



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

**PAION ANNOUNCES SUBMISSION OF NEW DRUG APPLICATION FOR  
REMIMAZOLAM BY ITS LICENSEE COSMO PHARMACEUTICALS IN THE  
U.S.**

- Third remimazolam marketing application by a licensee

Aachen (Germany), 08 April 2019 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) announces that its U.S. remimazolam licensee Cosmo Pharmaceuticals informed PAION today that Cosmo Pharmaceuticals submitted a New Drug Application (NDA) to the U.S. Food & Drug Administration (FDA) for remimazolam in the indication procedural sedation.

**End of inside information**

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Dr. Wolfgang Söhnngen, CEO of PAION AG, commented: *“We are excited that our licensee Cosmo has achieved this important milestone with remimazolam. With over 20 million gastrointestinal procedures requiring sedation performed in an outpatient setting annually, we believe there is significant market opportunity for remimazolam in the U.S., the world’s largest pharmaceutical market. We look forward to the FDA decision and our joint goal of bringing remimazolam to doctors and patients as quickly as possible.”*

PAION granted Cosmo Pharmaceuticals exclusive rights to develop and market remimazolam for the U.S. market back in 2016.

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**About remimazolam**

Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic that has shown positive results in clinical Phase III trials. 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. During clinical studies, remimazolam demonstrated efficacy and safety with around 2,400 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. The U.S. licensee, Cosmo Pharmaceuticals submitted the new drug application in procedural sedation in the U.S. in April 2019 and is responsible for any further development activities in the U.S. In Japan,

remimazolam licensee Mundipharma filed for market approval in general anesthesia in December 2018. In China, licensee Yichang Humanwell filed for market approval in procedural sedation in November 2018. In Europe, PAION initiated a Phase III study in general anesthesia in July 2018.

In addition to procedural sedation and general anesthesia, based on positive Phase II study results, ICU sedation beyond 24 hours is another possible attractive indication for further development in the EU by PAION as well as by its licensees in other territories.

Remimazolam is partnered in the U.S. (Cosmo Pharmaceuticals), Japan (Mundipharma), China (Yichang Humanwell), Canada (Pharmascience), Russia/CIS (R-Pharm), Turkey and the MENA region (TR-Pharm) and South Korea (Hana Pharm). For all other markets outside the EU, remimazolam is available for licensing.

### **About Cosmo Pharmaceuticals**

Cosmo is a specialty pharmaceutical company that aims to become a global leader in the field of optimized therapies for selected Gastrointestinal Disorders and Endoscopic Procedures. The Company's proprietary clinical development pipeline specifically addresses innovative treatments for IBD, such as Ulcerative Colitis and Crohn's Disease, and Colon Infections. In addition, the Company has developed and launched Eleview, a medical device for polyp and adenoma excision, in the U.S. and it has filed the NDA for Methylene Blue MMX, a diagnostic drug for the detection of lesions during colonoscopy. In addition, new chemical entities are being developed by its associate company Cassiopea S.p.A. for the topical treatment of skin diseases. Cosmo's MMX drugs already on the market are Lialda/Mezavant/Mesavancol, a treatment for IBD that is licensed globally to Giuliani and Shire Limited and Uceris, the first glucocorticosteroid indicated for the induction of remission in active, mild to moderate Ulcerative Colitis, licensed in the U.S. to Santarus/Salix/Valeant and in the rest of the world to Ferring as Cortiment. The FDA has also recently approved Aemcolo, Cosmo's first antibiotic for the treatment of Travelers' Diarrhea. Cosmo's proprietary MMX technology is at the core of the Company's product pipeline and was developed from its expertise in formulating and manufacturing gastrointestinal drugs for international clients at its GMP (Good Manufacturing Practice) facilities in Lainate, Italy. The technology is designed to deliver active ingredients in a targeted manner in the colon. For further information on Cosmo, please visit the Company's website: [www.cosmopharma.com](http://www.cosmopharma.com)

### **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. 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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