



Hyloris announces approval of Maxigesic® IV in eight European countries

Commercialization of Hyloris' second marketed product to start in early 2021

Liège, Belgium – 7 September 2020 – Hyloris Pharmaceuticals SA (Euronext Brussels: HYL), an innovative specialty pharmaceutical company focused on adding value to the healthcare system by reformulating well-known pharmaceuticals, today announces the approval of Maxigesic® IV in eight European countries.

Maxigesic® IV¹ is Hyloris' second product to reach the market, after Sotalol IV. Maxigesic® IV is the result of a co-development partnership with AFT Pharmaceuticals ("AFT") of New Zealand, who will launch the product through several distribution and licensing partners.

Through a series of decentralized procedures, which allows a product to be approved in more than one EU member state in parallel, the product is now being rolled out over Europe. The decentralized procedures which in total included 18 countries was concluded positively on the 29th April 2020 and was followed by national license applications. To date, AFT has obtained national Marketing Authorizations in Belgium, Sweden, Hungary, Romania, Croatia, Lithuania, Slovakia and Malta, while the remaining Marketing Authorizations are expected in the upcoming period. The commercialization in these territories is expected to start in early 2021.

Additional procedures have been initiated to obtain approval in further countries within the EU.

Earlier this year, AFT signed an exclusive agreement with two European distributors, Ever Pharma for Germany, France, Italy, Austria and Medochemie for Bulgaria, Cyprus, the Czech Republic, Hungary, Romania and Slovakia.

Maxigesic® IV was launched earlier this year in Australia, New Zealand and the UAE. Hyloris will receive a part of the margin generated in all countries where Maxigesic® IV will be commercialized except Australia and New Zealand.

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: "I'm delighted that AFT has already obtained approval in eight of the first wave of 18 European countries we have targeted for Maxigesic® IV. This milestone is a good foundation as we look to launch commercial activity early next year, and file with the FDA in due course. We are hopeful that Maxigesic® IV might be able to help a wide range of patients, both for the relief of mild to moderate pain, or as a better alternative to opioids for moderate to severe pain."

¹ Maxigesic® IV is a novel combination of paracetamol and ibuprofen in an intravenous form

In July 2020, AFT completed the enrolment of the open-label, multiple-dose, single arm exposure clinical Phase III trial of Maxigesic® IV in 232 patients with acute pain following orthopedic, general or plastic surgery.

The NDA filing of Maxigesic® IV in the US is expected to occur by the end of 2020.

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About Hyloris Pharmaceuticals SA

Based in Liège, Belgium, Hyloris is an early-stage innovative specialty pharmaceutical company focused on adding value to the healthcare system by reformulating well-known pharmaceuticals. Hyloris develops proprietary products it believes offer significant advantages compared to currently available alternatives, with the aim to address the underserved medical needs of patients, hospitals, physicians, payors and other stakeholders in the healthcare system. Hyloris' portfolio spans three areas of focus: IV Cardiovascular, Other Reformulations and Established Market (high-barrier generics). Hyloris currently has two early commercial-stage products, Sotalol IV for the treatment of atrial fibrillation, commercialized through its partner AltaThera, and Maxigesic® IV, a non-opioid analgesic product for the treatment of pain, developed with the Company's partner, AFT Pharmaceuticals. Additionally, Hyloris has 12 product candidates in various stages of development across the Company's wider portfolio. Read more at www.hyloris.com. Hyloris stands for "high yield, lower risk" and relates to the 505(b)(2) regulatory pathway for product approval on which the Issuer focuses, but in no way relates or applies to an investment in the Shares.