Clinical tests for medicines made from genetically modified plants

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UK regulators have approved Europe's first clinical trial of a monoclonal antibody produced from genetically modified plants. This landmark decision sets the stage for the testing, in humans, of an anti-HIV product made from genetically modified tobacco plants. It will open the door for trials of additional plant-derived medicines treating a range of diseases.

The trial will test the safety of a plant-derived antibody designed to stop the transmission of HIV between sexual partners when applied directly to the vaginal cavity. If proven safe in the 11 participants, the researchers can then go on to test the effectiveness of the product.

The clinical trial marks the culmination of the EU Framework 6 Pharma-Planta project, which was launched by a consortium of 30 academic and industrial partners in 2004 with €12 million in funding from the European Union. The primary goal was to develop an approved manufacturing process for recombinant pharmaceutical proteins made in plants and take one such product through all the development stages including the pivotal clinical trial.

Most biopharmaceuticals are currently made at great expense in fermentation vats containing bacteria or mammalian cells, but the mass production of medicines in genetically modified plants could reduce costs and therefore make an important contribution to global health, by improving access for the poor in developing countries where diseases such as HIV are a huge problem. In addition, the simple manufacturing process could be transferred to developing countries allowing production

"in the region for the region".

The approval granted by the UK Medicines and Healthcare products Regulatory Agency (MHRA) is a significant step forwards because it means a plant-based production system can comply with current Good Manufacturing Practice, the strict standards used in the industry to ensure medicine quality and consistency.

Professor Julian Ma, scientific coordinator for Pharma-Planta and Professor of Molecular Immunology at St George's, University of London, said: "This is a red letter day for the field. The approval from the MHRA for us to proceed with human trials is an acknowledgement that monoclonal antibodies can be made in plants to the same quality as those made using existing conventional production systems. That is something many people did not believe could not be achieved."

The clinical trial - which is being carried out at the University of Surrey Clinical Research Centre - will test a topically-applied anti-HIV microbicide. The active ingredient in the microbicide is a monoclonal antibody called P2G12. If successful, the investigators envisage that P2G12 will be used in combination with other HIV-neutralising antibodies, also produced in plants, to create a broadly protective vaginal microbicide product.

The genetically modified tobacco plants producing P2G12 were grown in state-of-the-art containment greenhouses at the Fraunhofer Institute for Molecular Biology and Applied Ecology, IME in Aachen, Germany, and the antibody was isolated and purified in a custom-designed processing plant on the same site, the first of its kind to be granted a license to manufacture recombinant pharmaceutical products from plants in Europe.

Professor Rainer Fischer, Pharma-Planta coordinator and Fraunhofer

IME Director, said: "We now have a facility in Europe for producing modern medicines in transgenic plants that is unique in the world, although this has taken many years and much investment to establish. This approval is a springboard for European plant biotechnology and will enable many important medical products to be realised."

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