3M Pharmaceuticals and Takeda to Collaborate on Potential Treatment for Cervical High-Risk HPV Infection and Cervical Dysplasia

3M and Takeda Pharmaceutical Company Limited (Takeda) announced today that the two companies entered into an exclusive co-development and joint marketing agreement to collaborate on a potential topical treatment for cervical high-risk human papillomavirus (HPV) infection and cervical dysplasia.

The compound is currently in early stage (Phase I) clinical testing. Under the terms of this agreement, 3M and Takeda will share further costs of development. Upon successful clinical development and regulatory approvals, the companies will jointly commercialize in the United States and European Union. Takeda will retain exclusive rights in Japan and certain Asian countries, and 3M will have exclusive commercialization rights in all other areas of the world.

The compound is part of the family of immune response modifier (IRM) molecules developed by 3M Pharmaceuticals. IRMs act in a novel way to stimulate the human body's immune system to fight virus-infected cells and tumor cells. 3M currently markets Aldara (imiquimod) Cream, 5%, the first topical IRM to be marketed globally, for the treatment of actinic keratosis, primary superficial basal cell carcinoma, and external genital and perianal warts.

"This is an excellent opportunity to advance the development and commercialization of a new pharmacological treatment for HPV infection in women at risk for cervical cancer," said Barry Labinger, division vice president, 3M Pharmaceuticals. "Working with Takeda enables us to combine 3M's proven IRM platform with Takeda's world-renowned leadership in delivering superior pharmaceuticals."

"We are excited to team with 3M on this program," said Yasuchika Hasegawa, president and chief operating officer, Takeda. "Combining 3M's ingenuity and IRM development expertise with Takeda's global development organization and commercialization capabilities will enable us to deliver a potentially innovative treatment for patients."

About HPV

HPV can infect the skin surface in any part of the body and is one of the most common sexually transmitted viruses(1). More than 100 types of HPV exist, including over 20 high-risk types that may cause abnormal cervical Pap smears(2). High-risk HPV is associated with 99.7 percent of cervical cancers(3). Of the 5.7 million abnormal Pap tests annually in the United States, an estimated 3 million represent one form of high-risk cervical HPV infection to be studied under this agreement(4). Additionally, high-risk HPV types in women over 30 years of age are likely to be persistent high-risk infections. Women with persistent high-risk HPV infections are at greater risk for progressing to cervical cancer(5).

The HPV infection market has significant unmet medical needs, including a pharmacological treatment that accelerates regression and prevents progression of cervical HPV infections. According to the American Social Health Association, most cervical HPV infections can be controlled by the woman's own immune system(6). The IRM in development may improve clearance of HPV infection by boosting the immune response for those patients experiencing persistent infection.

Forward-Looking Statements

This press release contains forward-looking statements about the potential of a new IRM molecule under development for the treatment of HPV infection and cervical dysplasia that reflect the current beliefs of 3M and Takeda. However, as with any pharmaceutical under development, there are substantial risks and uncertainties in the process of development and regulatory review. There are no guarantees that the product will be developed, receive regulatory approvals or prove to be commercially successful. 3M and Takeda undertake no duty to update forward-looking statements.

About 3M Pharmaceuticals -- Part of the 3M Health Care Family

3M Health Care, the largest of seven major 3M businesses, is dedicated to improving the practice, delivery and outcome of care in medical, dental, pharmaceutical, health information and personal care markets. 3M Pharmaceuticals, part of the 3M Health Care family, develops, manufactures and sells branded prescription drug products for dermatology, women's health, sexual health, cardiology and respiratory medicine.

About 3M -- A Global, Diversified Technology Company

Every day, 3M people find new ways to make amazing things happen. Wherever they are, whatever they do, the company's customers know they can rely on 3M to help make their lives better. 3M's brands include Scotch, Post-it, Scotchgard, Thinsulate, Scotch-Brite, Filtrete, Command and Vikuiti. Serving customers in more than 200 countries around the world, the company's 67,000 people use their expertise, technologies and global strength to lead in major markets including consumer and office; display and graphics; electronics and telecommunications; safety, security and protection services; health care; industrial and transportation.

Aldara, Scotch, Post-it, Scotchgard, Thinsulate, Scotch-Brite, Filtrete, Command and Vikuiti are trademarks of 3M.

About Takeda Pharmaceutical Company Limited

Takeda Pharmaceutical Company Limited is a research-based global company with its main focus on pharmaceuticals. As the largest pharmaceutical company in Japan and one of the industry's leaders worldwide, Takeda is committed to strive toward better health for individuals and progress in medicine by developing superior pharmaceutical products. Takeda is actively dedicated to enhance its pipeline for future growth through alliance as well as in-house R&D activities. For more information, visit <u>www.takeda.com.</u>

(1) American Social Health Association

(2) Wright TC, Sun XW, Koulos JP. Comparison of management algorithms for the evaluation of women with lowgrade cytologic abnormalities. Obstet Gynecol. 1995;85:202-210; Munoz N, Bosch FX, de Sanjose S, Herrero R, Castellsague X, Shah KV, Snijders PJF, Meijer CJLM. Epidemiologic Classification of Human Papillomavirus Types Associated with Cervical Cancer. NEJM. 2003;348(6):518-527; Bosch FX, Lorincz A, Munoz N, Meijer CJLM, Shah KV. The causal relation between human papillomavirus and cervical cancer. J. Clin Pathol. 2002;55:244-265.

(3) Walboomers JM, Jacobs MV, Manos MM, Bosch FX, Kummer JA, Shah KV, Snijders PJ, Peto J, Meijer CJ, Munoz N. Human Papilomavirus is a necessary cause of invasive cervical cancer worldwide. J Pathol. 1999;189(1):12-9.

(4) Incidence of Pap Test Abnormalities Within 3 Years of a Normal Pap Test - United States, 1991-1998. MMWR 2000;49(44) 1001-10003; Sawaya GF, Kerlikowske K, Lee NC, Gildengorin G, Washington E. Frequency of Cervical Smear Abnormalities Within 3 Years of Normal Cytology. Obstet Gynecol. 2000;96(2) 219-223.

(5) J-P Bory, J. Cucherousset, M. Lorenzato, R. Gabriel, C. Quereux, P. Birembaut, C. Clavel. "Recurrent Human Papillomavirus Infection Detected with the Hybrid Capture 2 Assay Selects Women with Normal Cervical Smears

at Risk for Developing High Grade Cervical Lesions," Int. J. Cancer 2002; 102: 519-525.

(6) American Social Health Association

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