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## **DIPHARMA and ALVOGEN announce launch of Diterin® 100mg tablets in South Korea**

***First drug now registered and commercially available in the Republic of South Korea for the treatment of Hyperphenylalaninemia (HPA) due to Phenylketonuria (PKU).***

**Chiasso, Switzerland and Seoul, South Korea, February 3<sup>rd</sup>, 2017** – Dipharma S.A. and Alvogen today announced that the pharmaceutical product Diterin® (Sapropterin Dihydrochloride 100mg tablets), indicated for the treatment of hyperphenylalaninemia (HPA) due to phenylketonuria (PKU), is now commercially available in the Republic of South Korea.

Diterin® is the only drug approved in South Korea by the Korean Ministry of Food and Drug Safety for the treatment of HPA due to PKU, a rare genetic disease leading to an abnormally high concentration of phenylalanine (Phe) in the blood, which can cause brain damage to people affected by it.

*“We are happy to provide Diterin® to the South Korean market, as this treatment can make a difference in the management of Phe levels for many patients suffering from lifelong PKU, contributing to prevent the appearance of potential transient to non-reversible mental impairment”* said Peter Vazharov, Alvogen S&M VP, Asia Pacific together with Marc-Olivier Geinoz, CEO of Dipharma S.A., who added: *“As part of Dipharma’s mission, we will continue to expand our portfolio of high-quality products - including Diterin® - to offer improved solutions to each and every patient suffering from inborn errors of metabolism all around the world”*.

Dipharma S.A. also confirms that patents and patents applications were filed protecting Diterin® and its active pharmaceutical ingredient - Sapropterin Dihydrochloride - in many countries of the world, including South Korea.

This commercial launch is resulting from an exclusive collaboration agreement between Dipharma S.A. and Alvogen, under which Alvogen owns the exclusive rights to commercialize Diterin® 100mg tablets in the Korean market. Dipharma S.A. is currently working to make Diterin® available in all the countries worldwide.

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### **About Diterin®**

Diterin® (Sapropterin Dihydrochloride) is a synthetic copy of the naturally occurring co-factor tetrahydrobiopterin (BH<sub>4</sub>) that works in conjunction with the enzyme phenylalanine hydroxylase (PAH) to metabolize the amino acid phenylalanine (Phe).

Diterin® is the first generic oral drug for the treatment of hyperphenylalaninemia (HPA) due to phenylketonuria (PKU) in patients of all age who have shown to be responsive to BH<sub>4</sub>. If left untreated, the disease leads to abnormally high levels of Phe in the blood, which can result in permanent neurological disorders in paediatric patients and cognitive deficits and psychiatric disorders in adults. By offering the body a synthetic copy of BH<sub>4</sub>, Diterin® works as a complement to a low-Phe diet, to help keep the level of Phe low in the body, and to preserve the brain from damage. Diterin® was developed by Dipharma S.A., Switzerland. Diterin® is a trademark owned by Dipharma S.A.

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## **About Dipharma**

Dipharma S.A. is a Swiss pharmaceutical company specialized in developing high quality, improved, medicines for rare diseases. Dipharma S.A. is part of a third generation group of family companies grown to a global presence.

With a portfolio of products for the treatment of Phenylketonuria, Gaucher Disease, Niemann Pick Type C, Hereditary Tyrosinemia Type 1, Urea Cycle Disorders and others, Dipharma SA works every day to provide improved solutions for people affected by inborn metabolic diseases at an affordable cost and with a global reach.

For more information, please visit [www.dipharma.ch](http://www.dipharma.ch)

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## **About Alvogen**

Alvogen is a global, privately owned pharmaceutical company focused on developing, manufacturing and selling generic, brands, over-the-counter brands (OTC) and biosimilar products for patients around the world.

The company has commercial operations in 35 countries with 2,300 employees and operates four manufacturing and development hubs in the US, Romania, Korea and Taiwan. North America is Alvogen's single largest market and other key markets include: South Korea, West Balkan, Poland, Romania, Bulgaria, Hungary, Taiwan, Thailand, Ukraine, Russia, Japan and China.

For more information, please visit [www.alvogen.com](http://www.alvogen.com)

## **About Alvogen Korea**

As of June 2015, Kunwha Pharmaceuticals and Dream Pharma started a new journey as one entity under the name of Alvogen Korea through the integration of the two trusted company: on one side Kunwha, a company with over 50-year-old tradition, focused on therapeutic drugs in nephrology, urology, and anti-infective, and on the other side Dream Pharma, which was a front runner in Korean anti-obesity market through the development of incrementally modified drugs for treatment of chronic diseases. Alvogen Korea maximizes each of the companies' strengths, becoming one of the strongest and most reliable pharmaceutical companies in the industry.

For more information, please visit [www.alvogenkorea.com](http://www.alvogenkorea.com)

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### **DISCLAIMER**

*This press release may contain certain forward-looking statements. Although the Company believes its expectations are based on reasonable assumptions, these forward-looking statements are subject to numerous risks and uncertainties, including scientific, business, economic and financial factors, which could cause actual results to differ materially from those anticipated in the forward-looking statements. The company assumes no responsibility to update forward-looking statements or adapt them to future events or developments.*

*Dipharma S.A. operates respectfully of any third party IP rights and/or regulatory exclusivities that may exist in each specific country.*

*This press release may contain information on pharmaceuticals that are not approved in your country or region.*