Mundipharma announces exclusive distribution agreement with Janssen for two primary care diabetes treatments Invokana® (canagliflozin) and Vokanamet® (canagliflozin / metformin) for selected European countries

- Agreement builds on existing alliance with Janssen and successful co-promotion of Invokana® by Mundipharma network's UK entity, Napp Pharmaceuticals Limited
- Significant patient need for treatment options with diabetes prevalence predicted to rise to 71 million by 2040[1]
- Reinforces Mundipharma's commitment to alliances and flexibility in diversifying into new therapy areas to maximise in-market expertise in primary and specialty care

4th September 2017 – The Mundipharma network of independent associated companies has entered into an exclusive distribution agreement with Janssen Pharmaceutica NV for primary care type 2 diabetes medicines Invokana® (canagliflozin) and Vokanamet® (a fixed-dose combination therapy of canagliflozin and metformin). The agreement includes all countries in the European Economic Area (EEA) and Switzerland where the products have obtained price and reimbursement approvals.

Invokana (canagliflozin) is a member of a novel class of drugs known as sodium glucose co-transporter 2 (SGLT2) inhibitors and was first approved in the European Union in November 2013. Canagliflozin is indicated for the treatment of adult patients with type 2 diabetes, to improve glycaemic control, where diet and exercise do not provide adequate glycaemic control either as monotherapy (when the use of metformin is contra-indicated or not suitable) or as add-on therapy. [2]

Vokanamet (a fixed-dose combination of canagliflozin and metformin) is approved in the European Union to improve glycaemic control of adult patients with type 2 diabetes, and combines two oral glucose-lowering medicinal products with different and complementary mechanisms of action. [3]

Under the distribution agreement, the responsibility for the sale, marketing and promotion of both products will transfer to Mundipharma in 14 of the 17 European markets where Janssen has already secured reimbursement, with the additional three to be included in the coming months. If Janssen obtains pricing and reimbursement for the Products in other countries, Mundipharma may elect to have such countries added to the Agreement. Janssen's affiliate, Janssen-Cilag International NV, remains Marketing Authorisation Holder (MAH) in the concerned countries (except that Janssen-Cilag AG remains MAH for Switzerland). Janssen maintains manufacturing responsibilities and will continue to be responsible for certain regulatory activities including pharmacovigilance and Marketing Authorisation updates in close collaboration with Mundipharma.

Following the successful co-promotion of Invokana with Janssen in the UK, Alberto Martinez, European Director of Commercial Operations, Mundipharma commented, "*We're excited to expand*

our alliance with Janssen, and further grow our specialist driven Primary care portfolio across Europe using our established pan-European salesforce, to help bring these important treatment options to patients.

"Through a successful diversification from our heritage in pain, Mundipharma has established a proven commercial capability across multiple therapy areas in primary care, specialty care and biosimilars. Thanks to our European reach, strong commercial focus and local in-market expertise, Mundipharma is a highly attractive proposition to potential partners and we envisage increased expansion over the next decade by seeking further alliances, with companies with innovative primary care medicines being key to that growth."

Notes to editors:

The European Economic Area (EEA) countries, as well as Switzerland, where Invokana (canagliflozin) and Vokanamet (a fixed-dose combination of canagliflozin & metformin) currently have pricing and reimbursement approvals are: UK, Ireland, Belgium, Bulgaria, the Netherlands, Luxemburg, Denmark, Sweden, Italy, Austria, the Czech Republic, Poland, and Slovakia.

More EEA countries may be added to the territory covered by this exclusive distribution agreement pending termination of other existing distribution agreements such as in Greece, Malta and Cyprus or after gaining Pricing and Reimbursement Approvals.

About canagliflozin

In 2013, Invokana (canagliflozin) was approved in the European Union for the treatment of adults with type 2 diabetes mellitus (T2DM), to improve glycaemic control either as a monotherapy or add-on therapy. The European approval of canagliflozin was based on a comprehensive global Phase 3 clinical trial Programme, which enrolled 10,285 patients in nine studies. [2,3,4,5,6,7,8,9,10,11,12]

Invokana (canagliflozin) is a prescription medicine used along with diet and exercise to lower blood sugar in adults with type 2 diabetes. Invokana is not for people with type 1 diabetes or with diabetic ketoacidosis (increased ketones indicated in blood or urine). It is not known if Invokana is safe and effective in children under 18 years of age. Canagliflozin does not have an indication for CV risk reduction.

About the Mundipharma network

The Mundipharma global network of privately-owned independent associated companies was founded in 1956 by doctors, and now operates in over 120 countries worldwide. We are focused on developing business partnerships to identify and accelerate meaningful technology across an increasingly diverse portfolio of therapy areas including respiratory, oncology, pain, and biosimilars. Consistent with our entrepreneurial heritage, we like to think we see what others don't by challenging conventional wisdom and asking different and challenging questions. By working collaboratively with all our stakeholders, the Mundipharma network develops medicines that create value for patients, payers and wider healthcare systems.

For more information, please visit: www.mundipharma.com.

For further information, please contact:

Mundipharma:
communications@mundipharma.com
T: +44 (0)1223 397 162

Hanover:

Sarah Ghabina
sghabina@hanovercomms.com
T: +44 7870 367 309
Fiona Dennehy
fdennehy@hanovercomms.com
T: +44 (0)20 3817 6616

References:

[1]IDF Diabetes Atlas – Seventh edition. http://www.diabetesatlas.org/ Last accessed August 2017.

[2] Invokana SmPC. Available at: http://ec.europa.eu/health/documents/community-register/2017/20170428137649/anx_137649_en.pdf Last accessed August 2017.

[3] Vokanamet SmPC. Available at: http://www.ema.europa.eu/docs/en_GB/document_library/Referrals_document/SGLT2_inhibitors_Canagliflozin_20/European_Commission_final_decision/WC500227133.pdf Last accessed August 2017.

[4] Lavalle-González FJ et al. Efficacy and safety of canagliflozin compared with placebo and sitagliptin in patients with type 2 diabetes on background metformin monotherapy: a randomised trial. Diabetologia. 2013;56(12):2582-92

[5] Schernthaner G et al. Canagliflozin compared with sitagliptin for patients with type 2 diabetes who do not have adequate glycemic control with metformin plus sulfonylurea: a 52-week randomized trial. Diabetes Care. 2013; 36(9):2508-15

[6] Cefalu WT et al. Efficacy and safety of canagliflozin versus glimepiride in patients with type 2 diabetes inadequately controlled with metformin (CANTATA-SU): 52 week results from a randomised, double-blind, phase 3 non-inferiority trial. Lancet. 2013; 382(9896):941-50.

[7] Bode B et al. Efficacy and safety of canagliflozin treatment in older subjects with type 2 diabetes mellitus: a randomized trial. Hosp Pract. 2013;41(2):72-84.

[8] Yale JF et al. Efficacy and safety of canagliflozin in subjects with type 2 diabetes and chronic kidney disease. Diabetes Obes Metab. 2013;15(5):463-73.

[9] Neal B, Perkovic V, et al. (2013). Rationale, design, and baseline characteristics of the Canagliflozin Cardiovascular Assessment Study (CANVAS)—A randomized placebo controlled trial. American Heart Journal; 166(2): 217-223

[10] Stenlof et al. Efficacy and safety of canagliflozin monotherapy in subjects with type 2 diabetes mellitus inadequately controlled with diet and exercise. Diabetes Obes Metab. 2013;15(4):372-82.

[11] Wilding JP et al. Efficacy and safety of canagliflozin in patients with type 2 diabetes mellitus inadequately controlled with metformin and sulphonylurea: a randomised trial. Int J Clin Pract. 2013;67(12):1267-82

[12] Forst T et al. Efficacy and Safety of Canagliflozin in subjects with Type 2 Diabetes on Metformin and Pioglitazone. Poster presented at the 4th World Congress on Controversies to Consensus in Diabetes, Obesity and Hypertension (CODHy), 2012;Nov.8-11; Barcelona, Spain, (P64).