

PRESS RELEASE

Date 27 June 2014

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

Subject Velphoro® (PA21) receives Positive CHMP Opinion

Velphoro® (PA21) recommended for approval in the European Union for the treatment of hyperphosphatemia in adult Chronic Kidney Disease patients on dialysis

Velphoro® (sucroferric oxyhydroxide) has received a positive opinion from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recommending marketing authorisation for the 28 EU countries for the control of serum phosphorus levels in adult patients with Chronic Kidney Disease (CKD) on haemodialysis (HD) or peritoneal dialysis (PD). The final decision on the approval by the European Commission is expected in autumn 2014.

Velphoro® (previously known as PA21) is an iron-based, calcium-free, chewable phosphate binder. The CHMP's positive opinion was based on a pivotal Phase III study which met its primary and secondary endpoints. The study demonstrated that Velphoro® successfully controls hyperphosphatemia with fewer pills than sevelamer carbonate, the current standard of care in patients with CKD on dialysis¹. The average daily dose to control hyperphosphatemia was 3.3 pills per day after 52 weeks.

Velphoro® 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. The active ingredient of Velphoro® is produced by Vifor Pharma in Switzerland. Velphoro® 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.

Hyperphosphatemia, an abnormal elevation of phosphorus levels in the blood, is a common and serious condition in CKD patients on dialysis. Most dialysis patients are treated with phosphate binders. However, despite the availability of a number of different phosphate binders, up to 50% of patients – depending on the region – are still unable to achieve and maintain their target serum phosphorus levels². In some patients, non-compliance due to the high pill burden and poor tolerability appear to be key factors in the lack of control of serum phosphorus levels^{3,4}. On average, dialysis patients take approximately 19 pills per day with phosphate binders⁵ comprising approximately 50% of the total daily pill burden. The recommended starting dose of Velphoro® is 3 tablets per day (1 tablet per meal), and Velphoro® could therefore help to improve phosphate management in patients who currently do not comply with treatment due to the high pill burden. Velphoro® is a new therapy with a lower pill burden that could help to improve the outcome of treatment.

For further information, please contact:

Galenica Investor Relations:

Jörg Kneubühler
CFO, Head Investor Relations
Tel. +41 58 852 85 29
E-mail: investors@galenica.com

Galenica Media Relations:

Christina Hertig
Head Corporate Communications
Tel. +41 58 852 85 17
E-mail: media@galenica.com

Fresenius Medical Care:

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

***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 2.3 million individuals worldwide. Through its network of 3,225 dialysis clinics in North America, Europe, Latin America, Asia-Pacific and Africa, Fresenius Medical Care provides dialysis treatments for 265,824 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-ag.com.

***Velphoro® (PA21)** 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® adsorbs the dietary phosphate in the gastrointestinal tract and prevents its uptake into the blood. The adsorbed phosphate is subsequently eliminated through the faeces.*

The Velphoro® Phase II clinical trial met both its primary and secondary endpoints. The serum phosphorus lowering efficacy of the two lowest active doses was numerically comparable to 4.8g/day sevelamer hydrochloride. Velphoro® was also well tolerated, with a comparable overall safety and tolerability profile.

The Phase III trial was an open-label, randomised, active controlled, parallel group study to investigate the safety and efficacy of Velphoro® compared to sevelamer carbonate, followed by a randomized comparison of Velphoro® maintenance dose versus Velphoro® inactive low-dose in dialysis patients with hyperphosphatemia.

Velphoro® is developed in collaboration with Fresenius Medical Care (www.fmc-ag.com). It is also currently undergoing Phase III clinical development in Japan by Kissei Pharmaceutical Co., Ltd.

Date 27 June 2014
Page 3/3
Subject Velphoro® (PA21) Velphoro® (PA21) receives Positive CHMP Opinion

References

1. Floege J et al. *Efficacy and safety of an iron-based phosphate binder, PA21, in hyperphosphatemic CKD patients on dialysis*; Poster SA-PO1103, ASN congress 2012, San Diego.
2. US-DOPPS Practice Monitor, October 2013; <http://www.dopps.org/DPM/>
3. Tonelli M, et al. *Oral Phosphate Binders in Patients with Kidney Failure*; NEJM 2010;362:1312–1324.
4. Wang S et al. *Serum phosphorus levels and pill burden are inversely associated with adherence in patients on hemodialysis*; Nephrol Dial Transplant 2013 Sep 5. [Epub ahead of print]
5. Chiu YW, et al. *Pill Burden, Adherence, Hyperphosphatemia, and Quality of Life in Maintenance Dialysis Patients*; Clin J Am Soc Nephrol 2009;4(6):1089–1096