



## CORPORATE NEWS

### **U.S. LICENSE AGREEMENT FOR BYFAVO™ (REMIMAZOLAM) BETWEEN PAION AND COSMO ASSIGNED FROM COSMO TO ACACIA**

Aachen (Germany), 15 July 2020 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) today announces that PAION, U.S. remimazolam licensee Cosmo Pharmaceuticals NV ("Cosmo") and Acacia Pharma ("Acacia") have agreed to assign the BYFAVO™ (remimazolam) license agreement signed in 2016 between Cosmo and PAION to Acacia. The terms of the license agreement remain unchanged but will now be between PAION and Acacia, with Cosmo no longer being a party to the agreement.

**Dr. Jim Phillips, CEO of PAION AG**, commented: *"We are very pleased that we have come to an agreement with Cosmo and Acacia, which will simplify what until now has been a three party relationship, and going forward we can interact directly with the Acacia team to support commercialisation. With the recent market approval of BYFAVO™ in the U.S., we are pleased to now be able to have a direct relationship with the end-commercialization partner. We want to thank Cosmo for their support in the past years and look forward to continuing to work with them as an investor and shareholder."*

*"We are very pleased to have been assigned the U.S. license to BYFAVO™ following its very recent approval by the U.S. Food and Drug Administration and are grateful for all the support provided by Cosmo,"* commented **Mike Bolinder, Acacia Pharma's CEO**. *"This new direct arrangement with PAION will allow us to better collaborate and access their deep expertise on the benefits of BYFAVO™ as we look to begin the commercialization of this important new product for procedural sedation in adult patients, alongside BARHEMSYS®, in the months ahead."*

**Alessandro Della Chà, CEO of Cosmo**, said: *"This assignment is important in order to let Acacia entertain a direct relationship with PAION. We look forward to continue to contribute to the success of BYFAVO™ as shareholders of both Acacia and PAION."*

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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 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 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 filed for market approval 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. 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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