CORPORATE NEWS

PAION ANNOUNCES U.S. FDA APPROVAL OF REMIMAZOLAM (BYFAVO™) FOR THE INDUCTION AND MAINTENANCE OF PROCEDURAL SEDATION

- PAION will receive a milestone payment of EUR 15 million from Cosmo and tiered royalties on net sales ranging from 20% to 25%
- Acacia, who will commercialize BYFAVO™ (remimazolam) in the U.S., is planning to launch in the second half of 2020
- Conference call hosted by Acacia scheduled for 9:00 am ET, Monday 6 July 2020

Aachen (Germany), 02 July 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 approved BYFAVO™ (remimazolam) for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. BYFAVO™ is a very rapid onset/offset intravenous benzodiazepine sedative for use during invasive medical procedures lasting 30 minutes or less, such as colonoscopy and bronchoscopy. Approximately 25 million such procedures take place annually in the U.S., of which ~90% use moderate sedation. Remimazolam is also in development for general anesthesia.

PAION has developed BYFAVO™ including the conduct of three Phase III clinical studies and granted Cosmo Pharmaceuticals NV (Cosmo) exclusive rights to develop and commercialize BYFAVO™ for the U.S. market in 2016. In January 2020, Acacia Pharma sub-licensed the commercial rights to BYFAVO™ in the U.S. from Cosmo.

Under the terms of the agreement with Cosmo, PAION will receive a milestone payment of EUR 15 million from Cosmo and is entitled to tiered royalties on net sales in the U.S. ranging from 20% to 25%, which may be adjusted under certain conditions but cannot fall below 15% of net sales.

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Dr. Jim Phillips, CEO of PAION AG, commented: *The U.S. marketing approval of BYFAVO™ marks the most significant milestone in PAION's history, and I congratulate everyone who has played a role in this important achievement. The U.S. is the world's largest pharmaceutical market, and we are excited to see the product PAION successfully developed being made available to doctors there. We wish Acacia a highly successful market launch in this important market, and we will be supporting their commercialisation efforts. We also look forward to remimazolam being rolled out in other countries around the globe as we and our partners work to gain additional marketing approvals."*

"*We are very pleased to announce today the approval of BYFAVO™ in the U.S. for procedural sedation in adult patients*," commented **Mike Bolinder, Acacia Pharma's CEO**. "*This marks the second FDA approval of an Acacia*

Pharma product since the start of 2020 and another major milestone in our evolution into an integrated hospital pharmaceutical company with strong development and commercialization capabilities. The addition of BYFAVO™ to our product portfolio strengthens our offering to anesthesiologists and enables us to further leverage our commercial infrastructure. I would like to thank our partners at PAION and Cosmo as well as the Acacia Pharma team and our stakeholders who have enabled us to bring this new and innovative therapeutic to market to address the needs of millions of patients each year undergoing procedures that require sedation."

Gerard A. Silvestri, MD, MS, Professor of Medicine at the Medical University of South Carolina, Charleston, SC, and past-president of the American College of Chest Physicians, commented: "*The approval of remimazolam (BYFAVO™) is very exciting for proceduralists as the field has not seen new sedation medications added to our armamentarium in decades. The drug performed very well in clinical trials, with an excellent sedation effect enabling 80-90% of procedures to be completed successfully. The cardio-respiratory safety profile looked very encouraging and there was a rapid return of patients to consciousness enabling them to be discharged in a timely manner*."

"*It is gratifying to see how successfully our new strategy is unfolding. We entered into new partnerships with RedHill Biopharma and Acacia before their own main products were approved by taking substantial equity stakes in these companies and integrating our products Aemcolo® and BYFAVO™ into each so that they could potentially have a more stable and efficient marketing organization. The approval of BYFAVO™ follows the approval of RedHill's Talicia® and Acacia's BARHEMSYS® and is the third FDA approval in nine months for products in companies in which we hold an equity stake. We are now looking forward to Acacia Pharma's transforming BYFAVO into a resounding success,*" said **Alessandro Della Chà, CEO of Cosmo Pharmaceuticals**.

"*BYFAVO™ is an important addition to the limited selection of drugs available for procedural sedation*," said **Acacia Pharma's Chief Medical Officer, Dr. Gabriel Fox**. "*BYFAVO™ demonstrated clear patient benefits in its extensive clinical trial program, offering very rapid onset and offset of action coupled with an incidence of cardio-respiratory and other adverse reactions similar to that seen in patients in the placebo group. We are grateful to all the clinical investigators and patients who made this approval possible through their participation in the development program*."

The safety of BYFAVO™ was evaluated in three pivotal studies in 669 patients undergoing colonoscopy (two studies) or bronchoscopy (one study), of whom 630 received BYFAVO™. In these studies, the most common adverse reactions (incidence greater than 10%) following BYFAVO™ administration were hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, and diastolic hypotension. The labeling for BYFAVO™ includes a Boxed Warning regarding appropriate training of personnel and equipment that must be available when administering BYFAVO™, during sedation and during the recovery period of the procedure. The Boxed Warning also addresses risks from concomitant use of BYFAVO™ with opioid analgesics and other sedative hypnotics.

Acacia Pharma's first product, BARHEMSYS® (amisulpride injection), was approved by the FDA on 26 February 2020 for the treatment and prevention of

postoperative nausea and vomiting (PONV) in adult patients and the company intends to launch both BARHEMSYS® and BYFAVO™ in the U.S. during the second half of 2020.

Conference Call hosted by Acacia Pharma

The Acacia Pharma management team will host a conference call Monday, 6 July 2020, at 9:00 ET.

For further information, please see:

- Press release Acacia Pharma (02 July 2020)

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., 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 Cosmo Pharmaceuticals, sublicensed to 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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