PRESS RELEASE

FDA ACCEPTS FILING OF NDA FOR REMIMAZOLAM IN THE U.S.

Aachen (Germany), 10 June 2019 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) announces, that its U.S. remimazolam licensee Cosmo Pharmaceuticals has informed today, that the U.S. Food and Drug Administration (FDA) has accepted the remimazolam New Drug Application (NDA) for review in the indication procedural sedation.

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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 a 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, 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 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. and its local licensee Cosmo Pharmaceuticals submitted a New Drug Application in April 2019. In Japan, licensee Mundipharma filed for market approval for remimazolam in general anesthesia in December 2018. In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018.

In Europe, PAION is currently focused on the development of remimazolam for general anesthesia, but is also evaluating the possibility of submitting a Marketing Authorization Application in procedural sedation based on the U.S. development program.

Development of remimazolam for intensive care unit (ICU) sedation is 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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