

## **Allium announcing a Significant progress on its Path to the Chinese Market:**

**The Company was exempted from CFDA requirement to conduct a clinical trial to test its urological stents on local population**

**The Company estimates that it will obtain marketing approval in China by the end of 2017**

**The China Food and Drug Administration (CFDA) has granted the exemption following review of the Company's extensive clinical data in multiple countries over time**

**Israel, Caesarea, April 25 2017 - Allium Medical (TASE:ALMD) - an Israeli medical device company, which specializes in minimally invasive solutions,** announced today that it has made significant progress on its path to the Chinese market. The China Food and Drug Administration (CFDA) has exempted the Company from the requirement to conduct a clinical trial to test its urological stents on the local population, following review of the Company's strong and comprehensive clinical data regarding those stents covering multiple countries over time.

The CFDA has asked the Company to provide supplementary technical and regulatory information and the Company intends to submit its reply in the next few weeks. Accordingly, the Company estimates that it will obtain the approval to market the stents in China by the end of 2017.

**Asaf Alperovitz, CEO of Allium group:** “The CFDA’s decision to exempt us from the requirement to conduct a clinical trial is a significant and unique achievement in the current Chinese regulatory environment. This exemption gives a significant push to our plan to successfully penetrate into this enormous and strategic market. The receipt of an approval to market the stents in China, which we expect will happen by the end of 2017, will trigger the initiation of our exclusive agreement with a leading Chinese distributor of products in the field of urology. Under the agreement, the Chinese distributor has undertaken to purchase at least \$16 million worth of stents over a period of 8 years while bearing most of the costs associated with market penetration.

We believe that introducing our products into the Chinese market without having to conduct a clinical trial will make the process quicker and will drive significant cost savings.

The Chinese market offers significant growth opportunities for Allium's urological stents business, both due of its size and due to the economic and social changes this country undergoes. Those changes include a rapidly aging population, increased urbanization and westernization of people's lifestyles and diet. as well as increasing wealth as a result of economic development. Furthermore, Chinese physicians and patients prefer minimally invasive treatments, which provide long-term solutions, to surgical procedures or short-term solutions. All these factors serve as drivers of increased demand for our stents in China", **said Alperovitz.**

The Company's urological stents are intended to treat ureteral obstructions. The stents are clinically designed to fit the anatomy and function of the ureter to provide a relatively long indwelling period and continuous intraluminal flow.

The stents are also covered with a special polymeric coating that prevents stone formation, tissue in-growth and recurrent obstructions. The procedure for placement of the stent is a minimally invasive procedure, which significantly reduces the risks and complications of a surgical procedure.

Allium has been granted approvals for the marketing of the urological stents across the European countries (CE approval), Israel, South Africa, Argentina, Canada, South Korea and Australia and approval procedures are underway in additional countries, including Russia and Mexico.

### **About Allium Medical**

Allium specializes in minimally invasive medical devices and owns a range of technologies and product lines in this field. The company's strategy is to create value by developing its own devices and technologies and by acquiring additional products and technologies that were developed by other parties. The company is led by highly experienced professionals, who possess extensive knowledge and experience of accelerated promotion of products from the development stage to the commercial stage, whilst securing long-term funding and economy of scale.