



# PRESS RELEASE

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Contact Galenica Investor Relations: Jörg Kneubühler, CFO Galenica Group, CEO Galenica Santé Galenica Media Relations: Christina Hertig, Head of Corporate Communications, Galenica Group Fresenius Medical Care: Oliver Maier, Head of Investor Relations

Subject Kissei receives Japanese approval for P-TOL<sup>®</sup> (in the USA and Europe commercialized as Velphoro<sup>®</sup>)

Sucroferric oxyhydroxide<sup>®</sup> receives approval by the Ministry of Health, Labour and Welfare in Japan for the treatment of hyperphosphatemia in chronic kidney disease (CKD) patients on dialysis under the name "P-TOL<sup>®</sup>" (in the USA and Europe commercialized as Velphoro<sup>®</sup>)

Kissei Pharmaceutical Co., Ltd. announced that a new drug application for "P-TOL<sup>®</sup> Chewable Tablets 250mg" and "P-TOL<sup>®</sup> Chewable Tablets 500mg" (sucroferric oxyhydroxide) for treatment of hyperphosphatemia has been approved by the Ministry of Health, Labour and Welfare in Japan.

P-TOL<sup>®</sup>/Velphoro<sup>®</sup> (previously known as PA21) is an iron-based, non-calcium-based, chewable phosphate binder. It decreases serum phosphate concentration by binding to phosphoric acid in the gastrointestinal tract and reducing in vivo phosphate absorption. The lowering effects of serum phosphorus concentration and safety at long-term administration of the Agent were confirmed in a phase III clinical study in Japan intended for chronic renal failure patients on hemodialysis with hyperphosphatemia.

Sucroferric oxyhydroxide was developed by Vifor Pharma. In 2011, all rights were transferred to Vifor Fresenius Medical Care Renal Pharma, a common company of Galenica and Fresenius Medical Care. Kissei Pharmaceutical Co., Ltd. holds an exclusive license to develop and commercialize the product in Japan. The active ingredient of Velphoro<sup>®</sup> is produced by Vifor Pharma in Switzerland. Velphoro<sup>®</sup> was approved by the US Food and Drug Administration (FDA) for the control of serum phosphorus levels in patients with CKD on dialysis in November 2013 and has been launched in the US by Fresenius Medical Care North America beginning of 2014. It has received EU marketing authorisation from the European Commission for the control of serum phosphorus levels in adult patients with CKD on haemodialysis or peritoneal dialysis in August 2014. Velphoro<sup>®</sup> is actually commercialized in 13 countries.

# For further information, please contact:

### **Galenica Investor Relations:**

Jörg Kneubühler CFO Galenica Group, CEO Galenica Santé Tel. +41 58 852 85 29 E-mail: investors@galenica.com

# Fresenius Medical Care:

Oliver Maier, Head of Investor Relations Tel. +49 6172 609 2601 E-mail: oliver.maier@fmc-ag.com

Galenica Ltd. P.O. Box · Untermattweg 8 · CH-3001 Bern Phone +41 58 852 85 17 · Fax +41 58 852 85 58 media@galenica.com · www.galenica.com Galenica Media Relations: Christina Hertig Head Corporate Communications Tel. +41 58 852 85 17

E-mail: media@galenica.com

The Galenica Group – excellence in the healthcare market

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> Galenica is a diversified Group active throughout the healthcare market which, among other activities, develops, manufactures and markets pharmaceutical products, runs pharmacies, provides logistical and database services and sets up networks. The Galenica Group enjoys a leading position in all its business sectors – Pharma, Logistics, Retail and HealthCare Information. A large part of the Group's income is generated by international operations. Galenica is listed on the Swiss Stock Exchange (SIX Swiss Exchange, GALN, security number 1,553,646).

For more information, please visit the company's website at www.galenica.com.

Fresenius Medical Care is the world's largest integrated provider of products and services for individuals undergoing dialysis because of chronic kidney failure, a condition that affects more than 2.6 million individuals worldwide. Through its network of 3,396 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatments for 286,768 patients around the globe. Fresenius Medical Care is also the world's leading provider of dialysis products such as hemodialysis machines, dialyzers and related disposable products.

For more information, please visit the company's website at www.fmc-aq.com.

Velphoro<sup>®</sup> is a chewable, iron-based phosphate binder containing a mixture of polynuclear iron (III)oxyhydroxide, sucrose and starches. Each tablet of Velphoro® contains the equivalent of 500mg of iron. When taken with meals, Velphoro<sup>®</sup> adsorbs the dietary phosphate in the gastrointestinal tract and prevents its uptake into the blood. The adsorbed phosphate is subsequently eliminated through the faeces.