

## PRESS RELEASE

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### ProBioGen receives Innovation Award Berlin-Brandenburg

*- Accolade for novel, proprietary vaccine production methods based on duck cell lines -*

Berlin, December 11, 2009 - ProBioGen AG, a leading biotechnology company in cell engineering and production of biopharmaceuticals, today announced it has received the Innovation Award Berlin-Brandenburg for its unique vaccine production methods based on duck cells. The joint accolade by the German states Berlin and Brandenburg is awarded each year to the states' most innovative companies.

According to the jury, Probiogen was chosen from 169 participants - thereof 21 life science companies - for its new duck cell line that removes the biggest obstacles for the fast and efficient production of vaccines, in particular for epidemic or pandemic diseases such as flu. Even though chicken cells have been used for vaccine production for decades, the traditional production method has a number of considerable disadvantages: supply of embryonated chicken eggs from bird flocks nurtured in sterile environments is limited and needs to be planned months ahead, virus cultivation in these eggs is demanding, and chicken cells are plagued by endogenous retroviruses that may become activated and contaminate vaccine lots under certain conditions.

To address these issues, ProBioGen has developed stable duck cell lines in a specific synthetic environment. Cultivation and infection of the cell lines has been adapted to chemically defined and highly scalable processes. The cell lines are independent of the breeding conditions necessary for live stock and have already been successfully modified further as packaging cell lines for production of certain modern vectorial vaccines in addition to highly attenuated poxviruses. Consequently, these proprietary duck cell lines allow for robust and versatile large-scale vaccine production and meet standardized safety criteria.

The potential of the lines has been demonstrated repeatedly in independent bioreactor runs for recombinant highly attenuated poxviruses. Clinically relevant constructs have been produced in a chemically defined process to titers of up to  $10^9$  infectious units per mL prior to any concentration or polishing steps.

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#### **About ProBioGen´s Duck Cell Lines (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.

## About ProBioGen AG

ProBioGen is a leading cell specialist. By combining deep molecular understanding of cells with state-of-the-art 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.

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