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Sumitomo Dainippon Pharma and Poxel Announce Strategic Partnership for Development and Commercialization of Imeglimin, an Investigational Therapeutic Agent for Type 2 Diabetes, in Japan, China and Eleven Other Asian Countries

- **Poxel and Sumitomo Dainippon Pharma to jointly develop Imeglimin for the treatment of type 2 diabetes in Japan, Sumitomo Dainippon Pharma assumes Phase 3 and commercialization costs**
- **Sumitomo Dainippon Pharma will be solely responsible for Imeglimin development and commercialization in China, South Korea, Taiwan and nine other Southeast Asian countries***
- **Poxel receives an upfront payment of ¥ 4.75 billion (approximately €36 million, \$42 million) plus future potential development milestone payments and sales-based payments of up to ¥ 29.25 billion (approximately €219 million, \$257 million), and escalating double-digit royalties on net sales**
- **The Phase 3 program for Imeglimin in Japan on track to be initiated in the fourth quarter of CY 2017**

OSAKA, Japan & LYON, France--(BUSINESS WIRE)-- Sumitomo Dainippon Pharma Co., Ltd (Head Office: Osaka, Japan; President: Masayo Tada; Securities Code: 4506, First Section of TSE, hereinafter called "Sumitomo Dainippon Pharma") and [POXEL SA](#) (Euronext – POXEL - FR0012432516), a biopharmaceutical company focused on the development of innovative treatments for metabolic disorders, including type 2 diabetes, announced today the signing of a strategic partnership for the development and commercialization of Imeglimin, an investigational therapeutic agent for type 2 diabetes, in Japan, China, South Korea, Taiwan and nine other Southeast Asian countries.* The partnership enables Sumitomo Dainippon Pharma to add an innovative late-stage development product to its well established diabetes drug franchise in the fast-growing diabetes market in Japan. Poxel also gains a leading pharmaceutical partner for Imeglimin with an extensive track record in late-stage development and commercialization in Asia. Diabetes is a fast-growing market in Asia and Japan is the second largest single market for type 2 diabetes outside of the U.S.

This press release features multimedia. View the full release here:

Under the Agreement, Poxel is entitled to receive an upfront payment of approximately ¥ 4.75 billion (approximately €36 million, \$42 million). The Phase 3 program for Imeglimin in Japan will be a joint development effort between Poxel and Sumitomo Dainippon Pharma. Sumitomo Dainippon Pharma will be responsible for costs associated with this program and will be responsible for the commercialization of Imeglimin in Japan. In China, South Korea, Taiwan and nine other Southeast Asian countries, Sumitomo Dainippon Pharma will be solely responsible for the development and commercialization of Imeglimin. In addition, Poxel is entitled to receive future potential development milestone payments of up to ¥ 2.75 billion (approximately €21 million, \$24 million), subject to the clinical development of Imeglimin. Furthermore, after launch, Poxel will receive escalating double-digit royalties on net sales and sales-based payments of up to ¥ 26.5 billion (approximately €198 million, \$233 million) in accordance with sales goals.

“This is a major milestone for Poxel and for the development of Imeglimin and we are extremely pleased to announce this strategic collaboration with Sumitomo Dainippon Pharma. Given Imeglimin’s unique profile and novel mechanism of action, which we believe is well-suited for Asian patients, it has the potential to be a very important new oral therapy for the treatment of type 2 diabetes. With their very long and successful history of commercializing diabetes products and as a leader in this region with a dedicated franchise, Sumitomo Dainippon Pharma will be an excellent partner for Imeglimin in Asia,” said Thomas Kuhn, CEO of Poxel. “Our near-term focus in Japan is to initiate the Phase 3 program and to work closely with Sumitomo Dainippon Pharma to support the Japanese New Drug Application submission.”

“In-licensing new products is part of a strategy to strengthen the domestic revenue base. Diabetes is one of our focus therapeutic areas for sales and marketing and we have a diverse type 2 diabetes product line with different mechanisms of action,” said Masayo Tada, Representative Director, President and CEO of Sumitomo Dainippon Pharma. “We see an opportunity to further strengthen our product line by developing Imeglimin as a candidate compound for treatment of type 2 diabetes with a new mechanism of action. Our hope is that the development and launch of Imeglimin will provide type 2 diabetes patients not only in Japan, but in other Asian countries, a treatment option to help them manage their disease.”

Poxel recently met with the Pharmaceuticals and Medical Devices Agency (“PMDA”) in Japan for the Imeglimin end of Phase 2 meeting to discuss the Phase 3 program plans and the data package required for a Japanese New Drug Application (“JNDA”) submission. Based on constructive interactions and feedback from the PMDA, the Phase 3 program in Japan will include three pivotal studies with approximately 1,100 patients and is on track to be initiated by the end of 2017.

Imeglimin has demonstrated in preclinical studies the potential to address the mitochondrial dysfunction which is believed to be at the core of type 2 diabetes pathophysiology. Imeglimin is an orally available drug candidate that has been shown in clinical studies to demonstrate glucose lowering benefits by simultaneously targeting all three key organs which play an important role in the treatment of type 2 diabetes: the liver, muscles and the pancreas. Imeglimin has completed Phase 1 and Phase 2 development in over 1,200 subjects in the U.S., EU and Japan.

About Imeglimin

Imeglimin is the first clinical candidate in a new chemical class of oral agents called the Glimins by the World Health Organization. Imeglimin has a unique mechanism of action ("MOA") that targets mitochondrial bioenergetics. Imeglimin acts on all three key organs which play an important role in the treatment of type 2 diabetes: the liver, muscles, and the pancreas, and it has demonstrated glucose lowering benefits by increasing insulin secretion in response to glucose, improving insulin sensitivity and suppressing gluconeogenesis. This MOA has the potential to prevent endothelial and diastolic dysfunction, which can provide protective effects on micro- and macro-vascular defects induced by diabetes. It also has the potential for protective effect on beta-cell survival and function. This unique MOA offers the potential opportunity for Imeglimin to be a candidate for the treatment of type 2 diabetes in almost all stages of the current anti-diabetic treatment paradigm, including monotherapy or as an add-on to other glucose lowering therapies.

About Poxel SA

Poxel uses its development expertise in metabolism to advance a pipeline of drug candidates focused on the treatment of metabolic disorders, including type 2 diabetes. We have successfully completed our Phase 2 clinical program for our first-in-class lead product, Imeglimin, which targets mitochondrial dysfunction, in the U.S., EU and Japan. Our second program, PXL770, a direct AMPK activator, is in Phase 1 development. We intend to generate further growth through strategic partnerships and pipeline development. (Euronext: POXEL, www.poxelpharma.com)

About Sumitomo Dainippon Pharma

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 provide innovative and effective pharmaceutical solutions to people not only in Japan but also around the world in order to realize our corporate mission. Sumitomo Dainippon Pharma aims to create innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the focus therapeutic areas. Sumitomo Dainippon Pharma has also positioned Psychiatry & Neurology, Diabetes/Cardiovascular and Speciality areas as our focus marketing areas in Japan. For more detail, please visit our website. ([URL:http://www.ds-pharma.com](http://www.ds-pharma.com))

*including: Indonesia, Vietnam, Thailand, Malaysia, The Philippines, Singapore, Republic of the Union of Myanmar, Kingdom of Cambodia, and Lao People's Democratic Republic.

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