



Advicenne receives approval for Marketing Authorization for ADV6209 in Pediatric Moderate Sedation

Nîmes, France, September 12, 2018 (5:45pm CEST) – Advicenne (Euronext: ADVIC), a specialty pharmaceutical company focused on the development of pediatric-friendly therapeutics for the treatment of orphan renal and neurological diseases, announced today that the company has received from European National regulatory authorities the marketing authorization approval for ADV6209 in pediatric moderate sedation, after completing a decentralized procedure. OZALIN® (ADV6209's brand name) is a new liquid solution developed by Advicenne in collaboration with the University Hospital of Amiens (Centre hospitalo-universitaire), France.

OZALIN® is indicated in children from 6 months to 17 years old, for moderate sedation before a therapeutic or diagnostic procedure or as premedication before anesthesia. It is the first oral midazolam liquid solution dedicated to pediatric anesthesiology.

In March 2016, Advicenne licensed the pediatric formulation to Primex Pharmaceuticals Ltd., a specialty pharmaceutical company that supplies high-quality anesthetics to healthcare institutions and professionals. The marketing authorization approval will trigger milestone and royalties payments to Advicenne. The total amount of the transaction could reach several tens of millions in euros.

"ADV6209 is one of the first products we have developed internally," commented Caroline Roussel, co-founder and Chief Operating Officer of Advicenne. "This major achievement illustrates Advicenne's capabilities and know-how in the development of pediatric products. The marketing authorization approval is the reward for years of efforts by our staff and partners."

Kari Sarvanto, Chief Executive Officer of Primex Pharmaceuticals Ltd., commented, "This is an important step for Primex in the area of pediatric anesthesia. The annual sales potential is between 100 million and 350 million euros, but more importantly, we can really elicit a difference for patients. This will pave our way to commercialization for future products in anesthesia and pediatrics."

Dr. Luc André Granier, Chief Executive Officer and Medical Director of Advicenne, added, "OZALIN® addresses an unmet medical need for children. We are proud to provide patients with adapted, efficient and safe products. Our pediatric-friendly approaches are now becoming reality for patients."

About Decentralized Procedure

The decentralized procedure allows a company to apply for a marketing authorization simultaneously in various European countries. It was introduced by Directive 2004/27/EC and is based on recognition by national authorities of a first assessment performed by one Member State. An identical application for marketing authorization is submitted simultaneously to the competent authorities of the Reference Member State and of the Concerned Member States. At the end of the procedure, the terms of the marketing authorization, as proposed by the Reference Member State, are approved in all the concerned countries.

About Advicenne

Advicenne (Euronext: ADVIC) is a specialty pharmaceutical company developing pediatric-friendly therapeutics for the treatment of orphan renal and neurological diseases. The Company's lead product is ADV7103 which has demonstrated positive results in a European pivotal phase 3 study in children and adults with distal Renal Tubular Acidosis (dRTA), is also being developed for a second indication, Cystinuria, an inherited renal tubulopathy.

Advicenne is planning to file ADV7103 for market authorization for dRTA in Europe in H2 2018 and anticipates its commercial launch in 2020 in Europe. In the United States, FDA has cleared its Investigational New Drug (IND) application to initiate a pivotal phase 3 clinical trial assessing ADV7103 in dRTA patients. The commercial launch in the United States is anticipated in 2021.

Advicenne is listed on the regulated market of Euronext in Paris (ISIN: FR0013296746; Euronext ticker: ADVIC). Advicenne, a company established in 2007, has its Headquarters in Nîmes, France.

www.advicenne.com

About Primex Pharmaceuticals Ltd.

Primex Pharmaceuticals aims to become the leading global innovative anesthesia company, and to expand in pediatric pharmaceuticals.

Primex Pharmaceuticals' global partner network operates in over 40 countries. The company is headquartered in Switzerland and all Primex products are manufactured in Europe. Primex Pharmaceuticals has proven underlying business operations and historical strong revenue growth.

www.primexpharma.com

Contacts:

Advicenne

Luc-André Granier, Sarah Delbaere, Julie Rachline
Email: investors@advicenne.com
+33 (0)4 66 05 54 20

Press Relations

Alize RP
Caroline Carmagnol & Tatiana Vieira
advicenne@alizerp.com
+33 (0)1 44 54 36 66

US Investor Relations

Rx Communications Group, LLC
Paula Schwartz
pschwartz@rxir.com
+001 917-322-2216

Financial communication

NewCap
Emmanuel Huynh & Alexia Faure
advicenne@newcap.eu
+33 (0)1 44 71 94 94