdom to establish whether it is safe or not. The first phase of the trial, which kicked off in June, involves testing the

safety of the vaginally-applied antibody called P2G12 in 11 healthy women. The results from these tests are expected in October and could bring the science world closer to the development of affordable HIV treatments. The antibody recognises proteins on the surface of HIV to block infection, although it hasn't yet proven to be effective in humans.

It took such a long time for the UK-based Medicines and Healthcare products Regulatory Agency (MHRA) to give researchers the green light to start the tests as they needed to be 100 % sure that the drugs did not contain any allergenic plant sugars or pesticides. Plants are attractive vehicles for the expression of recombinant pharmaceutical proteins as they are inexpensive and versatile systems, amenable to rapid and economical scale-up. Although the use of GM plants and crops for foodstuffs has proved controversial in Europe, public opinion is more positive towards their use in medicines and vaccines.

The drugs used in the trial are manufactured at a special facility in Aachen, Germany, using a process that yields 5 grammes of purified antibody from 250 kg of tobacco.

The PHARMA-PLANTA project, which clinched EUR 12 million under the 'Life sciences, genomics and biotechnology for health' Thematic area of the EU's Sixth Framework Program (FP6), was launched in 2004 and has the overall objective of using GM plants to cut the costs of drugs that are hard to produce. The scientists hope that this will in turn lead to increasing the availability of modern medicines in some of the world's poorest regions.

Although the use of GM pharmaceuticals has been developed before with human insulin and hepatitis B vaccine, this large-scale project is the first time plant-derived materials used in humans have been explored in the EU.

As well as studies on tobacco plants and drug-producing plants, previous results from the PHARMA-PLANTA consortium have seen new ways to produce water efficient seeds being developed, which helps plants cope with drought resistance and contributes to global food security.

These recent developments are also the latest in a line of several other plant-produced biological drugs that are making their way into clinics. The pharmaceutical firm Bayer has just received approval from the United States Food and Drug Administration (FDA) to test the safety of tobacco-produced human antibodies that attack non-Hodgkin's lymphomas. In Canada, the company SemBioSys Genetics found in a trial of 23 volunteers that its safflower-produced version of insulin is safe and works just as well as a version of the drug that is already available on the market.

More information: PHARMA-PLANTA: www.pharma-planta.net/

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