Vernalis signs agreement with Diosynth Biotechnology for phase III manufacture of V10153

26.09.2005 - Vernalis Plc has signed a contract with Diosynth Biotechnology for process development, scale-up and manufacturing of V10153 for Phase III clinical trials. The process development and manufacturing agreement will see Vernalis transfer the manufacturing process developed by the company to the Research Triangle Park facility of Diosynth Biotechnology for further process refinement and cGMP manufacturing commencing immediately. The Diosynth Biotechnology facility has been inspected by the FDA and EMEA. The goal of the collaboration is to complete cGMP Manufacture before the end of 2006.

V10153 is a novel thrombolytic agent that is being investigated in a Phase II study in Canada and the US in patients who have recently experienced an acute ischaemic stroke. V10153 is a modified version of human plasminogen, a naturally occurring protein, which, when activated, is responsible for dissolving blood clots in the body. The structural modification to V10153 is designed to target the drug at newly-formed blood-clots while leaving older clots unaffected, potentially reducing the risk of unwanted bleeding at other sites. V10153's safety profile to-date indicates that it has potential to extend thrombolytic treatment in stroke and other major thrombotic diseases. These include acute myocardial infarction (AMI), peripheral arterial occlusion, pulmonary embolism and deep vein thrombosis. In particular, V10153 has the potential to be effective and safe for use for a longer period after the onset of a stroke, enabling a broader group of patients to receive treatment.