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UMN Pharma Enters into Licensing Agreement with Dr. Timo Vesikari and Dr. Vesna Blazevic of the University of Tampere Vaccine Research Center for worldwide rights to a novel norovirus and rotavirus vaccine candidate.

Groups to jointly initiate studies in 2012

Akita, Japan, February 14, 2012 - UMN Pharma, a clinical-stage vaccine focused biopharmaceutical company, and Timo Vesikari, M.D. and Vesna Blazevic, Ph.D. of the University of Tampere Vaccine Research Center of Finland, announced today that they have entered into a licensing agreement that provides UMN Pharma with exclusive worldwide rights to develop and commercialize a novel norovirus VLP + rotavirus VP6 non-live injectable adjuvant-free vaccine candidate developed by a research group led by Dr. Vesikari and Dr. Blazevic for the prevention of two major causative agents of acute gastroenteritis in children. The vaccine will be produced using a cell-culture manufacturing method employing the Baculovirus Expression Vector System (BEVS), a next-generation technology platform for the manufacturing of biopharmaceutical products.

"We are delighted to enter into this collaboration with Dr. Timo Vesikari and Dr. Vesna Blazevic of the University of Tampere Vaccine Research Center" commented Masahiro Michishita, M.D., Ph.D., UMN's Founder and Executive Chairman. "This type of cutting edge vaccine technology fits perfectly with UMN Pharma's charter of addressing unmet medical needs. There is currently no norovirus vaccine on the market and the ability to vaccinate against both norovirus and rotavirus in one injection is a major breakthrough. Norovirus and rotavirus each result in the deaths of many children around the world annually and this novel vaccine candidate may allow us to protect these children."

"We are very enthusiastic about this collaboration with UMN Pharma, which will enable us to proceed to production of GMP quality vaccine for clinical trials in rapid succession. We are confident about the concept of our combined norovirus VLP + rotavirus VP6 vaccine, and look forward to entering a proof-of-concept trial in humans in the near future."



About norovirus/rotavirus vaccine candidate

The vaccine candidate is a norovirus VLP + rotavirus VP6 non live injectable adjuvant-free vaccine for the prevention of two major causative agents of acute gastroenteritis in one shot. The norovirus VLP + rotavirus VP6 combination vaccine is proven to be highly immunogenic in mice and the combination does not interfere, but rather potentiates the immune response of each component. The immune response is targeted against different viral strains of norovirus and rotavirus and is long lasting. Therefore the vaccine should induce cross-protective long lasting immunity against the two enteric viruses.

Norovirus is estimated to cause some 200,000 deaths and rotavirus 450,000 deaths annually worldwide. In developed countries deaths are uncommon, but both pathogens are associated with a high burden of disease as well as huge costs. As of today, there is no licensed vaccine against norovirus gastroenteritis. Live attenuated rotavirus vaccines are in use in several countries, but may be associated with problems like intussusception as well as other issues associated with live vaccines in general.

About Timo Vesikari, M.D.

Dr. Timo Vesikari is Professor of Virology and Director of Vaccine Research Center at the University of Tampere Medical School as well as Chief of Pediatric Infectious Disease at the Department of Pediatrics, Tampere University Hospital, Tampere, Finland. Dr. Vesikari obtained his medical degree in 1969 from the University of Helsinki and did postgraduate studies in 1972–1975 in New York at the Bellevue Hospital and the Roosevelt Hospital. He held several teaching positions at the University of Tampere, including Professor of Pediatrics in 1981–1987. Dr. Vesikari conducted the first clinical trials of live oral rotavirus vaccines in humans in 1982–1983, and, more recently, was the principal investigator of the first pediatric trials of Rotarix[®] (GSK) vaccine and the lead investigator of the Merck's RotaTeq[®] vaccine trial REST. The published results in 2006 of these two trials were selected as Lancet's Paper of the Year in 2007. In the past several years, Dr. Vesikari's group has worked on the development of non-live norovirus-rotavirus combination vaccine.



About Vesna Blazevic, Ph.D.

Dr. Vesna Blazevic has a Ph.D. in Immunology from University of Tampere Medical School, Tampere, Finland. She has three years postdoctoral research experience (1997-2000) from National Institute of Health (NIH), Bethesda, USA working on immune dysregulation in HIV infection and basic issues of cellular immunology. In the most recent years Dr. Blazevic has worked on development of DNA vaccines against HIV. She has a substantial background in viral and vaccine immunology, especially assessing vaccine immunogenicity and efficacy in preclinical and clinical settings. Dr. Blazevic has acted as the Vice President of Science and Technology at FIT Biotech Oy Plc in Finland prior to joining Vaccine Research Center at the University of Tampere in 2009 as a Head of Laboratory.

About the University of Tampere Vaccine Research Center

The University of Tampere Vaccine Research Center is a clinical research unit operating within the University of Tampere Medical School. It carries out clinical trials of vaccines in co-operation with the pharmaceutical industry. The Center was formally established in 2004. However, vaccine trials have been carried out in Tampere since 1979, and in accordance with Good Clinical Practice (GCP) since 1991.

The Center currently operates a network of 15 regional vaccine research clinics. The network of clinics enables the Center to carry out extensive national trials and contribute strongly to large multinational studies. Leading international vaccine manufacturers have a high opinion of the Center as a partner.

Research laboratory at the Center is dedicated to development of novel and innovative vaccines for children. For the last few years the main project has been development of a novel combination vaccine against norovirus and rotavirus gastroenteritis.



About UMN Pharma

UMN Pharma is a vaccine focused biopharmaceutical company headquartered in Akita, Japan. UMN has strong capability in the vaccine field as many key team members come out of large pharmaceutical companies and have proven track records bringing highly successful and recognizable vaccine programs to market.

UMN has a manufacturing plant in Akita and laboratory facilities in Yokohama and Akita, Japan. UMN Pharma is focused on the development of novel vaccine candidates produced using a cell-culture manufacturing method employing the Baculovirus Expression Vector System (BEVS), a next-generation technology platform for the manufacturing of biopharmaceutical products. UMN's lead program is entering Phase III clinical studies for pandemic and seasonal influenza with Astellas Pharma Inc. UMN Pharma is partnered with additional leading companies in Japan such as IHI Corporation and API Co., Ltd.

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