



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

**PAION AG: YICHANG HUMANWELL RECEIVES MARKET APPROVAL  
FOR REMIMAZOLAM IN PROCEDURAL SEDATION IN CHINA**

Aachen (Germany), 20 July 2020 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) announces that the National Medical Products Administration (NMPA) in China today published the granting of market approval for remimazolam for use in procedural sedation in China.

**End of inside information**

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*“The third marketing approval of remimazolam and the second in procedural sedation is a major milestone on the path to bringing this novel anesthetic to patients around the world, and we both congratulate Yichang Humanwell on this achievement, and await their confirmation of the marketing approval”, Dr. Jim Phillips, CEO of PAION AG, commented. “We anticipate the roll-out of remimazolam in China still in the second half of 2020.”*

Yichang Humanwell has the exclusive rights to develop and market remimazolam for the Chinese market.

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**About remimazolam**

Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic. In the human body, remimazolam is rapidly metabolized to an inactive metabolite by tissue esterases and is not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation or anesthesia if necessary. In clinical studies, remimazolam demonstrated efficacy and safety in around 2,900 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.

In Japan, licensee Mundipharma received market approval in general anesthesia in January 2020. In the U.S., former licensee Cosmo Pharmaceuticals received market approval in procedural sedation in July 2020. In China, licensee Yichang Humanwell received market approval in procedural sedation in July 2020. In South Korea, licensee Hana Pharm filed for market approval in general anesthesia in December 2019. In Europe, PAION submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in procedural sedation in November 2019

and results of an EU Phase III trial in general anesthesia are expected in the second half of 2020.

In addition to procedural sedation and general anesthesia, based on positive Phase II study results, ICU sedation is another possible indication for remimazolam.

Remimazolam is partnered in the U.S. (brand name BYFAVO™) with Acacia Pharma, in Japan (brand name Anerem®) with Mundipharma, in China with Yichang Humanwell, in Canada with Pharmascience, in Russia/CIS, Turkey and the MENA region with R-Pharm, and in South Korea and Southeast Asia with Hana Pharm. For all other markets including parts of the EU, remimazolam is available for licensing.

### **About PAION**

PAION AG is a publicly listed specialty pharmaceutical company focused on developing and commercializing 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. Remimazolam is partnered in multiple territories outside of Europe. Remimazolam was approved in the U.S. for procedural sedation in July 2020 and was approved in Japan for general anesthesia in January 2020. In China, licensee Yichang Humanwell received market approval in procedural sedation in July 2020 and in South Korea, licensee Hana Pharm filed for market approval for remimazolam in general anesthesia in December 2019.

In Europe, PAION is seeking approval of remimazolam for general anesthesia and for procedural sedation. PAION submitted a Marketing Authorization Application (MAA) for procedural sedation in November 2019. Results of a Phase III trial in general anesthesia are expected in the second half of 2020.

PAION's mission is to be a leading specialty pharmaceutical company in the fields of anesthesia and critical care by bringing novel products to market to benefit patients, doctors & other stakeholders in healthcare.

PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

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