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Development and Applications of Transgenic Pigs Producing Human Therapeutic Proteins

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The production of pharmaceutical glycoproteins in cultured animal cells has several problems including variable glycosylation levels, high costs of culture media, difficulties in scaling-up due to their "bottle-necked" production and so on. In contrast the production of such proteins from milk (or urine) of transgenic animals under established purification systems for the glycoproteins is cost-effective and relatively easy to scale up to match their increasing demand. we have produced a transgenic pig line harboring human erythropoietin(EPO) gene under regulatory control of whey acidic protein promoter. Two individuals of the transgenic pig line were tested for hEPO concentration in their milk. Their average concentration was up to 880 IU of recombinant human EPO. amino acid sequence of the rhEPO protein in the transgenic pig milk matched that of cmmercial rhEPO produced from cultured animal cells. Among transgenic animals producing human proteins, the eEPO trsngenic pig is most close to mass-production. We are now pursuing the goal to bring the final product in to manufacturing and clinical trials in cooperation with new korean bio-venture company. PMG Biopharming.

Since transgenic pigs harboring hEPO gene were produced, we have established transgenic pig lines harboring human genes control of mammary gland spesific promotors (WAP or β-casein promotor) or urinary bladder specific uroplakin II promotor. Several individuals of the transgenic pig lines were tested for human proteins concentration in their milk or urine.

The transgenic animal research has been receiving a great support from Korean Government since late 1990s and is about to receive a major

push in 2005 with launching or National grant program planned for next decades. Although several transgenic farm animals have been produced in Korea, there is no commercial product available from them yet. However, it is expected that the first successful product that can reach at least clinical trials will be come around within couple of years.