CORPORATE NEWS

PAION ANNOUNCES SUBMISSION OF THE MARKETING AUTHORIZATION APPLICATION FOR REMIMAZOLAM IN PROCEDURAL SEDATION TO THE EUROPEAN MEDICINES AGENCY

Aachen (Germany), 20 November 2019 – The Specialty Pharma Company PAION AG (FSE: PA8) today announces that a Marketing Authorization Application (MAA) for remimazolam, PAION's ultra-short-acting intravenous benzodiazepine sedative/anesthetic, for procedural sedation has been submitted to the European Medicines Agency (EMA).

The MAA includes the data from a comprehensive U.S. Phase III clinical program in procedural sedation in patients undergoing bronchoscopy or colonoscopy. In a pre-submission meeting with the EMA held earlier this year, the agency indicated that these data would be sufficient for submitting an MAA in procedural sedation. The MAA review process typically takes about one year.

Assuming approval in procedural sedation and positive results in the ongoing EU Phase III trial in general anesthesia, PAION plans to submit an extension of the marketing authorization, a so-called type-II-variation, for remimazolam for general anesthesia in Europe. The review process for an extension is generally significantly faster than for an MAA.

"*The submission of our MAA to the European Medicines Agency represents another significant step towards PAION becoming a focused specialty pharmaceutical company, with our own sales & marketing capabilities*" said Dr. Jim Phillips, CEO of PAION AG. "*PAION and its partners now have multiple applications for Marketing Authorizations underway in all key markets worldwide, and we look forward to working with the EMA during the review process with the goal of bringing remimazolam to the market as quickly as possible.*"

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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 submitted a New Drug Application (NDA) 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 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 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, Turkey and the MENA region (R-Pharm) as well as 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. PAION has completed clinical development for use in procedural sedation in the U.S. and its licensee Cosmo Pharmaceuticals submitted a New Drug Application in April 2019, for which a PDUFA decision date of 05 April 2020 has been set. 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 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.

Development 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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