AD-HOC ANNOUNCEMENT
INSIDE INFORMATION ACCORDING TO ARTICLE 17 MAR

PAION AG: MUNDIPHARMA RECEIVES MARKET APPROVAL FOR ANEREM® (REMIMAZOLAM) IN GENERAL ANESTHESIA IN JAPAN

Aachen (Germany), 23 January 2020 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) announces that Mundipharma, remimazolam licensee for Japan, today informed PAION that Japan's Ministry of Health, Labour and Welfare (MHLW) has approved the New Drug Application (NDA) for remimazolam (Japan trademark: Anerem®) in general anesthesia.

The NDA approval of remimazolam in Japan will trigger milestone payments between EUR 1.5 million and EUR 2.5 million coming from Mundipharma and Hana Pharm.

End of inside information

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"*Our first marketing approval of remimazolam is a major milestone for PAION, and we congratulate Mundipharma on this achievement*," said Dr. Jim Phillips, CEO of PAION AG. "*With the aging of the population, there is an increasing need for effective anesthetics with a favorable cardio-respiratory safety profile, and Japan is one of the world's largest pharmaceutical markets. We expect the approval in Japan to be the first of several marketing approval decisions in 2020 and anticipate the roll-out of remimazolam in countries around the globe*."

PAION granted Mundipharma exclusive rights to develop and commercialize remimazolam for the Japanese market in 2017. Under the terms of the agreement, PAION is entitled to receive payments totaling up to EUR 25 million depending upon the achievement of certain regulatory and commercial milestones in three indications – procedural sedation, general anesthesia and intensive care unit (ICU) sedation. PAION is also entitled to receive tiered royalties starting in the low double-digits to over 20% of net sales, depending on sales levels and sales price (National Health Insurance (NHI) price), which will be determined by the Japanese government.

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About remimazolam
Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic. In the human body, remimazolam is rapidly metabolized to an inactive metabolite by tissue esterases and is not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation or

anesthesia if necessary. In clinical studies, remimazolam demonstrated efficacy and safety in around 2,500 volunteers and patients. Data so far indicate that remimazolam has a rapid onset and offset of action combined with a favorable cardio-respiratory safety profile.

In Japan, licensee Mundipharma received market approval in general anesthesia in January 2020. In the U.S., licensee Cosmo Pharmaceuticals submitted a New Drug Application for procedural sedation in April 2019, with a PDUFA decision date of 05 April 2020. In China, licensee Yichang Humanwell filed for market approval in procedural sedation in November 2018. In South Korea, licensee Hana Pharm filed for market approval in general anesthesia in December 2019. In Europe, PAION submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in procedural sedation in November 2019 and a Phase III trial in general anesthesia is ongoing.

In addition to procedural sedation and general anesthesia, based on positive Phase II study results, ICU sedation beyond 24 hours is another possible attractive indication for further development in Europe by PAION as well as by its licensees in other territories.

Remimazolam is partnered in the U.S. (Cosmo Pharmaceuticals), Japan (Mundipharma), China (Yichang Humanwell), Canada (Pharmascience), Russia/CIS, Turkey and the MENA region (R-Pharm) as well as South Korea and Southeast Asia (Hana Pharm). For all other markets outside the EU, remimazolam is available for licensing.

About PAION

PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize innovative drugs for out-patient and hospital-based sedation, anesthesia and critical care services. PAION's lead compound is remimazolam, an intravenous, ultra-short-acting and controllable benzodiazepine sedative/anesthetic. Remimazolam is partnered in multiple territories outside of Europe. In Japan, remimazolam was approved for general anesthesia in January 2020. In the U.S., a New Drug Application (NDA) for procedural sedation is under review, with a PDUFA date of 5 April 2020. In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018 and in South Korea, licensee Hana Pharm filed for market approval for remimazolam in general anesthesia in December 2019.

In Europe, PAION is seeking approval of remimazolam for general anesthesia and for procedural sedation. PAION submitted a Marketing Authorization Application (MAA) for procedural sedation in November 2019. A Phase III trial in general anesthesia is ongoing.

Development for intensive care unit (ICU) sedation is part of the longer-term life-cycle plan for remimazolam.

PAION's mission is to be a leading specialty pharmaceutical company in the fields of anesthesia & critical care by bringing novel products to market to benefit patients, doctors & stakeholders in healthcare. PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

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