



## PRESS RELEASE

### PAION GRANTS EXCLUSIVE LICENSE TO MUNDIPHARMA FOR DEVELOPMENT AND COMMERCIALIZATION OF REMIMAZOLAM IN JAPAN

- EUR 1 million upfront payment to PAION
- Additional regulatory and commercial milestone payments of up to EUR 25 million
- Royalties ranging from low double-digits to over 20%

Aachen (Germany), 18 December 2017 – PAION AG, a specialty pharma company (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8), and Mundipharma today announce that they have entered into a license agreement for remimazolam with PAION granting Mundipharma an exclusive license for the development and commercialization of PAION's lead drug candidate, remimazolam, in Japan.

Under the terms of the agreement, Mundipharma has the right and obligation to further develop remimazolam in all indications in Japan with PAION's support. Mundipharma will bear all cost for market authorization and distribution.

PAION will receive a EUR 1 million upfront payment. PAION is also entitled to receive additional payments totaling up to EUR 25 million depending on the achievement of certain regulatory and commercial milestones in the 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.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: *"We are excited to have Mundipharma as our partner for remimazolam in Japan. It was important for us that Mundipharma is also committed to collaborate on the further development for ICU sedation and procedural sedation after successful filing in general anesthesia. They have an impressive track record in the global pharmaceutical market and have a growing and successful presence in Asia. We look forward to intensive collaborative efforts towards regulatory filing in a timely manner to advance remimazolam in this important territory as quickly as possible."*

Mundipharma CEO, Raman Singh added: *"Strong collaborative partnerships continue to drive our growth and increase our ability to meet patient needs in Japan and across Asia. We're excited about the potential for remimazolam as a treatment for general anesthesia as well as other indications, and we look forward to working with PAION as we continue to expand our product portfolio with synergistic treatments."*

In January 2016, PAION held a pre-NDA meeting with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA). The PMDA stated that they considered the non-clinical and clinical data package for remimazolam to be complete for filing for the indication “induction and maintenance of general anesthesia.” The PMDA previously had confirmed that both the raw materials produced by PAION in Europe as well as the finished formulation of remimazolam fulfilled the requirements for filing in Japan. Based on the positive pre-NDA meeting, PAION has started to prepare filing for remimazolam in Japan. Mundipharma will now take over these responsibilities with PAION’s support.

###

### **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 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 in over 1,700 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.

Remimazolam is currently in the final stage of clinical development for procedural sedation in the U.S. After completion of the ongoing development, the implementation of a pediatric development plan already agreed with the FDA is planned. A full clinical development program for general anesthesia was completed in Japan, and a Phase II study in general anesthesia was completed in the EU. Based on the positive results of the Phase II study, development for ICU sedation beyond 24 hours is another attractive indication.

Remimazolam is partnered in the U.S., Canada, China, Russia (CIS), Turkey, the MENA region, South Korea, and Japan with Cosmo Pharmaceuticals, Pharmascience (Pendopharm), Yichang Humanwell, R-Pharm, TR-Pharm, Hana Pharm, and Mundipharma, respectively. For all other markets, 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 to be used in 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 which is in the final stage of clinical development for use in procedural sedation in the U.S. Currently, PAION is mainly focusing its business and financial resources on successfully completing its development program in procedural sedation in the U.S. Outside the U.S., PAION has so far focused on the development of remimazolam in the indication general anesthesia. A full clinical development program for general anesthesia was completed in Japan and PAION is preparing filing in Japan. In the EU, PAION is currently planning to continue the clinical development program. Development of remimazolam in the indication intensive care unit (ICU) sedation is also part of the longer term life-cycle plan for remimazolam.

PAION is headquartered in Aachen (Germany) with a further site in Cambridge (United Kingdom).

PAION's vision is to become an acknowledged "PAIONeer" in sedation and anesthesia.

**Contact**

Ralf Penner  
Vice President Investor Relations/Public Relations  
PAION AG  
Martinstrasse 10–12  
52062 Aachen – Germany  
Phone +49 241 4453-152  
E-mail [r.penner@paion.com](mailto:r.penner@paion.com)  
[www.paion.com](http://www.paion.com)

**Disclaimer:**

This release contains certain forward-looking statements concerning the future business of PAION AG. These forward-looking statements contained herein are based on the current expectations, estimates and projections of PAION AG's management as of the date of this release. They are subject to a number of assumptions and involve known and unknown risks, uncertainties and other factors. Should actual conditions differ from the Company's assumptions, actual results and actions may differ materially from any future results and developments expressed or implied by such forward-looking statements. Considering the risks, uncertainties and other factors involved, recipients should not rely unreasonably upon these forward-looking statements. PAION AG has no obligation to periodically update any such forward-looking statements to reflect future events or developments.