



FOR IMMEDIATE RELEASE

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**FDA Approves Animas® Vibe® Insulin Pump and Continuous Glucose Monitoring System
For Use in Children**

*Insulin Pump System Offers Children Ages Two and Older an Integrated Solution for
Diabetes Management*

CHESTERBROOK, Pennsylvania, January 11, 2016 – Animas Corporation announced that FDA has approved the use of the Animas® Vibe® Insulin Pump and Continuous Glucose Monitoring (CGM) System for the management of diabetes in children and adolescents, ages two to 17. The Animas® Vibe® System was the first integrated system featuring Dexcom G4® PLATINUM CGM technology, and is the only such system available in the U.S. for pediatric patients as young as age two. The Animas® Vibe® System allows patients and their caregivers to view glucose data and administer insulin right from the pump, making it easy to fine tune insulin delivery to help manage their diabetes.

“CGM-enabled systems, like the Animas® Vibe® System, provide patients with a more complete glucose picture, which is acutely important for children since they might not always be aware of the symptoms associated with high or low blood sugars,” said Dr. Brian Levy, Chief Medical Officer, Animas. “The approval of the pediatric indication for Animas® Vibe® System enables parents and caregivers to both deliver insulin precisely, and monitor glucose trends accurately in children as young as age two with one integrated device.”

The value of insulin pump therapy has been demonstrated in numerous clinical studies, showing significant improvement in blood glucose control when compared to multiple daily injections. Furthermore, studies have shown that patients who used insulin pump therapy in combination with CGM obtained lower HbA1c levels, relative to patients who used multiple daily injections and self-monitoring of blood glucose.^{1,2} This greater insight into blood glucose trends helps children with Type 1 diabetes and their parents to make more informed decisions about their insulin needs.

In addition to the inclusion of CGM, the Animas® Vibe® System offers a unique combination of features including:

- **Fine-tuned insulin delivery** – Equipped with a Swiss-made motor, the Animas® Vibe® Insulin Pump offers as low a basal increment as 0.025 U/hr across all available ranges (0.025 U/hr to 25.00 U/hr) and a low bolus increment of 0.05 U across all available bolus ranges (0.05 U to 35.00 U) to adjust and deliver precise increments of insulin, which is acutely important to children and teens given their higher insulin sensitivities.
- **Waterproof durability** – The only CGM-enabled pump that is waterproof to 12 feet for up to 24 hours; Dexcom G4® PLATINUM Sensor and Transmitter are water resistant up to eight feet for 24 hours. (CGM readings may not be transmitted from the CGM to the pump while in water.) This allows children to live their lives as they want, not as their diabetes dictates.



- **Customizable Alerts** – Customizable alarms to indicate high and low glucose levels. There is also a built-in, non-adjustable hypo safety alert set at 55 mg/dL, that may provide extra peace of mind to both parents and the patients themselves.
- **CGM in full color** – The first CGM-enabled pump with a high-contrast color screen with color-coded trend arrows to show where glucose is heading and how fast, revealing the latest glucose values and trends at a glance.
- **An accurate, longest-wear sensor** – With Mean ARD (Absolute Relative Difference) as the industry standard for measuring CGM accuracy, the Dexcom G4[®] PLATINUM Sensor 13-percent Mean ARD provides exceptional performance and accuracy for reliable results. Dexcom sensors are the only sensors approved for up to seven days of wear.
- **One of the smallest introducer needles** – The Dexcom G4[®] PLATINUM Sensor is tiny, round and flexible with one of the smallest introducer needles available.

“It’s been our goal as a company to not only develop the best treatment solutions available, but also ensure that every member of the diabetes community, including children, may access these tools,” said John Wilson, Worldwide Vice President of Insulin Delivery, Animas. “We’re thrilled that the FDA approval of this new indication for the Animas[®] Vibe[®] System for the first time now allows children as young as age two access to a CGM-enabled pump.”

Expanding the global presence of the Animas[®] Vibe[®] System, along with providing solutions for children with diabetes and their parents, has been a top priority for Animas. The Animas[®] Vibe[®] System is also currently available to children ages two and older in parts of Europe, Australia, New Zealand, and Canada.

Orders for the Animas[®] Vibe[®] System are currently being accepted, with anticipated shipment to patients beginning this month. For more information, visit www.animas.com.

¹ Bergenstal et al, Effectiveness of Sensor-Augmented Insulin Pump Therapy in Type 1 Diabetes. *The New England Journal of Medicine*. 2010; 363(4):311-320.

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.

Important Safety Information

The Animas[®] Vibe[®] Insulin Pump and CGM System is intended for the delivery of insulin and for continuous glucose monitoring (CGM) for the management of insulin-requiring diabetes. The Animas[®] Vibe[®] System’s CGM, which includes the Dexcom G4[®] PLATINUM Sensor and Transmitter, is indicated for detecting trends and tracking patterns in persons age 2 and older. The system is intended for single patient use and requires a prescription.

Contraindications: Insulin pump therapy is not recommended for people unwilling or unable to test their blood glucose four to six times per day, unwilling or unable to see their healthcare professional regularly, or whose vision or hearing does not allow recognition of pump alerts, warnings, and alarms. The Animas[®] Vibe[®] Insulin Pump must be removed before MRI or CT scan, and the Dexcom G4[®] PLATINUM Sensor and Transmitter must be removed before MRI, CT scan, or diathermy treatment.



Taking acetaminophen-containing medications while wearing the sensor may falsely raise sensor glucose readings.

Warnings: Connecting to the pump before receiving the necessary training could result in serious injury or death. Younger children may inadvertently press the pump buttons and deliver insulin, which can lead to hypoglycemic events. Caregivers are responsible for helping to ensure safe and effective delivery of insulin to people in their care, including using the safety features on the Animas® Vibe® System to help prevent injury. CGM glucose readings are not to be used to make treatment decisions. The sensor and transmitter do not replace a blood glucose meter. The sensor and transmitter are not to be used during pregnancy or while on dialysis. Sensor placement is only approved for sites under the skin of the belly (abdomen) in adults and the belly or upper buttocks for ages 2 to 17 (pediatrics). Patients should seek professional medical help if a sensor breaks and no portion of it is visible above the skin, or if there is infection or inflammation. Any broken sensors or adverse events should be reported to Customer Service. Contact Customer Service at 1-877-937-7867 or visit www.animas.com/safety for detailed indications for use and safety information.

About Animas

With a shared vision of “creating a world without limits” for people with diabetes, Animas Corporation is a part of the Johnson & Johnson Diabetes Care Companies (JJDC), a cross-company collaboration that reflects an ongoing commitment to better serve the diabetes community with integrated solutions that meet the needs of people with diabetes across the continuum of care. JJDC includes LifeScan, Inc., a world leader in blood glucose monitoring; Calibra Medical, Inc. developer of a unique 3-day wearable insulin patch, and Animas Corporation, which provides a wide range of insulin delivery products for people living with diabetes, including the Animas® Vibe® insulin pump and CGM system and the OneTouch® Ping® Glucose Management System. . 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 www.animas.com.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the approval of a new indication for the Animas® Vibe® Insulin Pump and Continuous Glucose Monitoring (CGM) System. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Animas Corporation and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; manufacturing difficulties and delays; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Johnson & Johnson’s Annual Report on Form 10-K for the fiscal year ended December 28, 2014, including in Exhibit 99 thereto, and the company’s subsequent filings with the Securities and Exchange Commission. Copies of these filings



are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither Animas Corporation nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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