



## PRESS RELEASE

### PAION ANNOUNCES CLINICAL DEVELOPMENT PROGRESS WITH REMIMAZOLAM BY ITS PARTNER HANA PHARM IN SOUTH KOREA

- Hana Pharm has started a Phase III trial in general anesthesia
- Remimazolam administered to first patient in March 2018

Aachen (Germany), 22 March 2018 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) today announces that its South Korean remimazolam license partner Hana Pharm has informed PAION that their first Phase III trial in general anesthesia has started recruitment.

The Phase III study is a single-blind randomized comparative clinical trial of efficacy and safety of remimazolam versus propofol in 198 patients undergoing general anesthesia and is being conducted at 12 sites including Seoul National University Hospital. The trial is being recruited in South Korea.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: *“This is great news for PAION and Hana Pharm. We are delighted by the strong commitment to remimazolam by our South Korean partner Hana Pharm. We look forward to learn more about the progress towards the Phase III study and filing in South Korea.”*

The rights to develop and market remimazolam in South Korea were granted to Hana Pharm in 2013.

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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 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 in the final stage of clinical development for procedural sedation in the U.S. Currently, an integrated overall analysis of all clinical studies with remimazolam is being conducted in preparation of Cosmo’s filing for market approval. After completion of the development for procedural sedation, Cosmo will be responsible for any further development activities in the U.S. The U.S. license partner currently plans to file for market approval in procedural sedation in the fourth quarter 2018/first quarter 2019. A full clinical

development program for general anesthesia was completed in Japan, and the remimazolam license partner for this region, Mundipharma, is planning filing for market approval in this indication in Japan in 2018. In Europe, it is planned to start a Phase III study in general anesthesia in the second half of 2018 which can be expected to be the only necessary outstanding trial for filing for market approval in Europe based on the scientific advice obtained from the European Medicines Agency (EMA) in January 2018.

Based on the positive results of a Phase II study, ICU sedation beyond 24 hours is another possible attractive indication for further development in the EU by PAION as well as by partners in the licensed territories.

Remimazolam is partnered in the U.S., Canada, China, Russia (CIS), Turkey, the MENA region, South Korea and Japan with Cosmo, Pharmascience (Pendopharm), Yichang Humanwell, R-Pharm, TR-Pharm, Hana Pharm, and Mundipharma, respectively. 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 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. In the EU, PAION is currently planning to continue the clinical development program by starting a Phase III trial in the second half of 2018. 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.

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