



**AD-HOC ANNOUNCEMENT  
INSIDE INFORMATION ACCORDING TO ARTICLE 17 MAR**

**PAION ANNOUNCES SUBMISSION OF NEW DRUG APPLICATION FOR  
REMIMAZOLAM BY ITS PARTNER MUNDIPHARMA IN JAPAN**

- First marketing application in general anesthesia
- Second remimazolam marketing application by a license partner in 2018
- Submission triggers milestone payments to PAION totaling EUR 2 million

Aachen (Germany), 21 December 2018 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) announces that its Japanese remimazolam licensee Mundipharma has informed PAION today about the submission of a New Drug Application (NDA) to the Japanese Pharmaceuticals and Medical Devices Agency (“PMDA”) for remimazolam in the indication general anesthesia.

The NDA submission triggers a milestone payment of EUR 1 million from Mundipharma. In addition, PAION will receive milestone payments of EUR 0.5 million each from its South Korean licensee Hana Pharm for the NDA submission in Japan and its Turkish licensee TR-Pharm. The payment from TR-Pharm is dependent upon transfer of the Japanese filing dossier translated into English, which will happen during 2019.

**End of inside information**

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Dr. Wolfgang Söhngen, CEO of PAION AG, commented: *“We are excited that our licensee Mundipharma has submitted a regulatory filing for remimazolam in general anesthesia. We are very proud of this first filing in an ICH region. This is a great achievement following the NDA submission in China in procedural sedation earlier this year. Furthermore, it represents a significant step for us and our partners in South Korea and Turkey as they will use the Japanese dossier for their regulatory filings. Safe and efficient anesthesia is needed by millions of patients worldwide. We believe that remimazolam can make an important difference compared to current treatment options. We look forward to the PMDA decision.”*

The exclusive rights to develop and market remimazolam for the Japanese market were granted to Mundipharma in 2017.

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**About remimazolam**

Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic that has already shown positive results in clinical Phase III trials. 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 and anesthesia if necessary. During clinical studies, remimazolam demonstrated efficacy and safety with around 2,400 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.

PAION has completed clinical development of remimazolam for procedural sedation in the U.S. The U.S. licensee, Cosmo Pharmaceuticals, currently plans to file for market approval in procedural sedation by the end of the first quarter 2019 and is responsible for any further development activities in the U.S. In Japan, remimazolam licensee Mundipharma filed for market approval in general anesthesia in December 2018. In China, licensee Yichang Humanwell filed for market approval in procedural sedation in November 2018. In Europe, PAION initiated a Phase III study in general anesthesia in July 2018.

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 the EU by PAION as well as by its partners.

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

#### **About Mundipharma**

Mundipharma's independent associated companies are privately owned entities covering the world's pharmaceutical markets. Mundipharma is a prime example of a company that consistently delivers high quality products while standing by the values that represent the company. Our mission is to alleviate the suffering of patients with cancer and non-cancer pain and to substantially improve their quality of life. Mundipharma is dedicated to bringing to patients with severe and debilitating diseases the benefit of novel treatment options in fields such as pain, oncology, ophthalmology, respiratory disease, rheumatoid arthritis and antiseptics. In efforts to combat infectious diseases around the world, Mundipharma has and continues to donate BETADINE® products.

For more information please visit: [www.mundipharma.com.sg](http://www.mundipharma.com.sg)

#### **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 drug candidate for which PAION has completed the clinical development for use in procedural sedation in the U.S. Outside the U.S., PAION is currently focused on the development of remimazolam for general anesthesia. Development of remimazolam for intensive care unit (ICU) sedation is also part of the longer-term life-cycle plan for remimazolam.

PAION's vision is to become an acknowledged "PAIONeer" in sedation and anesthesia. PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

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