Januvia at a glance

- Januvia (sitagliptin) was the first DPP-4 (dipeptidyl peptidase-4) inhibitor to be launched in the UK in 2007.
- Taken orally, Januvia was the first once daily DPP-4 inhibitor, and currently offers the broadest range of indications of all licensed DPP-4 inhibitors in the UK. The European Medicines Agency has accepted Januvia for restricted first line use when diet and exercise alone do not provide adequate glycaemic control and when metformin is inappropriate due to contraindications or intolerance. Januvia is the only diabetes treatment in the DPP-4 inhibitor class to have a restricted first line indication.

- Januvia, an incretin enhancer, is licensed for add-on treatment of type 2 diabetes in patients on metformin, a sulphonylurea or a glitazone (as ‘dual therapy’), or for patients on metformin and sulphonylurea, or metformin and glitazone combinations, (as ‘triple therapy’) who need additional glycaemic control. Januvia is the only DPP-4 inhibitor currently approved for ‘triple therapy’ in the European Union (EU). In October 2008, the Scottish Medicines Consortium (SMC) accepted Januvia for use within NHS Scotland for ‘dual’ and ‘triple’ therapy, as above.

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JANUVIA TIMELINE: MILESTONES AT A GLANCE

September 2009 – Over 250,000 prescriptions in the UK
Januvia has received over a quarter of a million prescriptions in the UK since its launch in April 2007.

July 2009 – Approval in 86 countries
Januvia has received approval in 86 countries and is available in every region around the world.

8 June 2009 – Januvia shown to have a broad range of use and efficacy in the longer term (ADA)
Over ten posters presented on Januvia at the ADA congress, show a broad range of uses for the DPP-4 inhibitor as well as providing confirmation of its longer term efficacy (either alone or in combination with metformin over two years) for the treatment of type 2 diabetes. Januvia was shown to offer significant blood sugar lowering efficacy in combination with insulin.

June 2009 – Januvia accepted for triple therapy in combination with a PPARγ agonist (e.g. a TZD) and metformin
European Commission approval of Januvia for use in triple combination with a PPARγ agonist (i.e. a thiazolidinedione (TZD)) and metformin, when diet and exercise plus dual therapy with these agents do not provide adequate glycaemic control.

27 May 2009 – NICE publish new guideline on the use of newer agents for blood glucose control in type 2 diabetes
The guideline recommends that two medicines in the DPP-4 inhibitor class, including Januvia, should be considered as a second-line therapy instead of a sulphonylurea (SU) when blood glucose control remains or becomes inadequate with metformin (Hba1c ≥ 6.5% or other higher level agreed with the individual) in patients at significant risk of hypoglycaemia or its consequences, or if a person does not tolerate SUs or SUs are contraindicated. In addition, it recognises the role of Januvia as the only DPP-4 inhibitor licensed for use in triple therapy with metformin and SU where metformin and an SU do not adequately control blood sugar, and insulin is considered inappropriate or unacceptable to the patient.

December 2008 – Launch of Januvia CV outcomes study
Clinical trial (TECOS) launched to determine the CV outcomes of Januvia versus placebo. The first patient was enrolled in December 2008, and 14,000 patients will be recruited for the study which is estimated to take two years.

1 December 2008 – Januvia data in elderly patients
Januvia is shown to significantly reduce blood sugar levels in elderly patients with type 2 diabetes, with a low incidence of hypoglycaemia, according to new data presented at the Annual Scientific Meeting of the Gerontological Society of America.
October 2008 – Expert consensus statement on use of newer agents (Diabetes & Primary Care)
A consensus paper developed by lead diabetes experts on the use of newer antihyperglycaemic agents in the type 2 diabetes treatment pathway was published. It concluded that the DPP-4 inhibitors and GLP-1 analogues have a number of benefits, notably related to the low incidence of hypoglycaemia and low risk of weight gain.11

9 September 2008 - Two year data, Januvia initial combination with metformin (EASD)
Data presented at the EASD congress demonstrated that combination therapy with Januvia and metformin provided substantial and durable improvements in blood sugar levels (as measured by HbA1c) over two years and was generally well tolerated.13

24 September 2008 – Prix Galien UK Award
Januvia awarded ‘highly commended’ in the UK Prix Galien awards.

11 June 2008 – Januvia shown to have a 93% lower risk of hypoglycaemia than glipizide (ADA)
Data presented at the ADA congress demonstrated that Januvia was associated with a 93% lower risk of symptomatic hypoglycaemia compared to glipizide in combination with metformin in patients with type 2 diabetes.12

May 2008 – DPP-4 inhibitors named medicines of notable public-health interest
The European Medicines Agency (EMEA) annual report listed DPP-4 inhibitors, including Januvia, as medicines of “notable public-health interest”.

January 2008 – Tolerability and efficacy data for Januvia added to metformin v placebo (CMRO)
When added to ongoing metformin therapy, Januvia (100mg) once daily was shown to be well-tolerated and resulted in significant glycaemic improvement in patients with moderately severe type 2 diabetes (HbA1c ≥ 8.0% and ≤11.0%) according to data published in Current Medical Research and Opinion. Compared with placebo, Januvia showed a significant net reduction in HbA1c of 1.0% when measured at 18 weeks – with 22% of patients treated with Januvia achieving an HbA1c of <7.0% by the end of the study versus 3.3% in the placebo group. Januvia was found to be well tolerated with a neutral effect on body weight and no significant increase in risk of hypoglycaemia and

21 January 2008 – CHMP positive opinion for two additional uses of Januvia
The CHMP gave a positive opinion to extend the indication for Januvia to include, add-on therapy to a sulphonylurea (‘dual therapy’), or a sulphonylurea plus metformin (‘triple therapy’).

8 October 2007 – SMC accepts Januvia for restricted use within NHS Scotland
Januvia accepted for restricted use within NHS Scotland for treatment of patients with type 2 diabetes mellitus, to improve glycaemic control. Recommended for use in combination with metformin when diet and exercise, plus metformin, do not provide adequate glycaemic control. It should be used in patients when the addition of sulfonylureas is not appropriate, and represents an alternative to other agents such as thiazolidinediones.

18 September 2007 – One year data, Januvia initial combination with metformin (EASD)
Data presented at the EASD congress, demonstrated that initial combination therapy with Januvia and metformin provides significant and sustained improvement in blood sugar control compared to metformin alone, over a one-year period. When used in combination in healthy adults, the different mechanisms of action of Januvia and metformin had a complementary effect on glucagon-like peptide-1 (GLP-1) levels, a hormone that is an important regulator of blood sugar levels.16

4 December 2007 – Scrip Award
Januvia shortlisted in the ‘Best New Drug’ category.

October 2007 – First two million prescriptions
First two million Januvia prescriptions issued to patients with type 2 diabetes globally.5

20 April 2007 – Januvia launched in the UK
Januvia, the first DPP-4 inhibitor is launched in UK in tablet form for treatment of patients with type 2 diabetes mellitus, to improve glycaemic control. Januvia was the first once daily DPP-4 inhibitor available in the UK.

References