

## PRESS RELEASE

### PAION ANNOUNCES CLINICAL DEVELOPMENT PROGRESS WITH REMIMAZOLAM BY ITS PARTNER R-PHARM IN RUSSIA

- R-Pharm successfully completes patient recruitment of a Phase III trial in general anesthesia
- No safety concerns

Aachen (Germany), 17 May 2018 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) today announces that its Russian remimazolam license partner R-Pharm has informed PAION that their Phase III trial in general anesthesia has successfully completed recruitment.

The Phase III study was a multicentre, single-blind randomized comparative clinical trial of efficacy and safety of remimazolam and propofol in 150 surgery patients undergoing general anesthesia. The trial was recruited in Russia.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: *“Our collaboration with R-Pharm represents an important pillar of our strategy for the worldwide development of remimazolam. The study will further increase the efficacy and safety database for remimazolam. We are very pleased by our partner’s rapid recruitment and are now looking forward towards filing in 2018.”*

Vasily Ignatiev, CEO of R-Pharm, stated, *“Taking into consideration consistent growth in demand for anesthetics with high safety profile, R-Pharm and PAION cooperate intensively in order to introduce new medicine for clinical practice. Phase II and Phase III trials conducted in the United States and Japan show that Remimazolam is efficient as a sedating agent.”*

The rights to develop and market remimazolam in Russia were granted to R-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.

PAION has completed clinical development of remimazolam 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 Pharmaceuticals, 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 for which PAION has completed the clinical development for use 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 an additional site in Cambridge (United Kingdom).

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

#### **About R-Pharm**

R-Pharm is a Russian private pharmaceutical company founded in 2001, which employs over 3,600 highly qualified specialists in over 60 branches. R-Pharm operates in Russia and CIS, USA, Germany, Japan and India. The company is involved in R&D, manufacturing, marketing and distribution of innovative pharmaceutical products from a broad number of therapeutic areas in specialty/hospital care. The company has operational GMP compliant manufacturing sites at Yaroslavl, Kostroma and Illertissen (Germany).



R-Pharm is building a modern Pharmoslavl facility for the synthesis of active pharmaceutical ingredients in Rostov (Russia).

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