Letter of Intent for In-licensing of Novel DNA Vaccines for Influenza

AnGes MG, Inc. (AnGes) and Vical Inc. (Vical) have entered into a Letter of Intent (LOI) indicating their mutual interest to license the development and marketing rights of Vical's pandemic influenza DNA vaccines in Japan to AnGes. AnGes plans to pursue with due diligence of the pandemic influenza DNA vaccines, and both parties intend to negotiate terms and conditions potentially leading to a license agreement.

Currently, there are outbreaks of bird flu in various regions worldwide. During such outbreak, it is considered that the bird virus mutates into a new virus which enables spread from person to person. Due to the newness of the virus, there is virtually no immunity to it, so that if the new strain of flu infects people, the infection could spread around the world quickly, causing a pandemic which could lead to a huge health damage and relevant social impact is of high concern.

The damage in Japan caused by the new influenza virus is simulated to be about 13-25 million of infections and 170,000-640,000 cases of death, by the MHLW.

On the other hand, in respect to development of such novel influenza vaccines, as there is no such strain in existence, no matching vaccine can be manufactured before such outbreak. Therefore, it is considered that as for pandemic vaccines, it is highly important that it can be quickly manufactured in large scale upon any outbreak of such new influenza virus.

Vical's pandemic influenza DNA vaccines has a potential significant advantage over conventional vaccines because DNA vaccines can be manufactured in 6-8 weeks rather than about six months required for conventional vaccines. Furthermore, the shelf life of such vaccines is quite long, and it is already known that there are more than 2 years of stability. Through this, it is probably possible to stockpile vaccines to prepare for any coming pandemic influenza.

The preliminary Phase I clinical trial data demonstrated that DNA vaccines can safely achieve significant immune responses against H5N1 pandemic influenza in humans. *1.

*1 : According to Vical's press release of Jul. 17, 2008, up to 67% of evaluable subjects in the higher dose cohorts achieved HI titers, an index of antibody responses, of at least 40, and at least a four-fold increase from Baseline HI titers.