Animas® Vibe™ Insulin Pump and Dexcom G4™ PLATINUM CGM System is Now Approved for Children with Type 1 Diabetes

The only CGM-enabled insulin pump with the latest Dexcom sensing technology, is now available for use in children as young as 2 years old

High Wycombe, UK, 06 March 2014: Animas Corporation today announced CE Mark approval of the Animas® Vibe™ insulin pump and Dexcom G4™ PLATINUM CGM system for children, aged 2-17, with type 1 diabetes in the UK & Ireland.

Animas® Vibe™ is a continuous glucose monitoring (CGM)-enabled insulin pump, integrated with the Dexcom G4™ PLATINUM sensor, the latest and most advanced technology available from Dexcom. The sensor is approved for up to 7 days of wear.

Animas® Vibe™ displays glucose trends in colour and is waterproof*, allowing children more freedom for sports and playtime activities and for uninterrupted insulin delivery. Animas® Vibe™ also delivers precise dosing to help meet children’s changing needs. The Dexcom G4™ PLATINUM introducer needle is the smallest available in comparison to Medtronic Enlite and Abbott Navigator.†

Expanding the global presence of Animas® Vibe™ has been a top priority for Animas, and today marks the first time the full system is available for children to help manage their diabetes.

Key Facts:

- Animas Corporation announced CE Mark approval of Animas® Vibe™ insulin pump and Dexcom G4™ PLATINUM CGM system for children, ages 2-17, with type 1 diabetes.
- Animas® Vibe™ features a high-contrast colour screen, featuring colour-coded trend lines and arrows to indicate direction and rate of glucose change, revealing trends at a glance.
- Animas® Vibe™ has customisable low and high alerts.
- For extra peace of mind, there is also a non-adjustable hypoglycaemia alert at 3.1mmol/L.
- Animas® Vibe™ insulin pump delivers precise insulin dosing, with a basal rate as low as 0.025 U/hr and bolus as low as 0.05 units to help meet children’s insulin needs.
- Dexcom G4™ PLATINUM CGM is the only sensor approved for up to 7 days of wear.
- The Animas® Vibe™ System consists of the Animas® Vibe™ Insulin Pump paired with the Dexcom G4™ PLATINUM Sensor and Transmitter.

Quotes:

Juan Toro, Vice President, Animas Corporation, said: “The paediatric approval of Animas® Vibe™ with CGM sensing technology in the UK and Ireland marks a significant milestone for children living with type 1 diabetes. By bringing together the unique features of the Animas insulin pump with the benefit of Dexcom CGM technology, we are proud to further support children in managing their diabetes and performing at their best in all aspects of life.”

Dr. Brian Levy, Chief Medical Officer, Animas Corporation, said: “Clinical studies have shown that patients who use CGM experience significant improvement in blood glucose control1,2. Through this paediatric approval, Animas® Vibe™ is now able to provide a new option for young patients looking for an insulin delivery system with CGM capabilities.”

Dr. Fiona Campbell, Consultant Paediatrician and Diabetologist at St. James's University Hospital, Leeds, said: “Type 1 diabetes is a challenging disease to manage, especially in...
growing children. Activities as simple as going to school, visiting a friend’s house for dinner or partaking in sports and exercise are heavily influenced by the need for stable glucose levels. The addition of the CGM to the Animas® Vibe™ insulin pump is a great step forward in helping children in the UK take ownership of their diabetes – we know that effective glucose management early in life supports better health outcomes in adulthood."

Clinical studies\(^1,2,3\) have shown that people with type 1 diabetes who use CGM therapy to help manage their disease often experience significant improvements in glucose control. Furthermore, those who use insulin pump therapy in combination with CGM obtain lower HbA1c levels relative to baseline and relative to patients who use multiple daily injections and self-monitoring of blood glucose.

ENDS

Notes to Editors

About the Animas® Vibe™ Dexcom G4™ CGM technology

- The system consists of the Animas® Vibe™ insulin pump paired with the Dexcom G4™ PLATINUM sensor and transmitter; it is intended for single patient use in persons with diabetes. Dexcom CGM is the only sensor approved for up to seven days of wear.
- The Animas® Vibe™ insulin pump is indicated for continuous subcutaneous insulin infusion for the management of insulin-requiring diabetes in adult and paediatric patients. It is intended to accept and display data from the glucose sensor.
- The system is also a glucose-monitoring device indicated for detecting trends and tracking patterns in persons (age 2 and older) with diabetes. The system is intended for use by patients at home and in healthcare facilities.

About Animas Corporation

Animas® is dedicated to creating a world without limits for people with diabetes through a wide range of products, including Animas® Vibe™, the OneTouch® Ping® Glucose Management System, and the Animas® 2020 insulin pump\(^2\). Animas, from the Latin word meaning “true inner self or soul,” has been committed since 1996 to meeting individual patient needs through the development of life-performance technology and customer service 24 hours a day, 7 days a week, 365 days a year. To learn more about Animas, visit http://www.animascorp.co.uk/

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\* The Animas insulin pump is waterproof up to 3.6 metres for 24 hours. The Dexcom G4® PLATINUM Transmitter is water-resistant up to 8 feet (2.4 metres) for 24 hours. CGM readings may not be captured when the pump or transmitter is immersed in water.

\(†\) Measured as the cross-sectional areas of the introducer needle.

\(‡\) Not all products are available in all countries.

2. Effectiveness of Continuous Glucose Monitoring in a Clinical Care Environment, Evidence from the JDRF-CGM Trial. Diabetes Care, Vol 33, Number 1, Jan 2010.