AD-HOC ANNOUNCEMENT
INSIDE INFORMATION ACCORDING TO ARTICLE 17 MAR

PAION AG: COSMO ANNOUNCES BRIEF EXTENSION OF FDA REVIEW PERIOD FOR NDA FOR REMIMAZOLAM

Aachen (Germany), 12 March 2020 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) today announces that the U.S. Food and Drug Administration (FDA) has informed Cosmo Pharmaceuticals (Cosmo) about the extension of the review period for the New Drug Application (NDA) for BYFAVO™ (remimazolam) by up to 90 days in order to complete its review of additional data submitted in January and February 2020.

FDA has set a new Prescription Drug User Fee Act (PDUFA) goal of reviewing and acting on the NDA of no later than 5 July 2020 (previous PDUFA target date was 5 April 2020).

End of inside information

###

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 2,500 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., licensee Cosmo Pharmaceuticals submitted a New Drug Application for procedural sedation in April 2019, with a PDUFA decision date of 05 July 2020. In China, licensee Yichang Humanwell filed for market approval in procedural sedation in November 2018. 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 a Phase III trial in general anesthesia is ongoing.

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. (Cosmo Pharmaceuticals, sublicensed to Acacia Pharma), Japan (Mundipharma), China (Yichang Humanwell), Canada (Pharmascience), Russia/CIS, Turkey and the MENA region (R-Pharm) as well as South Korea and Southeast Asia (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. Remimazolam is partnered in multiple territories outside of Europe. In Japan, remimazolam was approved for general anesthesia in January 2020. In the U.S., a New Drug Application (NDA) for procedural sedation is under review, with a PDUFA date of 5 July 2020. In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018 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. A Phase III trial in general anesthesia is ongoing.

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

Disclaimer: