CORPORATE NEWS

PAION STARTS EU PHASE III TRIAL WITH REMIMAZOLAM IN GENERAL ANESTHESIA

- Multicenter, randomized and active-controlled European (EU) Phase III trial in approximately 500 patients undergoing elective surgery
- Evaluation of efficacy and safety, including hemodynamic stability, of remimazolam compared to propofol in general anesthesia
- Patient recruitment expected to be completed in 2019

Aachen, 24 July 2018 – The Specialty Pharma Company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange Prime Standard: PA8) today announces the initiation of an EU Phase III clinical trial with remimazolam, an ultra-short-acting benzodiazepine sedative/anesthetic, for the induction and maintenance of general anesthesia.

The randomized, single-blind, propofol-controlled, confirmatory Phase III trial is expected to enroll approximately 500 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) undergoing non-emergency surgery at more than 20 European trial centers. Patient recruitment is expected to be completed in 2019.

The primary objective of the trial is to demonstrate the non-inferiority of remimazolam compared to propofol for the induction and maintenance of general anesthesia during elective surgery. The key secondary objective is to show improved hemodynamic stability (avoidance of intraoperative drop of blood pressure and vasopressor usage) compared to propofol.

The trial was designed in consultation with EU key opinion leaders in general anesthesia. Based on Scientific Advice obtained from the European Medicines Agency (EMA) in January 2018, PAION expects that a positive Phase III trial in combination with previously completed clinical studies in Europe and Japan should be sufficient for filing for market approval for the indication of general anesthesia in the EU.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: "*The initiation of this Phase III trial is an important milestone for PAION. The aging population is resulting in a growing number of medical interventions with increasing complexity. It is now accepted evidence that significant hypotension during general anesthesia is common and associated with significant sequelae. If remimazolam confirms its benign hemodynamic profile in the Phase III trial, the drug potentially could offer a safer therapeutic alternative to anaesthesiologists and could enhance the quality of life for patients and their families after an intervention. This could also lead to significant cost savings*."

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About remimazolam
Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic that has already shown positive results in clinical Phase III trials. In the human body, remimazolam is rapidly metabolized to an inactive metabolite by tissue esterases and not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation and anesthesia if necessary. During clinical studies, remimazolam demonstrated efficacy and safety in over 1,700 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. Currently, an integrated overall analysis of all clinical studies with remimazolam is being conducted in preparation of Cosmo's filing for market approval. After completion of the development for procedural sedation, Cosmo will be responsible for any further development activities in the U.S. The U.S. license partner currently plans to file for market approval in procedural sedation in the fourth quarter 2018/first quarter 2019. A full clinical development program for general anesthesia was completed in Japan, and the remimazolam license partner for this region, Mundipharma, is planning filing for market approval in this indication in Japan in 2018. In Europe, a Phase III study in general anesthesia was started in July 2018 which can be expected to be the only necessary outstanding trial for filing for market approval in the EU based on the Scientific Advice obtained from the EMA in January 2018.

Based on the positive results of a Phase II study, ICU sedation beyond 24 hours is another possible attractive indication for further development in the EU by PAION as well as by partners in the licensed territories.

Remimazolam is partnered in the U.S., Canada, China, Russia (CIS), Turkey, the MENA region, South Korea and Japan with Cosmo Pharmaceuticals, Pharmascience (Pendopharm), Yichang Humanwell, R-Pharm, TR-Pharm, Hana Pharm, and Mundipharma, respectively. 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 to be used in 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 has so far focused on the development of remimazolam for the indication of general anesthesia. A full clinical development program for general anesthesia was completed in Japan. In the EU, PAION initiated a Phase III trial in July 2018. Development of remimazolam in the indication intensive care unit (ICU) sedation is also part of the longer-term life-cycle plan for remimazolam.

PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

PAION's vision is to become an acknowledged "PAIONeer" in sedation and anesthesia.

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