EPS Holdings, Inc.
Suzuken Co., Ltd.
Bushu Pharmaceuticals Ltd.
News Release

EPS Holdings, Suzuken Group, and Bushu Pharmaceuticals Sign Partnership Agreement to Support the Introduction of Unapproved Drugs (Drug Loss Products) into the Japanese Market

2024/5/9, EPS Holdings, Inc., News Release --- EPS Holdings, Inc. (headquarters: Shinjuku Ward, Tokyo, Representative Director: Hao Yan; hereinafter, "EPS Group") announces that it has entered into a partnership agreement with Suzuken Co., Ltd. (headquarters: Nagoya City, President and CEO: Shigeru Asano; hereinafter, "Suzuken"), Suzuken's consolidated subsidiary, Sanwa Kagaku Kenkyusho Co., Ltd. (headquarters: Nagoya City, President and CEO: Shusaku Isono; hereinafter, "SKK"), and Bushu Pharmaceuticals Ltd. (headquarters: Kawagoe City, Saitama Prefecture, President and CEO: Tadao Takano; hereinafter, "Bushu Pharma") for a joint business to support the launch of drug loss products in Japan.

1. The Situation of Drug Loss in Japan

In recent years, Japan has faced a growing issue with drug loss, which refers to drugs that have been approved in other countries but remain unapproved in Japan. Reports have in fact shown that about 70% of the new drugs approved in Europe and the U.S. in the past five years are products that have not been approved in Japan[*1]. Furthermore, about half of the unapproved drugs in Japan have been granted orphan drug designation by either the U.S. Food and Drug Administration (FDA) or the European Medicines Agency (EMA)[*2], highlighting the fact that clinically important drugs have either not been developed in Japan or are experiencing delays in development.

While various factors are involved in the cause of drug losses in a complicated manner, one factor is thought to be the shift in the development and marketing of new drugs in Europe and the U.S. from large pharmaceutical companies to emerging pharmaceutical companies that do not have Japanese subsidiaries[*3]. Many of these emerging pharmaceutical companies are established in the U.S., and it is speculated that their priority is to develop and market their products in the U.S. and Europe, and their priority to enter the Japanese market is relatively low. This is due to the financial aspects, lack of understanding of the Japanese market and its regulations, language barriers, and other factors. On the other hand, numerous emerging pharmaceutical companies are considering the possibility of future expansion into Japan and are hesitant to out-license their development and marketing rights in Japan prematurely, as this might limit their future options.

*1: Quoted from the Office of Pharmaceutical Industry Research, Policy Research News No. 63, July 2021, 'Drug Lag: The Situation and Characteristics of Unapproved Drugs in Japan'
*2: Quoted from the Office of Pharmaceutical Industry Research, Policy Research News No. 66, July 2022, 'Drug Lag: Can Unapproved Drugs Meet Japan's Unmet Medical Needs?'
*3: Quoted from 'Pharmaceutical Industry Vision 2021'

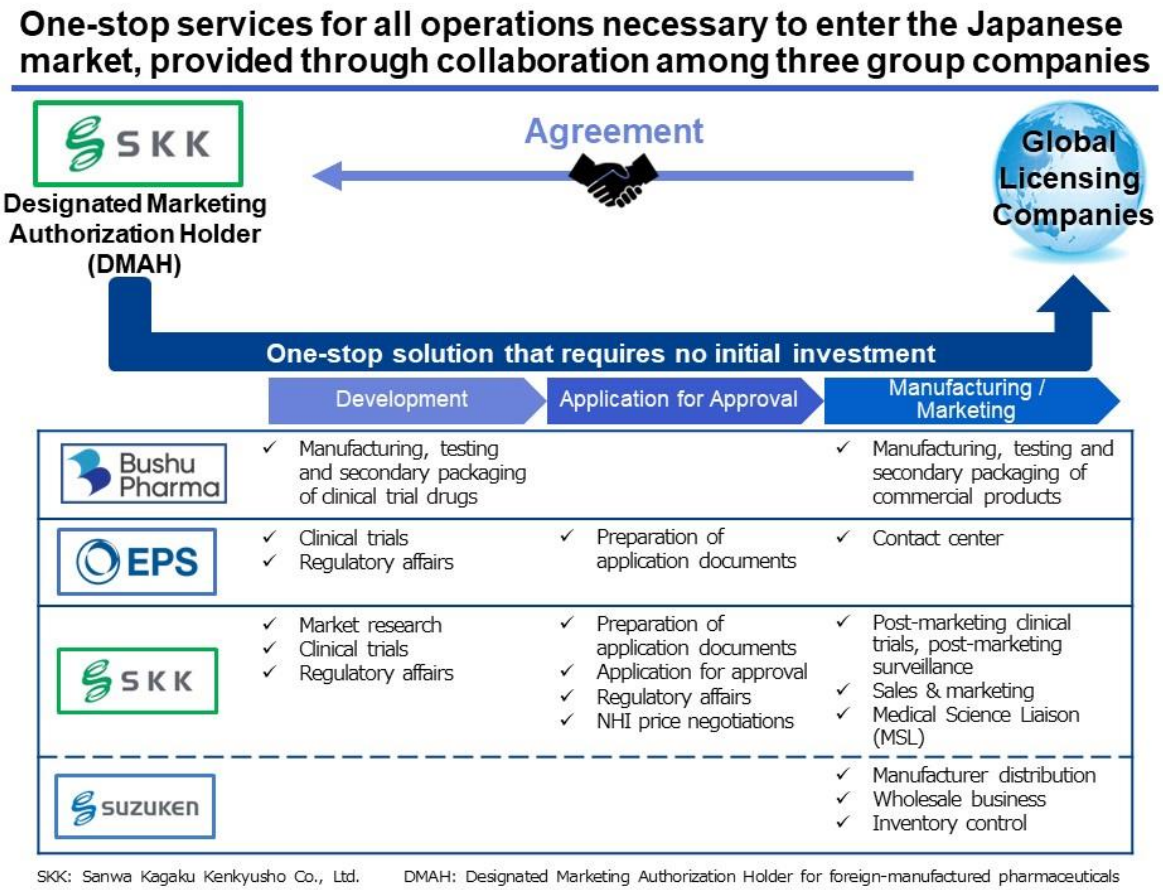
(Please note that the references listed above are available only in Japanese, and the titles have been translated solely for the purpose of this document's publication.)

2. Outline of the Business Model

This business model is a one-stop service that provides the roles necessary to enter the Japanese market, from development, application for approval of manufacturing and marketing, manufacturing, sales and marketing, and distribution, through the cooperation of the three group companies, Suzuken Group, EPS Group, and Bushu Pharma. (Reference: Business Model Diagram)

Although approval of new drugs requires an application for approval by the marketing authorization holder in Japan, it is possible to use the foreign exceptional approval system under the Pharmaceutical and Medical Device (PMD) Act. By appointing a Japanese marketing authorization holder, even if the company is not based in Japan, the foreign licensing company can obtain approval using its own company name. In this business model, SKK will serve as the Designated Marketing Authorization Holder (DMAH), and the three group companies will collaborate to develop, apply for manufacturing and marketing approval, and commercialize unapproved drugs in Japan.

Reference: Business Model Diagram



3. Characteristics of the Business Model

(1) Providing one-stop support for entering the Japanese market

Traditionally, licensing companies seeking to enter the Japanese market had to individually conduct activities aimed at development and commercialization within Japan themselves. This business model allows SKK to serve as the point of contact, combining the CDMO[*4] functions of Bushu Pharma, the

CRO[*5] and CSO[*6] functions of EPS Group, and the pharmaceutical manufacturing capability of SKK along with the manufacturer distribution and wholesale distribution capabilities of the Suzuken Group, to provide a comprehensive one-stop service.

(2) Assisting in obtaining approvals under the name of the licensing company
This business model allows for obtaining approval under the licensing company's name without having to establish a Japanese subsidiary or securing personnel for entry into the Japanese market, by utilizing the foreign exceptional approval system. This will contribute to increasing the recognition and branding of the licensing company in the Japanese market. In addition, on behalf of the licensing companies, the three group companies, which have extensive experience in their respective fields in Japan, will collaborate to provide high-quality services, including manufacturing of drugs, the roles required as the marketing authorization holder, and stable supply of pharmaceuticals.

(3) Offering a business model that requires no initial investment
In accordance with the financial circumstances of licensing companies, such as emerging pharmaceutical companies, SKK and EPS Group will bear the costs associated with development in Japan. Following the market launch, we will provide a pay-for-performance service that recoups development costs from future sales. This enables the licensing companies with financial constraints to enter the Japanese market without risk.

*4: CDMO: Contract Development and Manufacturing Organization
*5: CRO: Contract Research Organization
*6: CSO: Contract Sales Organization

4. Roles of Each Company

(1) EPS Group
Support for development and contact center operations, etc.

(2) Suzuken Group
Liaison with licensing companies, development and regulatory authority correspondence, general affairs related to manufacturing and marketing business as a designated marketing authorization holder, sales and marketing operations, and post-marketing distribution of specialty drugs, etc.

(3) Bushu Pharma
Production of drugs for clinical trials and commercial purpose, and secondary packaging services in compliance with the Japanese regulations (including final packaging and labeling), etc.

5. Future Outlook

The three group companies will work together to actively engage with foreign emerging pharmaceutical companies in order to secure early agreements for this business model and to expedite the launch of drugs not yet approved in Japan. By doing so, we aim to deliver highly anticipated new drugs to patients.

■ About Suzuken (https://www.suzuken.co.jp/en/)

The Suzuken Group has defined health creation as its primary business domain and is engaged not only in its core business of ethical drug distribution but also in the comprehensive development of medical and health-related businesses. These activities include the research, development, and manufacturing of new drugs, support services for pharmaceutical manufacturers, as well as the operations of pharmacy and nursing care businesses. Furthermore, the Suzuken Group is the only pharmaceutical wholesaler that boasts a comprehensive distribution function, which we refer to as the healthcare distribution platform, ranging from pharmaceutical manufacturers to wholesalers, and extending further to medical institutions and pharmacies. This enables us to address the diversifying and increasingly sophisticated demands of medical distribution from the perspectives of manufacturers, medical institutions, pharmacies, and even patients, offering a one-stop solution.

■ About Sanwa Kagaku Kenkyusho (https://www.skk-net.com/en/)

SKK is a subsidiary of Suzuken, one of Japan's leading pharmaceutical wholesalers, and is headquartered in Nagoya City, Aichi Prefecture. SKK is a pharmaceutical company that is capable of handling the entire process from R&D to the sales and marketing of pharmaceuticals, providing ethical drugs and diagnostic agents mainly in the fields of diabetes and kidney diseases. Embracing the corporate philosophy of Patient-friendly medicines for people worldwide", SKK considers its mission as developing and delivering pharmaceuticals that contribute to improving the quality of life (QOL) of patients.

■ About EPS Holdings (https://www.eps-holdings.co.jp/en/)

Since its establishment as a CRO pioneer in 1991, EPS Holdings has provided solutions regarding drug development, post-marketing development, marketing and sales, as well as consultation. In addition, it has been a healthcare solution provider offering new value to pharmaceutical companies, medical device companies, hospitals, clinics and academia through big data & AI, and regenerative medicine initiatives. In 2021, we established a drug discovery business to support the clinical development of drug candidates originating in academia as well as in domestic and foreign bio-ventures, and started a business providing marketing support in Japan and other countries.

■ About Bushu Pharmaceuticals (https://www.bushu-pharma.com/en/)

As one of the leading contract manufacturers of pharmaceutical products in Japan, Bushu Pharma offers a broad range of optimal solutions for technology transfer, pharmaceutical production, packaging, and logistic services based on 25 years of experience and expertise as a CDMO in all phases of development, from R&D projects for pharmaceuticals such as solid dosage formulations, primary packaging of solid dosage forms, production of injectable solutions, and more, to marketing approval of new drugs.

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