



PRESS RELEASE

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

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

Aachen (Germany), 08 October 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 Phase III trial in general anesthesia has successfully completed recruitment.

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

Dr. Wolfgang Söhnngen, CEO of PAION AG, commented: *“Congratulations to our South Korean partner Hana Pharm for the fast patient recruitment which is another proof of the strong commitment to remimazolam by our partner. We look forward to learn more about the results of the Phase III study and filing in South Korea.”*

Dr. Younha Lee, CEO of Hana Pharm, stated: *“We are very pleased that the recruitment of the patients for the Phase III trial has been successfully completed and that the anesthesiologists who have participated in trials have shown great satisfaction and expectation with remimazolam until now. This trial will once again demonstrate the efficiency and high safety profile of remimazolam and that will play a big role in Hana’s further growth as well. We strongly believe that this project will strengthen the partnership between Hana Pharm and PAION.”*

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 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).

PAION 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
www.paion.com

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