

Patent granted for ProBioGen's avian cell line AGE1.CR

Berlin, July 10, 2008 - ProBioGen AG, a leading biotechnology company in cell engineering and production of biopharmaceuticals, has been granted patent protection for AGE1.CR, a proprietary duck cell line developed for the production of human and animal vaccines and proteins.

The granted patent as parent, ProBioGen also claims the use of a duck cell line that is infected with Modified Vaccinia Ankara (MVA) and that replicates MVA.

MVA is among the most promising vectors intended as recombinant vaccine against chronic infectious diseases such as AIDS, tuberculosis and malaria. High attenuation of MVA has increased safety for human vaccinees but also requires production on avian cells. In the granted patent, ProBioGen demonstrates for the first time that MVA replicates in duck cells and that duck cells (contrary to chicken cells currently used for MVA production) are free of endogenous particle-associated retrovirus activity.

"AGE1.CR is a stable duck cell line adapted to industrial-grade suspension processes for production of highly attenuated viruses and vectors requiring specially modified packaging cell lines," highlighted Dr Ingo Jordan, Director Subcellular Systems. "Due to its favourable glycosylation properties, which clearly distinguish AGE1.CR from other manufacturing cell lines such as CHO, recombinant protein production is evaluated together with industrial sponsors."

"This patent is a major milestone for ProBioGen and its licensing partners. In our cooperation with IDT Biologika, the cell line was developed to seamlessly fit into industrial processes and to meet the requirements of biopharmaceutical sponsors. An exhaustive testing following EU and US guidelines has been completed to provide the basis for accelerated IMPD/IND filing," said Dr Volker Sandig, Vice President Cell and Vector Biology at ProBioGen.

About ProBioGen AG

ProBioGen is a cell specialist. By combining deep molecular understanding of cells with state-of-theart industry process engineering and production know-how, ProBioGen's technologies enable biopharmaceutical companies to develop products with superior efficiency, safety and a more favourable cost profile. Since its inception in 1994, the company has processed more than 300 cell lines and established a GMP unit based on disposable reactor technology, which supports all currently available manufacturing processes. The company is headquartered in Berlin.

For more information, please visit www.probiogen.de

About AGE1.CR

AGE1.CR has been developed by ProBioGen in cooperation with IDT Biologika GmbH to replace embryonated chicken eggs and chicken embryonic fibroblasts as substrate for production of human and animal vaccines. The immortal cell line obviates dependence on external supply of pharmaceutical grade calf serum and SPF chicken and thus allows production of therapeutics and vaccines in closed systems. AGE1.CR is derived from specific tissue of a single duck embryo without feeder cell layers. This cell line fully supports the production of a wide spectrum of wild-type and recombinant viruses, including highly attenuated poxviruses. In the AGE1.CR cell line from muscovy duck no particle-associated retrovirus activity has been detected. The approach in generating the cell line is consistent with the "defined risk" guidelines issued by the FDA. Exhaustive analytical tests required for regulatory submission with US and European regulatory agencies have been performed. The resulting data package provides a strong background for application of AGE1.CR as a producer cell line for biopharmaceuticals.

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