AlphaNavi Pharma Established as a Carve-Out Business Venture from Sumitomo Dainippon Pharma with Investment

Kyoto University Innovation Capital Co., Ltd. (Head Office: Sakyō-ku, Kyoto, Japan; President and CEO: Koji Murota; hereinafter called “Kyoto iCAP”) and Sumitomo Dainippon Pharma Co., Ltd. (Head Office: Osaka, Japan; Representative Director, President and CEO: Hiroshi Nomura; hereinafter called “Sumitomo Dainippon Pharma”) today announced AlphaNavi Pharma Co., Ltd. (Head Office: Sakyō-ku, Kyoto, Japan; Representative Director, President and CEO: Yoshihiro Oyamada; hereinafter called “AlphaNavi”) was established as a carve-out business venture from Sumitomo Dainippon Pharma, and allocated new shares to third-parties.

The round A financing allocated new shares totaling more than 900 million yen to an investor coalition of businesses consisting of Kyoto iCAP, Shinsei Capital Partners, Ltd., SMBC Venture Capital Co., Ltd, Nippon Venture Capital Co., Ltd., Chushin Venture Capital Co., Ltd. and Sumitomo Dainippon Pharma.

AlphaNavi is a business venture carved out from Sumitomo Dainippon Pharma that was established in January 2019 by two employees of Sumitomo Dainippon Pharma, with support from Kyoto iCAP. Sumitomo Dainippon Pharma decided to begin the carve out with DSP-2230 (product code), which was created by the company and is currently under development for neuropathic pain, to specifically promote its research and development for neuropathic pain associated with genetic mutations, through collaboration with outside parties. With manufacturing, development, and marketing rights for DSP-2230 licensed from Sumitomo Dainippon Pharma, AlphaNavi aims to deliver DSP-2230 as a first-in-class drug to patients with painful neuropathy such as episodic infantile limb pain syndrome.

Episodic infantile limb pain syndrome is a rare disease with high unmet medical need. The condition was identified by the research groups of Koizumi Akio, M.D., Ph.D., Emeritus Professor of Graduate School of Medicine, Kyoto University and Tsutomu Takahashi, M.D., Ph.D., Professor of Graduate School of Medicine, Akita University. They found Japanese family lines in which individuals experienced periodic episodes of pain, triggered by cold or fatigue since their infancy. They named the condition “episodic infantile limb pain syndrome.” Their research determined that the episodic pain was caused by a single nucleotide mutation in the SCN11A gene (Nav1.9), a voltage-gated sodium channel, and that this mutation triggered the hyper excitability of this channel localized in peripheral nerves, resulting in the onset of pain.

AlphaNavi intends to execute a joint research agreement on non-clinical studies for DSP-2230 with Professor Emeritus Koizumi so that the company can further clarify the effectiveness and features of DSP-2230 in diseases with high unmet medical need, such as episodic infantile limb pain syndrome and proceed to clinical development accordingly.

Kyoto iCAP highly regards AlphaNavi’s corporate philosophy of working to deliver novel drugs as quickly
as possible to patients suffering from neuropathic pain, for which few existing drugs have been effective. Due to the potential of AlphaNavi’s development pipeline, Kyoto iCAP has given consistent support to the business development of this company, including carve-out implementation, since before its incorporation. Sumitomo Dainippon Pharma expects that the research and development of DSP-2230 based on new development strategies will be accelerated by the DSP-2230 carve-out and relevant open-innovation activities, through industry-academia collaboration, with AlphaNavi playing a central role, leading to an important contribution to the treatment of diseases with great unmet medical need.

Professor Emeritus Koizumi, science and technology adviser of AlphaNavi, states: “Episodic infantile limb pain syndrome manifests primarily in early childhood to adolescence, and its severe pain significantly impairs patients’ quality of life. In many cases, those involved in school and preschool education do not understand this disease, so it is likely that patients and their families face great difficulty when the patients enroll in such institutions. I hope many patients with gene mutation will be clearly identified and be helped through AlphaNavi’s activities.”

Professor Takahashi, joint research partner of Emeritus Professor Koizumi, remarks: “Now that we have identified the cause of episodic infantile limb pain syndrome, for which existing drugs have been ineffective, we believe that a therapy that inhibits the action of the causative gene could result in the development of the most promising treatment.”

Mr. Oyamada, CEO of AlphaNavi, states: “In recent years, it has been clarified worldwide that voltage-gated sodium channel mutations trigger pain. DSP-2230 is expected to relieve pain by inhibiting abnormal nervous excitement caused by this mutation. Through industry-academia collaboration, focusing on patients and their families, AlphaNavi hopes to promote the development of DSP-2230 in a rapid and efficient manner.”

Overview of AlphaNavi Pharma Co., Ltd.:
1. Incorporated: January 2019
2. Head Office: 36-1 Yoshida-honmachi, Sakyo-ku, Kyoto, Japan (at International Science Innovation Building, Kyoto University)
3. Representative Director: Yoshihiro Oyamada
5. Description of business: Research and development of voltage-gated sodium channel selective inhibitors, such as DSP-2230

Reference Information:

About carve-out
The term “carve-out” refers to a portion of a company’s business that is established as an independent entity through the introduction of outside capital investment to incorporate it as a startup company.
About DSP-2230
DSP-2230 is a voltage-gated sodium channel selective inhibitor based on a novel mechanism created by Sumitomo Dainippon Pharma. In non-clinical trials with neuropathic pain, this drug has shown potential to have excellent analgesic effects without causing side effects associated with existing drugs in the central nervous system or the cardiovascular system. It is therefore expected to become a novel analgesic with an acceptable safety profile in clinical studies as well. DSP-2230, currently under development targeting neuropathic pain, has completed a Phase 1 study with sites in the United States, the United Kingdom, and Japan.

About Episodic Infantile Limb Pain Syndrome
This disease refers to cold- or fatigue-induced pain episodes expressed in upper and lower limbs of infants, whose onset has been shown to be associated with a mutation of the SCNA11A gene. For more details, refer to Kyoto University’s presentation, linked below.
http://www.kyoto-u.ac.jp/ja/research/research_results/2016/160527_1.html

About Kyoto University Innovation Capital Co., Ltd. (“Kyoto iCAP”) 
Kyoto iCAP is a wholly owned subsidiary of Kyoto University established in December 2014. Its purpose is to provide investment and support to companies founded by researchers belonging to Kyoto University (including spin-offs from joint research companies) for commercializing knowledge (including research results, technology, etc.). The KYOTO-iCAP 1st Fund was created from a 16billion-yen capital contribution from Kyoto University and private financial institutions, in January 2016. KYOTO-iCAP is a general partner of the Fund. The fund management period is 15 years, that enables KYOTO-iCAP to support Kyoto University-originated ventures with long-term and to provide equity from the seed stage to practical application. The university is one of the top research institutions in Asia.

About Sumitomo Dainippon Pharma Co., Ltd.
Sumitomo Dainippon Pharma defines its corporate mission as "to broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide". By pouring all our efforts into the research and development of new drugs, we aim to realize our corporate mission and provide innovative and effective pharmaceutical solutions to people not only in Japan but also around the world. Sumitomo Dainippon Pharma's goal is to create innovative pharmaceutical products in the focus research areas of Psychiatry & Neurology, Oncology and Regenerative Medicine/Cell Therapy.

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