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AnGes MG, Inc.

The Efficacy and Safety of Oral CIN Therapeutic Vaccine reconfirmed in an Investigator-initiated Clinical Study (STEP 2)

AnGes MG Inc. ("AnGes") announced today that positive results were obtained from an investigator-initiated clinical study (STEP 2) of a CIN therapeutic vaccine (therapeutic vaccine for precancerous conditions of cervix) conducted by the principal investigator Dr. Kei Kawana. (Obstetrics & Gynecology of the University of Tokyo Hospital)

HPV (human papilloma virus) is detected from early stage of precancerous lesion and is known to cause cervical cancer. Expression of the HPV oncoproteins, specifically E7, increases as it progresses into cervical intraepithelial neoplasia (CIN), and contributes to the development of cervical cancer.

The CIN therapeutic vaccine effectively induces mucosal HPV E7 antigen-specific cellular immune response on the neoplastic lesions and could promote CIN3 (late stage of CIN) lesions to disappear. It is expected to become the world's first orally administrable innovative therapeutic vaccine to prevent development of cervical cancer.

The previous investigator-initiated clinical study ("STEP 1") was done in 2009 at University of Tokyo to evaluate the safety and efficacy dose of the CIN therapeutic vaccine. STEP 1 study targeted CIN3 patients requiring cervical conization. The study results showed regression of CIN3 lesions and success in avoiding cervical conization in all patients of 4 capsules group. Since safety issues were not observed in STEP 1, the additional clinical study (STEP 2) was carried out with optimized dose, in which the efficacy and safety were reconfirmed, and the clinical utility of this therapeutic vaccine once again verified.

AnGes plans to proceed further with the evaluation of the safety and efficacy of the CIN therapeutic vaccine.

Vast majority of those who progress from precancerous lesions to intraepithelial neoplasia is in the peak child-bearing age. Among those who have undergone conization of cervix have increased risks of premature delivery, low birth weight and caesarean section.

Therefore, being able to avoid cervical conization is of a great significance and early realization of this therapeutic vaccine is desired.

This trend will have no effect on the business performance for the fiscal year of 2013.

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Disclaimer: This is a translation of the news release posted in Japanese. In case of any deviations between the two language versions, the original document in Japanese shall take precedence.

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