

PRESS RELEASE

PAION ANNOUNCES SUCCESSFUL COMPLETION OF RUSSIAN REMIMAZOLAM PHASE III CLINICAL TRIAL BY PARTNER R-PHARM

Aachen (Germany), 06 November 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 conducted in Russia has been successfully completed.

The Phase III trial was a multicentre, single-blind randomized clinical trial comparing the efficacy and safety of remimazolam and propofol in surgery patients undergoing general anesthesia. The trial was conducted in six medical facilities in Russia and included 150 patients, randomized in two groups, one half was administered with remimazolam, while the other half received propofol. The trial data further confirmed the high safety and efficacy profile of remimazolam.

Following this successful completion of the Phase III clinical trial, R-Pharm plans to file for marketing authorization with the Ministry of Healthcare of the Russian Federation in Q1 2019.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: *“We congratulate our partner R-Pharm on the successful completion of the Phase III clinical trial in general anesthesia. The study further increases the efficacy and safety database for remimazolam. We now look forward towards filing in the Russian Federation.”*

“We are inspired by the results of this Phase III clinical trial. The research, conducted in Russia, came to the same conclusions as several other international trials. PAION’s remimazolam is an anesthetic agent that fully meets all safety and efficacy requirements and standards existing for this type of treatment,” Chief Medical Officer of R-Pharm, Mikhail Samsonov, said.

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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 with around 2,000 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, a Phase III study in general anesthesia was started in July 2018 which can be expected to be the only necessary outstanding trial for filing for market approval in the EU based on the Scientific Advice obtained from the 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 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. A full clinical development program for general anesthesia has been completed in Japan. In the EU, PAION initiated a Phase III trial in July 2018. 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).

About R-Pharm

R-Pharm is a Russian hi-tech pharmaceutical group of companies founded in 2001 that employs over 3,600 highly qualified specialists and has over 70 branches. R-Pharm operates in Russia, CIS, USA, Germany, Japan and other countries. The company is involved in R&D, manufacturing, marketing, sales and distribution of innovative pharmaceutical products from a broad number of therapeutic areas in specialty/hospital care.

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