Debiotech has introduced, for the first time worldwide, its New JewelPUMP platform for Diabetes Therapy at EASD 2012 in Berlin, Germany.

Lausanne, Switzerland, October 11, 2012. The JewelPUMP, which was revealed for the first time at the ADA 2010 congress in Orlando, is the center of a lot of attention and expectations from Diabetic patients worldwide.

During the EASD in Berlin, DEBIOTECH presented the result of two years of intensive work aimed at addressing patient needs and regulatory requirements for a product platform that goes beyond any competitive offering today.
Based on an ultra-miniaturized and highly precise MEMS pump chip technology, developed and manufactured in partnership with ST Microelectronics, the JewelPUMP is addressing still unmet needs for diabetic patients.

"The JewelPUMP is the result of a tremendous effort to bring the best of what advanced technology can offer for the benefit of the patient, while complying with newly established regulatory requirements for insulin pumps," says Frédéric Neftel, MD, President and CEO of DEBIOTECH SA. "We not only wanted to make the pump really small, extremely safe and accurate, we also wanted to make it really convenient to use while being concealed and so discreet that you would forget you are under pump therapy. The results we had the pleasure to present at the EASD are aligned with those objectives thanks to an entirely new integrated platform of products intended to fulfill diabetic patients needs and the latest regulatory requirements. The comments and encouragements we received from the large number of visitors we welcomed in our booth in Berlin are certainly the greatest reward our engineers and technicians could get for their intense work and commitment to diabetes care."
"The JewelPUMP is far more than just a patch-pump. It is a miniaturized and very slim insulin delivery system, weighing only 25 grams and holding up to 500 Units of insulin, more than any insulin pump had ever been able to accommodate. As a result, the patient can use his JewelPUMP for an entire 7 day period without any refill or replacement needed." says Stephane Proennecke, PhD, JewelPUMP Project Leader at DEBIOTECH. "The JewelPUMP is attachable to an auto-inserted cannula patch, from which it can be detached and re-attached at will, the cannula patch being replaced every 3 days without having to change or refill the pump, thereby offering more freedom to the patient. The JewelPUMP is directly programmed from a large display remote controller, that we wanted to also become a telephone and a BGM reader. Therefore we had to develop our own medical device, the JewelCOM, which is a state-of-the-art PDA-Phone, works on an open Android OS, includes a slot for the patient's SIM card as well as a BGM reader for a new highly precise glucostrip, the JewelSTRIP, matching the latest accuracy standards. In order to increase the security level, we added an extra SIM card to the phone, for the JewelCARD, which makes each patient's JewelCOM remote controller specific to his personal JewelPUMP with a patient specific communication protocol. This makes the JewelPUMP the most secure remotely controlled medical device ever conceived."
"The JewelPUMP also has two secured bolus buttons, in case you would have forgotten your remote controller, so that you can program and deliver a bolus at any moment in time," says Severin Leven, PhD, Head of the JewelPUMP Electronic team at DEBIOTECH SA. "As soon as your JewelPUMP gets within reach of the JewelCOM again, the amount of insulin injected will be automatically added to your history and taken into account. We also wanted to bring the best of electronics to the JewelPUMP and have therefore made the control module a re-usable part to be attached to the single-use pump-reservoir module. This makes the system more environmentally friendly and helps reduce overall cost. The communication between the JewelPUMP and the JewelCOM is using the new Bluetooth low energy mode and, thanks to the MEMS pump-chip, the JewelPUMP can operate for 7 days on a single green battery (mercury and lithium free). We have even incorporated a temperature sensor into the JewelPUMP to inform the patient in case the insulin would be over-exposed to heat. Last but not least, we have added a sensor to automatically detect any disconnection of the JewelPUMP from the cannula patch to automatically suspend the insulin delivery until it is reattached. In short, we have tried to make sure everything that can be done to increase safety and ease-of-use will be part of your JewelPUMP experience."

"The design of the JewelPUMP has been a real challenge, given the number of functionalities we wanted to incorporate while keeping everything in a patch size," says Olivier Magnenat, Head of the JewelPUMP Mechanical Construction group at DEBIOTECH. "At the same time, we wanted to ensure that every step of using the JewelPUMP would be intuitive, convenient and safe. The result, as came out of our patient studies, is in conformity with our objectives with every step of using the JewelPUMP being natural and associated to a feeling of security. We were even able to incorporate a vibrator alarm inside the patch-pump, to keep alarms extremely discreet, only to be noticed by the patient himself. We also accommodated an air filter inside the reservoir to prevent any air-bubble from passing through the pump. Of course the JewelPUMP is also waterproof for bathing and swimming."
"We also worked a lot on the interface of the JewelCOM, to make it really easy to use," says Pascal Bauermeister, Head of the Software Engineering team at DEBIOTECH. "By using intuitive icons and navigation on a large multicolor touchscreen
interface, we wanted to reduce the risk of use errors and simplify the learning process, while making it really a pleasure to use. We also integrated the requirements set by a number of diabetic patients and experts from different countries who helped us develop the JewelPUMP. As such, you can program your bolus (simple, dual or extended), taking into account your Insulin on Board, but also calculate your insulin needs based on either your carbs, portions or food intake, with an insulin sensitivity that can be varied according to different periods of the day. You can adapt your basal profile according to your exercise, review your BG measurements over one or several days or weeks, see your BG statistics, as well as history of events, personalize various alarm settings, as well as setting periods where you don't want to be disturbed, all directly on your JewelCOM. Of course your BGM being now also part of your JewelCOM, it makes it easy to calculate your insulin needs and program your bolus, while only using one single Phone-PDA-BGM-remote device. Finally, in the presence of others the JewelCOM always looks like being your phone, so that you can entirely control your JewelPUMP without anyone else noticing."

"Another important aspect for the patient is the way we can make him have access to all the information needed to comply with his therapy over time, thanks to the JewelCARE software," says Konstantinos Sfyrikis, PhD, JewelCARE Software Engineer at DEBIOTECH. "We wanted to offer a software that would enable him, but also the Healthcare Practitioner, to easily follow all important parameters his therapy over time. This includes visual indicators, statistics and diagrams that are useful to immediately visualize a patient's conditions and trends. It will help adjusting the therapy without unnecessary delays. For the Practitioner, the JewelCARE software also makes it possible to follow multiple patients and
receive messages whenever conditions require his immediate attention. In the future, the JewelCARE will be able to receive all of the JewelPUMP information via the JewelCLOUD in real time, thanks to the JewelCOM telephone capability."

"We wanted the JewelPUMP to be the safest insulin pump," says Eric Chappel, PhD, MEMS Project Leader at DEBIOTECH."The use of a MEMS pump-chip enables to deliver every single 0.02 Units of insulin within 5% accuracy and this independently of external conditions. This represents instantaneous and basal deliveries that are far more constant than any existing system today. In addition, we have incorporated a functional sensor inside the MEMS pump-chip which provides a signal that is analyzed by the electronics of the JewelPUMP and helps detect and discriminate any possible failure almost instantaneously. As an example, the JewelPUMP will detect an occlusion on the cannula during a basal rate in a few minutes, where other pumps would need several hours. The same sensor is also used to test every single JewelPUMP during production and ensures the delivery to the patient of a fully functional and accurate JewelPUMP disposable module, something which has never been possible at this level on disposable medical pumps."
“All this has been made possible thanks to the intensive collaboration between Debiotech and ST Microelectronics” adds Gian-Luca Lettieri, PhD, Production Manager at DEBIOTECH. “By combining our design with ST’s extensive manufacturing experience, we are able to offer a high performance and affordable commercial product”.

"The JewelPUMP has been successfully used on 35 diabetic patients, as part of a multi-center study in combination with the Dexcom continuous glucose monitor, for the development of new algorithms for a closed-loop system", says Ary Saaman, Director of Regulatory Affairs at DEBIOTECH. "The purpose is for us to prepare the future and be able to incorporate such newly developed very precise algorithms into a later generation of the JewelPUMP to move diabetes therapy into a new era. Knowing how much time will be needed before such a system can be approved for use, it is our responsibility to work on it already from today."
"We know how many expectations the JewelPUMP has created. Unfortunately we cannot give any precise date regarding its market launch at this stage, but we are actively working to complete the necessary work in order to submit files to the regulatory agencies, in Europe as well as in the US," says Laurent-Dominique Piveteau, PhD, Director of Business Development at DEBIOTECH. "As everyone knows, this requires extensive clinical trials and product validation that we are preparing very seriously. We are also working in parallel on a partnership with medical device companies who will be responsible for the marketing and sales activities, while ensuring the quality of service and support diabetic patients deserve. Be assured that DEBIOTECH is highly committed to making the JewelPUMP available to all diabetic patients worldwide, with the continuous support of numerous diabetes patients and diabetologists."

More information is available at:

[www.jewelpump.com](http://www.jewelpump.com)

_JewelPUMP™ is currently under final stage development. It is not yet CE Marked and has not yet been submitted for 510k clearance._

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