

## **Sucessful pre-clinical trial results for the Allevetix system which is intended to treat type-2 Diabetes and Obesity**

**The system approaches a huge market estimated to reach \$2.3 billion by 2018**

**Main goals achieved in the large animal trials:**

- **Proof of effective and safe implantation and explantation**
- **Significant reduction in caloric absorption**
- **The implanted sleeve remained in its intended position throughtout the entire follow-up period proving the soltion's safety and effectiveness**

**Israel, Caesarea, December 18, 2016 – Allium Medical (Tel-Aviv – ALMD) – Israeli medical devices company**, specializing in minimally-invasive solutions, announced the successful completion of the pre-clinical trial phase in large animals with its Allevetix system. The unique solution is designed to significantly reduce the absorption of sugars and fats through a system that includes an implanted sleeve in the small intestine that is anchored in the stomach. The system creates an effective barrier between the chyme (consisting of gastric juices and partly digested food) that passes from the stomach to the small intestine and the absorbing tissue of the upper segment of the small intestine.

The pre-clinical trial included the implantation of the system in 20 pigs, where several criteria were tested during the implantation period, including:

the safety and efficacy of the endoscopic implantation and explantation of the implant, the safety and efficacy of the anchoring mecahnism, and the system's ability to substantially reduce the caloric absorption.

The development project is supported (45%) by the Singapore-Israel Industrial R&D Foundation (SIIRD), and is performed in technological, clinical, regulatory and commercial collaboration between the company and the National University of Singapore (NUS). In

the upcoming months, the SIIRD will conduct an audit to verify the compliance with the criteria for the successful completion of the development phase and the pre-clinical trials. In light of the successful big animal trial results, the company expects successful audit results. Furthermore, the company is planning to submit in the coming months a summary financial report in order to obtain the remaining balance of the non-dilutive grant in the amount of \$250,000.

Following the successful animal trials, the company is planning to initiate its First in Man clinical trial towards the end of 2017, subject to obtaining all the required regulatory approvals.

**Asaf Alperovitz, CEO of Allium:** “The successful trial constitute an important and promising milestone for us. Our unique solution may become an efficient, safe and reversible alternative to the gastric bypass surgery. The sleeve was easily introduced into the intestine in a simple endoscopic procedure, distinguishing it from the prevalent alternative today which is an irreversible bariatric surgery, that frequently involves significant complications and a high recurrence rate. At the end of the follow up period, the sleeve was smoothly and safely extracted. Consequently, we intend to initiate First in Human trials already in 2017, subject to obtaining of all the required regulatory authorizations.”

“The American Diabetes Association<sup>1</sup> recently reported new guidelines, which advocate the consideration of bariatric surgery as a treatment option for diabetic patients with a BMI index < 35 (moderate obesity). This is contrary to previous guidelines whereby the procedure was recommended only to patients with a BMI index > 35. Therefore, we believe that the potential market for the Allevetix system will grow substantially, even beyond the estimated \$2.3 billion in 2018. The Allevetix system will provide a safe, efficient and reversible alternative to bariatric surgery, that is currently recommended for the treatment of diabetes, even in patients who suffer from moderate obesity.”

---

<sup>1</sup> <http://care.diabetesjournals.org/content/39/6/924>

“The development and commercialization project follows Allium’s strategy of focusing on minimally-invasive medical solutions using novel technologies while, appealing to rapidly growing markets. We believe that there is a substantial economic potential and great value to our shareholders in this project,” concluded Alperovitz.

**Dr. Dean Keren, leading gastroenterologist** from the Bnai Zion Medical Center, Haifa, Israel who led the animal trials: “Obesity is recognized as a global epidemic. Today approximately 2 billion people in the world suffer from overweight, and it is expected to reach 2.7 billion by the year 2025. In an effort to manage the disease, apart from the pharmaceutical treatment that does not treat the direct causes of diabetes, there is the option of invasive surgery. In spite of its proven efficacy, surgical intervention in the treatment of obesity is performed only in a small percentage of patients. In many cases, surgical intervention in such patients is problematic due to their poor physical state resulting from a combination of obesity and diabetes. Additionally, there are concerns regarding the performance of surgical procedures due to related complications and relatively high rates of recurrence. Therefore, there is a significant unmet need in the market to transition from invasive procedures to safe and simple endoscopic treatments with minimal side-effects.”

“I expect impressive results with a dramatic effect on sugar levels to be demonstrated in the planned humans trial with the Allevetix system. Unlike the surgical procedure, the Allevetix treatment does not alter the anatomy of the digestive system, and several weeks after its implantation, it would present a significant decrease in blood sugar level (HbA1c). It is important to note that the endoscopic treatment with the system will be safe and efficient and enable a simple extraction of the system at any given time. In my assessment, the system has a huge potential to become a safe, effective and reversible alternative to surgery with an appeal to an even greater number of patients including at-surgical-risk patients.”

### **Target markets – obesity and type-2 diabetes:**

Over 320 million people around the world suffer from type-2 diabetes associated with obesity. The medical costs attributable to obesity in the US alone are estimated at \$147 billion annually<sup>2</sup>. The global bariatric surgery devices market was valued at \$1.2 billion in 2011 and is expected to grow at a CAGR of 9.7% to reach \$2.3 billion in 2018<sup>3</sup>. Owing to the unique properties of the system (especially, its reversibility, minimally invasive, efficacy and safety) and in light of the new guidelines reported recently by the American Diabetes Association for the treatment of diabetes, growth potential in this market could be even higher.

### **About Allevetix:**

The Allevetix system, which is presently in advanced development stages, is designed to significantly reduce the sugar absorption in the blood by the isolation of the chyme (digested food) from the nutrient absorption mechanism. This is accomplished by a unique sleeve, the GDS (Gastro Duodenal Sleeve) that is attached to the wall of the small intestine and anchored in the stomach using the novel and innovative Anchoring mechanism.

The system combines two principle mechanisms: reduction of sugar absorption in the blood (Mal-Absorptive) by means of the GDS, and an additional restrictive component that is achieved through the anchoring system.

### **About Allium Medical:**

Allium is an Israeli company that specializes in minimally invasive medical solutions and presents a variety of technologies and product lines in this area. The Company's strategy is to create value by expanding the basis of internal developments and by acquiring product lines and additional technologies. The Company is managed by professionals with knowhow and experience in an effective promotion of products, from the development to the commercial stage, while securing financing and ensuring economies of scale.

---

<sup>2</sup> CDC – Center for Disease Control and Prevention.

<sup>3</sup> Global Data Report 2012