



**AD-HOC ANNOUNCEMENT  
INSIDE INFORMATION ACCORDING TO ARTICLE 17 MAR**

**PAION ANNOUNCES THAT NMPA ACCEPTS SUBMISSION OF NEW  
DRUG APPLICATION FOR REMIMAZOLAM BY CHINESE LICENSEE  
YICHANG HUMANWELL**

- First remimazolam marketing application by a license partner
- Yichang Humanwell successfully completed remimazolam clinical development in procedural sedation in 2018
- NDA submission triggers milestone payment of EUR 0.5 million to PAION

Aachen (Germany), 16 November 2018 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) announces that its Chinese remimazolam licensee Yichang Humanwell informed PAION today that National Medical Products Administration (NMPA) has accepted their New Drug Application (NDA) for remimazolam in procedural sedation for review. The NDA submission triggers a milestone payment of EUR 0.5 million from Yichang Humanwell.

Recently, Yichang Humanwell successfully completed remimazolam clinical development in procedural sedation.

**End of inside information**

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Dr. Wolfgang Söhngen, CEO of PAION AG, commented: *“The acceptance of the NDA submission for review by Chinese regulators is an important achievement on the path to bringing remimazolam to patients. We congratulate our partner Yichang Humanwell on successfully advancing remimazolam to this important stage. We believe that, if approved, remimazolam has the potential to meaningfully improve efficacy and safety in sedation and anesthesia and make an important difference to patients. We look forward to the NMPA decision.”*

The exclusive rights to develop and market remimazolam for the Chinese market were granted to Yichang Humanwell in 2012.

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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 towards year-end 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).

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