

## **Almirall launches Efficib<sup>®</sup> in Spain, a combination product of sitagliptin and metformin intended for the treatment of type 2 diabetes mellitus**

- **Efficib<sup>®</sup> is indicated for type 2 diabetes patients when diet and physical exercise, and the administration of metformin in monotherapy, do not adequately control blood glucose levels.**
- **The combination of sitagliptin and metformin in a single tablet has not been associated with weight gain or the risk of hypoglycemia, unlike metformin by itself.**
- **Incorporating Efficib<sup>®</sup> into its product portfolio enables Almirall to offer a new medicine for glycemic control.**

**Barcelona, 5 May 2009.-** Almirall, the international company based in Spain, launches in its home country Efficib<sup>®</sup> (sitagliptin and metformin combination in a single tablet) for the treatment of type 2 diabetes. The launch forms part of the co-marketing agreement signed with Merck Sharp & Dohme (MSD), by virtue of which MSD grants Almirall marketing rights of sitagliptin in Spain under the trademark Tesavel<sup>®</sup>, which has been on the market since December 2008, as well as the combination of sitagliptin and metformin under the trademark Efficib<sup>®</sup>.

Efficib<sup>®</sup> is indicated as an adjunct to diet and exercise to improve glycemic control in patients inadequately controlled on metformin alone<sup>1</sup> or those already being treated with the combination of sitagliptin and metformin. Efficib<sup>®</sup> is also indicated in combination with a sulphonylurea<sup>1</sup> (i.e., triple combination therapy) as an adjunct to diet and exercise in patients inadequately controlled on their maximal tolerated dose of metformin and a sulphonylurea.

The combination of sitagliptin and metformin in a single tablet does not have weight gain association or risk of hypoglycemia, unlike metformin by itself. It targets the three main defects of type 2 diabetes: lack of insulin production by pancreatic beta cells, insulin resistance and excess of hepatic glucose production.

One notable advantage of this new presentation is the presumed improvement of compliance by use of two antidiabetic agents in one tablet to improve glycemic control.

Efficib<sup>®</sup> combines in a single tablet 50 mg of sitagliptin, the first dipeptidyl peptidase-IV inhibitor marketed in Spain, and 1000 mg of metformin. With the incorporation of Efficib<sup>®</sup> in its product portfolio Almirall offers a combination product of oral blood glucose-lowering drugs, with complementary mechanism of action to improve glycaemic control. In reference to the launch, Enrique Domínguez, Almirall's General Manager Spain, says: "We are pleased to be incorporating Efficib<sup>®</sup> into our portfolio as this new product will greatly benefit many type 2 diabetes patients by enabling them to control their glucose levels more efficiently and easily".

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<sup>1</sup> Efficib<sup>®</sup> *patient* information leaflet

## Incidence of type 2 diabetes

Type 2 diabetes is the most common form of diabetes, occurring in 80-90% of cases of the disease. Current forecasts estimate that in 2025 there will be 380 million<sup>2</sup> people affected by diabetes around the world, making it one of the biggest pandemics that society will have to face in the 21st century.

Inappropriate control of the disease can lead to serious cardiovascular risks and complications such as stroke, heart or kidney disease and blindness amongst others.<sup>3</sup> At the moment over half type 2 diabetes patients already on treatment do not achieve target glycemic control figures.<sup>4</sup>

For Almirall the diabetes field is one of its most recent areas of growth. Enrique Domínguez adds *"the launch of Efficib<sup>®</sup> reinforces our commitment to the fight against this disease"*.

## Efficib<sup>®</sup>: new diabetes treatment

The combination of sitagliptin and metformin in a single tablet has been approved by the European Medicines Agency (EMA) since 21 July 2008 and adopted by the 27 European Union Member States, and Norway and Iceland. In Spain, the combination has been commercialised since 18 November 2008 by MSD under the trademark Janumet<sup>®</sup>.

Sitagliptin's clinical development programme, which also covers the combination with metformin, is backed by 55 studies involving around 12.000 patients. Sitagliptin also has two years' clinical experience and over 10 million prescriptions globally, along with 2.5 million prescriptions of the sitagliptin and metformin combination.

## About Almirall

Almirall is an international pharmaceutical company based on innovation and committed to health. Headquartered in Barcelona, Spain, it researches, develops, manufactures and commercialises its own R&D and licensed drugs with the aim of improving people's health and wellbeing.

The therapeutic areas on which Almirall focuses its research resources are related to the treatment of asthma, COPD (Chronic Obstructive Pulmonary Disease), rheumatoid arthritis, multiple sclerosis, psoriasis and dermatology in general.

Almirall's products are currently present in over 70 countries while it has direct presence in Europe and Latin America through 11 affiliates.

For further information please visit the website at: [www.almirall.com](http://www.almirall.com)

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<sup>2</sup>Diabetes Atlas Third Edition, International Diabetes Federation 2007. IDF. [http://www.eatlas.idf.org/index.asp?doc\\_id=II008416161510](http://www.eatlas.idf.org/index.asp?doc_id=II008416161510), (consulted 24 April 2009)

<sup>3</sup> Fact sheet 312 of the WHO. November 2008. Diabetes.

<sup>4</sup> Liebel, A., Mata, M., Eschwège, E., *Evaluation of risk factors for development of complications in type 2 diabetes in Europe*. Diabetology. 2002; 45(7):s23-s28

## More information: Ketchum/SEIS

Sonia San Segundo/Victorino Ballesteros  
sonia.sansegundo@ketchum.com  
Tel.: 00 34 91 788 32 00