

## Mundipharma Announces Launch of **INVOKANA**<sup>®</sup> and **VOKANAMET**<sup>®</sup> in Norway for the Treatment of Type 2 Diabetes as Part of Exclusive Distribution Agreement with Janssen

- **Invokana**<sup>®</sup> and **Vokanamet**<sup>®</sup> are now available across the whole of Scandinavia, and in a total of 18 markets across Europe
- There is a significant patient need for new and effective diabetes treatment options, as the number of people with the condition in Europe is predicted to rise to 67 million by 2045<sup>1</sup>
- Janssen has a partnership with the Mundipharma global network of associate companies, who are the exclusive distributor for both **Invokana**<sup>®</sup> and **Vokanamet**<sup>®</sup> in countries in the European Economic Area (EEA) and Switzerland where the products currently have Pricing and Reimbursement status. This is with the exception of Spain, where the product is co-promoted by both Janssen and Mundipharma

**CAMBRIDGE, UK: 19.03.19** – The Mundipharma network of independent associated companies is pleased to launch the type-2 diabetes mellitus (T2DM) treatments **Invokana**<sup>®</sup> (canagliflozin) and **Vokanamet**<sup>®</sup> (canagliflozin, metformin) in Norway. In line with the partnership with Janssen Pharmaceutica NV, Mundipharma now exclusively distributes and markets these treatments across 18 countries in the European Economic Area (EEA) and Switzerland. With the launch in Norway, **Invokana** and **Vokanamet** are now available across the whole of Scandinavia, following the launches in Sweden and Denmark.

**Invokana**, a once-daily oral tablet, is part of the sodium glucose co-transporter 2 (SGLT2) inhibitor class and has been approved in the European Union since 2013.<sup>2</sup> **Vokanamet** combines two oral glucose-lowering medicinal products (canagliflozin and metformin) with different and complementary mechanisms of action.<sup>3</sup>

*“We are delighted to extend our European footprint for **Invokana** and **Vokanamet** to provide healthcare professionals in Norway with two new treatment options to manage type 2 diabetes,”* said Dr Vinicius Gomes de Lima, European Medical Affairs Lead. *“Type 2 diabetes is a growing epidemic in Europe and effective*

*treatments are needed to help reduce the burden of the disease in patients. **Invokana** and **Vokanamet** have shown improvement in glycaemic control and reduction of cardiovascular morbidity and mortality as well as improvements in renal outcomes which is of real importance in this disease.”*

Approximately 58 million people in Europe currently live with T2DM, which is set to rise to 67 million by 2045.<sup>1</sup> If left untreated, patients are at greater risk of developing serious complications, such as cardiovascular (CV) disease and kidney failure.<sup>4</sup>

Last year, the European Medicines Agency (EMA) approved label updates for **Invokana** and **Vokanamet** to include data on the reduction in major adverse CV events in patients with T2DM who had either a history of CV disease or at least two CV risk factors.<sup>5</sup> The label update was supported by the results from the CANVAS clinical trial, the largest completed CV outcomes trial to date for an SGLT2 inhibitor.<sup>6</sup> The American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) also issued a Consensus Report in October 2018 which recommends SGLT2 inhibitors with a proven CV benefit as the preferred oral treatment after metformin for T2DM patients with chronic kidney disease (CKD) or clinical heart failure and atherosclerotic CV disease.<sup>7</sup>

New data for canagliflozin from the CREDENCE study will be presented at the upcoming World Congress of Nephrology during the late-breaking abstract session on Monday 15<sup>th</sup> April. The study evaluated the effect of canagliflozin on renal protection in patients with T2DM and CKD.

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## **Notes to the editors:**

### **About INVOKANA®**

**Invokana®** (canagliflozin) is an oral, once-daily medication which belongs to a new class of medications called sodium glucose co-transporter 2 (SGLT2) inhibitors. SGLT2 inhibitors work by inhibiting SGLT2, which promotes the loss of glucose via the urine, lowering blood glucose levels in adults with type 2 diabetes. Canagliflozin was approved in the European Union by the European Commission in November 2013. **Invokana®** is indicated for the treatment of adults with insufficiently controlled T2DM as an adjunct to diet and exercise, as monotherapy when metformin is considered inappropriate due to intolerance or contraindications and in addition to other medicinal products for the treatment of diabetes. Approval was based on a comprehensive global Phase III clinical trial programme.<sup>2</sup>

## **About VOKANAMET®**

**Vokanamet®** (a fixed-dose combination of canagliflozin and metformin) is approved in the European Union for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise. **Vokanamet®** combines two oral glucose-lowering medicinal products with different and complementary mechanisms of action.<sup>3</sup>

## **About the Mundipharma network**

Mundipharma is a global network of privately-owned independent associated companies whose purpose is to move medicine forward.

With a high performing and learning organization that strives for innovation and commercial excellence through partnerships, we successfully transformed and diversified our European portfolio of medicines to create value for patients, payers and wider healthcare systems across important therapeutic areas such as Diabetes, Respiratory, Oncology, Pain and Biosimilars.

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## **References**

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<sup>2</sup> INVOKANA SmPC. Available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/002649/WC500156456.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002649/WC500156456.pdf) Last accessed February 2019.

<sup>3</sup> VOKANAMET SmPC. Available at: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/EPAR\\_-\\_Product\\_Information/human/002656/WC500166670.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/002656/WC500166670.pdf) Last accessed February 2019.

<sup>4</sup> Update to International Diabetes Federation, 2016, Complications of Diabetes [Online] Available at: <https://www.idf.org/aboutdiabetes/what-is-diabetes/complications.html> Last accessed February 2019.

<sup>5</sup> INVOKANA Label. Available at: <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/INVOKANA-pi.pdf> Last accessed February 2019.

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<sup>6</sup> Neal B et al. Canagliflozin and Cardiovascular and Renal Events in Type 2 Diabetes. *The New England Journal of Medicine* (2017);377:644-657

<sup>7</sup> Davies, M.J. et al. Management of hyperglycemia in type 2 diabetes, 2018. A consensus report by the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD). *Diabetes Care* (2018) Dec; 41(12):2669-2701