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Eucreas[®], a single-tablet combination of Galvus[®] and metformin, recommended for EU approval for type 2 diabetes

- *Following approval, Eucreas will be first single-tablet combination of a DPP-4 inhibitor and metformin in EU*
- *Recommended approval based on additional robust reduction in blood sugar when Galvus added to metformin*
- *Galvus when added to metformin is well tolerated with no weight gain and low incidence of hypoglycemia*

Basel, September 21, 2007 – Novartis has received a positive opinion recommending European Union approval for Eucreas[®], an oral tablet combining Galvus[®] (vildagliptin) and metformin, as a new treatment for patients with type 2 diabetes. Following approval, Eucreas will be the first single-tablet combination of a DPP-4 inhibitor and metformin approved in the EU.

The positive opinion for Eucreas was issued by the Committee for Medicinal Products for Human Use (CHMP), which reviews medicines for the European Commission (EC). The Commission generally follows the CHMP's recommendations and is expected to issue a decision within three months.

The recommendation was based on data showing additional robust reductions in blood sugar when Galvus, a member of a new class of diabetes medicines called DPP-4 inhibitors, was added to metformin – one of the most prescribed oral anti-diabetes therapies. In clinical studies, Galvus administered in combination with metformin resulted in additional blood sugar reductions of 1.1% as measured by HbA1c¹, the gold standard measure of blood sugar control².

Importantly for patients, Galvus, when added to metformin, is also well tolerated. In clinical trials, the addition of Galvus to metformin provided robust blood sugar control without weight gain and with fewer hypoglycemia side effects (i.e. dangerously low blood sugar)³ than other type 2 diabetes medicines such as sulfonylureas or thiazolidinediones.

“The anticipated European approvals of Eucreas and Galvus will allow us to offer new treatment options to patients with type 2 diabetes and to help them gain better blood sugar control,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “With a significant proportion of type 2 diabetics still not reaching their blood sugar goals, Eucreas and Galvus have the potential to help millions of patients, and we are committed to making these treatments available as soon as possible.”

Galvus received a positive opinion from the CHMP in July 2007 recommending European approval as an add-on to the most common oral anti-diabetes medicines, with the broadest range of indications for any drug in the DPP-4 class.

Eucreas has been recommended for use in type 2 diabetes patients who are inadequately controlled with metformin alone or are being treated with Galvus and metformin as separate tablets. Eucreas is recommended for use twice-daily at a dose of either 50 mg Galvus/850 mg metformin or 50 mg Galvus/1000 mg metformin.

“With Eucreas, patients who are not reaching their blood sugar goals on metformin alone will have an effective and well tolerated treatment option to gain better blood sugar control,” said Prof Emanuele Bosi, Director of the Diabetes & Endocrinology Unit at San Raffaele University Hospital in Milan, Italy.

Prof Bosi added: “In clinical studies, Galvus added to metformin demonstrates additional significant blood sugar reductions and is well tolerated. The combination of Galvus and metformin does not cause weight gain and has a low incidence of hypoglycemia, the two most common side effects of current treatments for patients with type 2 diabetes.”

Data presented earlier this week at the European Association for the Study of Diabetes (EASD) congress demonstrated that patients inadequately controlled on metformin are four times more likely to achieve blood sugar control with the addition of Galvus compared to placebo (or sugar pill)⁴.

A study of 544 patients with type 2 diabetes who were inadequately controlled on metformin showed that 35.5% achieved glycemic control (HbA1c < 7.0%) when Galvus was added to metformin, compared to 9.4% of those receiving metformin with placebo⁴. The American Diabetes Association recommends an HbA1c of less than 7.0% to minimize risk of complications in type 2 diabetes patients².

Eucreas combines two agents to provide robust blood sugar control by increasing insulin, decreasing glucagon and targeting insulin resistance. Galvus works through a novel mechanism of action by targeting the dysfunction in the pancreatic islets that causes high blood sugar levels in people with type 2 diabetes. Metformin works mainly by decreasing the production of sugar by the liver and increasing insulin sensitivity. In Eucreas, Galvus and metformin work to restore the natural function of the body in controlling blood sugar.

In clinical trials, Galvus demonstrated an overall incidence of side effects similar to placebo. The most common side effects seen in the Galvus clinical program were stuffy nose, headaches, dizziness and upper respiratory tract infection.

Type 2 diabetes is a progressive disease in which control of blood sugar deteriorates over time. If left untreated or not kept under control, it can lead to heart and kidney disease, blindness, and vascular or neurological problems⁵. Studies show that more than half of those currently taking medication to manage their condition are still not reaching their blood glucose goals⁶. Due to the progressive worsening of blood sugar control during the natural course of type 2 diabetes, combination therapy usually becomes necessary⁷.

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Novartis Media Relations

John Gilardi
Novartis Global Media Relations
+41 61 324 3018 (direct)
+41 79 596 14008 (mobile)
john.gilardi@novartis.com

Navjot Rai
Novartis Pharma Communications
+41 61 324 6498 (direct)
+41 79 777 6400 (mobile)
navjot.rai@novartis.com

e-mail: media.relations@novartis.com

Novartis Investor Relations

International
Ruth Metzler-Arnold
Katharina Ambuehl
Nafida Bendali
Pierre-Michel Bringer
Jason Hannon
Thomas Hungerbuehler
Richard Jarvis

North America
Ronen Tamir +1 212 830 2433
Jill Pozarek +1 212 830 2445
Edwin Valeriano +1 212 830 2456

Central phone no: +41 61 324 7944
e-mail: investor.relations@novartis.com

e-mail: investor.relations@novartis.com