Press Release
For Immediate Release

Mēdunik Canada

Dedicated to treating rare diseases

MEDUNIK CANADA

is pleased to announce that Health Canada has granted market authorization for Pheburane™

BLAINVILLE, QC (Canada) – January 27th, 2015 – Medunik Canada, a Canadian pharmaceutical company specialized in orphan drugs, is pleased to announce that Health Canada has issued a Notice of Compliance (NOC) for PHEBURANE™ (a tasteless oral formulation of sodium phenylbutyrate), indicated as adjunctive therapy in the chronic management of urea cycle disorders (UCD), involving deficiencies of carbamylphosphate synthetase, ornithine transcarbamylase or argininosuccinate synthetase. Canadians living with a urea cycle disorder will now have access to an approved tasteless medication for the treatment of this metabolic disease.

“We worked very hard to develop a tasteless oral formulation of sodium phenylbutyrate and we are pleased to see that Medunik has succeeded in making Pheburane™ accessible to Canadians in need of this treatment option." said Pierre Mambrini, CEO of Lucane Pharma.

"UCDs are part of the rare disease family and today, I am proud and excited that the few Canadians looking to improve the management of their chronic condition have now access to Pheburane™. We are convinced that this will provide patients and their family with a real benefit.” said Éric Gervais, Executive Vice-President of Medunik Canada.

About PHEBURANE™ and Urea Cycle Disorders (UCD)
Sodium phenylbutyrate is an ammonia scavenger used in the management of UCD. This molecule is particularly distasteful to patients resulting in serious difficulties in compliance with treatment. Methods to improve compliance to treatment may involve reformulation into sweetened suspensions to improve product acceptability, which has a very limited effect, and the invasive administration via nasogastric or gastrostomy tubes. PHEBURANE™’s new formulation of sodium phenylbutyrate totally masks the unpleasant taste of the active substance.

UCDs are caused by a deficiency of one of the enzymes in the urea cycle which is responsible for the removal of ammonia, a potent neurotoxin, from the body. The urea cycle involves a series of biochemical steps in which nitrogen, a waste product of protein metabolism, is removed from the blood and converted to urea which is excreted in the urine. In UCDs, the nitrogen removal is blocked and it accumulates in the form of ammonia. Left untreated, UCDs can cause dangerously increased levels of ammonia in the bloodstream (hyperammonemia) resulting in brain damage, coma and, if untreated, death.

PHEBURANE™, developed by Lucane Pharma is under an exclusive distribution deal in Canada with Medunik Canada. Lucane Pharma was granted a marketing authorisation valid throughout the European Union for PHEBURANE™ in July 2013.

About Medunik Canada
Medunik Canada's vision is to improve the health and quality of life of Canadians living with rare diseases. Medunik Canada was created in December 2009 with the mission to make orphan drugs available to Canadians through turn-key partnerships with international companies interested in making their products available to Canadian patients in need of otherwise unavailable treatments. Medunik Canada's main therapeutic areas among others cover hyperammonaemia due to N-acetylglutamate Synthase (NAGS) deficiency and other urea cycle disorders (UCD). For more information, visit www.medunikcanada.com.

About Lucane Pharma:
Founded in Paris in late 2009 with private financing, Lucane Pharma develops, registers and sells drugs solely dedicated to the management of rare diseases. Over the last 4 years, Lucane Pharma has been successful in developing and registering with the European Union its first products in the area of metabolic diseases and has just been granted (April 2014) by the European Medicines Agency (EMA) a Marketing Authorization for GranuPAS, a drug for the treatment of multi-drug resistant tuberculosis. Several other drugs are at the development stage, mostly in the area of metabolic diseases.

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For information:
Media Relations: Ron Vaillancourt +1 450 433-4441 #280 rvaillancourt@medunikcanada.com
Web Site : www.medunikcanada.com

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