PHARMADEV S.A.

Geneva May 16, 2023

RIBAVIRIN

PHARMADEV S.A. is a Swiss company with an affiliate PHARMADEV HEALTHCARE Ltd (Dublin, Ireland) for EU.

Founded in 2007 PHARMADEV develops patented generic plus products to improve their tolerance and efficacy but focus on few products for a better knowledge of their potential.

- Ribavirin, antiviral indicated in Human hepatis C and hemorrhagic fevers. with patented process formulation to improve compliance. PHARMADEV owns Market Authorizations for three (3) strengths i.e. 200, 400 and 600 mg film-coated tablets.

CEO: F. FAURAN Ph.D., MSc.

DIRECTOR: J-L BARNOUX Pharm.D., MSc.

Ribavirin is a guanosine related nucleoside substance with antiviral properties. It is indicated in the treatment of human viral hepatitis C in combination with direct antiviral agents (DAA) and in the treatment and prophylaxis of hemorrhagic fevers.

Ribavirin film-coated tablets manufacture process to improve patient's compliance.

To improve the compliance with treatments that can last months with a posology of 1 to 3 g per day in up to three (3) intakes per day we have developed a manufacturing process patented (WO 2010-058104, FR 293 84 33) which reduces significantly the tablet weight and consequently allows a range of three (3) dosages: 200, 400 and 600 mg of ribavirin film-coated tablets (FCT).

PHARMADEV expertise (10 years manufacturing) and supply (GMP plant in France) are relevant of two different domains:

Human Viral hepatis C

The indication is the treatment of human chronic hepatis C in combination with interferons. Initially the combination was with interferons and from 2015 with direct antivirals agents (DAA). The treatment is in practice restricted to a small number of patients (decompensated cirrhosis and transplantation) consequence of the high-penetration of the new DAA replacing the historical combination of ribavirin with interferons.

The Market Authorizations (MA) was granted in 2010 to IDD (International Drug Development, Paris, France) appointed by PHARMADEV for regulatory purposes for France (MA 200 mg NL38787, MA 400 mg NL38788, MA 600 mg NL38786).

The product was licensed to BIOGARAN, MYLAN and SANOFI (ZENTIVA). In 2015, joined MRP's for MYLAN and IDD (FR/H/0503/001-2-3/MR with FR as RMS) granted MYLAN MAs for FR, BE, NL, CZ and DE and for IDD for FR, IL and DE. The overall supply was done by PHARMADEV from Orleans plant (France).

Treatment and prophylaxis of hemorrhagic fevers

PHARMADEV HEALTHCARE Ltd (Dublin, Ireland) has obtained in 2018 for RIBAVIRIN the status of ORPHAN DRUG (ODD) in the treatment of acute hemorrhagic fevers: Crimean Congo Hemorrhagic Fever (CCHF: EMA 132079/2018) and Lassa Fever (LF: EMA 132080/2018) endemic tropical countries.

The EMA guideline regarding Bioterrorism treatment and prophylaxis with Ribavirin (CPMP/4048/01, rev.6) is consistent with civil and or military protection and constitution of security stock.

An injectable form, currently under development, is more appropriate for an emergency.

Rue du Mont-Blanc 7 - Case Postale 1507 - CH 1211 GENEVA, SWITZERLAND

Tel.: + 41 78 648 43 27 - TVA: CH 660-1100007-7 - RC: CH 660-1100007-7