

Global Medical Solutions Taiwan Signs FACBC Joint Development and Distribution Agreement with Nihon Medi-Physics to Develop and Commercialize FACBC, a new PET imaging agent, for the Diagnosis of Recurrence of Prostate Cancer in Taiwan

November 19, 2018, Taipei, Taiwan – Global Medical Solutions Taiwan, Ltd., a leading radiopharmaceutical company in Taiwan, today announced that it has entered into an exclusive agreement with Nihon Medi-Physics Co. Ltd. (NMP) to develop and commercialize FACBC in Taiwan. FACBC is an agent for the positron emission tomography (PET) imaging of recurrent prostate cancer.

NMP has the worldwide right of FACBC. Through NMP's partner, FACBC has been granted for marketing by Food and Drug Administration in the United States and European Medicines Agency in the European Union for positron emission tomography (PET) imaging in men with suspected prostate cancer recurrence with elevated blood prostate specific antigen (PSA) levels following prior treatment. Same as in Taiwan, there are many patients with elevated PSA levels after the treatment, and it is difficult for current diagnostic methods such as CT, MRI and bone scintigraphy to identify where the recurrent tumor is in the body. FACBC is a potential diagnostic agent to fill such an unmet medical need. Under the terms, Global Medical Solutions Taiwan will submit the Marketing Authorization Application to Taiwan FDA; manufacture and distribute FACBC in Taiwan upon the Marketing Authorization approval.

“FACBC fits perfectly in our product portfolio by strengthening our offering in PET imaging agents for use in oncology” said Mr. Haig Bagerdjian, President and CEO of Global Medical Solutions. “We expect the virtues of FACBC to significantly benefit patients with suspected recurrent prostate cancer by assisting the physicians in the diagnosis.”

“As a part of our growth strategy, we have actively worked on building tie-ups with companies in the Asian countries. This time we are very pleased that we got the first foothold by partnership with GMS, which has many achievements as a radiopharmaceutical company in Taiwan. By FACBC, we are very much looking forward to serving Taiwanese patients and medical professionals as soon as possible” said Mr. Hisashi Shimoda, President of Nihon Medi-Physics Co. Ltd.

In Taiwan, prostate cancer is the fifth most common cancer in men; and is the seventh cause of death among men with malignant tumor, according to the 2015 Taiwan Cancer Registry Annual Report published by Health Promotion Administration, Ministry of Health and Welfare of Taiwan. Patients are monitored by prostate-specific antigen (PSA) after initial therapy. An elevated PSA level can indicate biochemical recurrence. FACBC imaging is capable of localizing the recurrent tumors and could be a useful tool to provide better management to the patients.

About Global Medical Solutions Taiwan

Global Medical Solutions Taiwan is a leading radiopharmaceutical company in Taiwan. Global Medical Solutions Taiwan manufactures, dispenses, and distributes time-critical radiopharmaceuticals for nuclear medicine, including therapeutics and PET & SPECT imaging. Global Medical Solutions Taiwan purchased the rights of TRODAT-1, an imaging agent for labeling with ^{99m}Tc to be used in assisting the diagnosis of Parkinson's Disease. Global Medical Solutions Taiwan is currently establishing a GMP factory for the manufacturing of PET radiopharmaceuticals, further enhancing Global Medical Solutions Taiwan's leading position in the industry. Global Medical Solutions Taiwan is a wholly owned subsidiary of Global Medical Solutions, Ltd., which engages in SPECT and PET radiopharmacy operations, pharmaceutical & device manufacturing, and logistics for diagnostic, therapeutic, and theranostic medical needs. GMS operates in Armenia, Australia, Brazil, China, Hong Kong, New Zealand, Philippines, Russia, Taiwan, Thailand, and Vietnam as well as globally distributes its unique portfolio of products.

About Nihon Medi-Physics Co. Ltd.

Nihon Medi-Physics Co. Ltd. is a leading radiopharmaceutical company in Japan. Nihon Medi-Physics Co., Ltd. engages in the research, development, manufacture, sale, and purchase of radioactive pharmaceuticals, as well as radioactive medical devices and their related products for hospitals in Japan. It offers single photon emission computed tomography (SPECT) diagnostic agents and positron emission tomography (PET) diagnostic agents that offer diagnostic information from various aspects ranging from morphological images to functional changes in blood flow and metabolism; and Iodine-125 radioactive seeds, a medical device for brachytherapy. The company was founded in 1973 and operates as a joint venture between Sumitomo Chemical Company, Limited and GE Healthcare Limited.

About FACBC

FACBC is invented by the researchers at Emory University in the United States. It is a synthetic amino acid analogue radiolabeled by F-18 and targeting the amino acid transporters specifically overexpressed in tumor cells compared to normal cells. Lots of clinical researches conducted by Emory University and many other institutes worldwide have been shown that FACBC has comparable tumor uptake to FDG with much lower background signals in the brain and pelvic area. Moreover, FACBC shows lower uptake to the inflammatory tissues compared to FDG. Nihon Medi-Physics has been granted a world-wide exclusive right from Emory University to make, use, and sell FACBC as a diagnostic imaging agent. Nihon Medi-Physics has granted Blue Earth Diagnostics an exclusive right of FACBC in western countries, and Blue Earth Diagnostics has obtained approvals from US FDA and EU EMA to market FACBC as a diagnostic agent for the recurrent prostate cancer.

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