Allium Medical reports on another significant achievement for Gardia:

Gardia's WIRION® received FDA IDE approval for the WISE LE clinical study

Asaf Alperovitz: "This is a significant achievement, as in addition to the FDA approval of WIRION® for the carotid indication, it will open for Gardia the large and growing US market of peripheral arterial catheterization. We believe that the approval of our unique solution involving the use of WIRION® in conjunction with all FDA-approved atherectomy devices significantly increases the potential value of the Gardia system".

Dr. William A. Gray, MD from Lankenau Heart Institute in Philadelphia, Study PI: "We are very excited to begin this trial to support the use of Gardia's unique embolic protection system to improve patient safety in lower limb interventions".

- **The indication for peripheral arterial catheterization in PAD (Peripheral Arterial Disease) patients will open a large and rapidly growing market of estimated 8-12 million patients in the US alone, with 600 thousand related catheterization procedures annually[1].**
- **The FDA approved Gardia's IDE (Investigational Device Exemption) for performing a clinical study in the US with WIRION, a unique protection**

[1] Partners clinical study, The SAGE Group, AMA heart and stroke statistics 2013 update, Millennium Research Group 2013, i-Data research 2012, guidelines for PAD ACC-AHA.

system, for use with all atherectomy devices (directional, rotational, orbital, laser). Currently, only Covidien, has a protection system, Spider FX, indicated for use in the peripheral arteries. The Spider FX indication is limited to the use with its own (directional) atherectomy devices.

- **The FDA also approved the study design – the type and size of the demographic required for the trial, the total number of patients required to prove safety, as well as the interim targets allowing the company to complete the trial already in its early stage after recruiting only 100 patients[2].**
- **The trial will be conducted at up to 10 leading medical centers in the US, and the company is expected to begin recruiting patients in the upcoming months.**

Israel, Caesarea, May 8 2016 – Allium Medical (TASE: ALMD), an Israeli medical device company specializing in minimally invasive technologies announced today that it received FDA approval for its IDE to perform a clinical study in the US with the WIRION for use in the peripheral arteries.

The market of peripheral arterial procedures has seen a significant growth in the past several years, especially with the introduction of atherectomy devices for wide-spread use. These devices open severely and extensively blocked blood vessels, mechanically or through the use of a laser. To the best knowledge of the company management, the indication for peripheral arterial catheterization opens a large and rapidly growing market of estimated 8-12 million patients in the US alone, with 600 thousand related invasive catheterizations annually[3].

There is an increased use of protection devices in such procedures due to relatively high number of particles released. Gardia's protection system features a guide wire of choice for the entire

[2]The main goal of the trial is to demonstrate the safety profile of the system, as compared to the safety profile demonstrated by Covidien in the trial for its system, which is the only one cleared by the FDA for use in peripheral arteries. The secondary goals of the trial are to examine the functionality of the system and its features, including debris collection. The trial will include around 150 patients, with a 30-day follow up period for each, at up to 10 leading medical centers in the US. This will be an open clinical trial, with an historic control group. According to the protocol approved for the trial, the company is expected to obtain interim results following 100 patients (about two thirds of the total number of participants). At that stage the company may complete the trial early, provided the results meet the performance goal outlined in the trial protocol.

[3] Partners clinical study, The SAGE Group, AMA heart and stroke statistics 2013 update, Millennium Research Group 2013, i-Data research 2012, guidelines for PAD ACC-AHA.

course of the catheterization – a significant and unique benefit, specifically in peripheral arteries, given the relatively high length of blockages. Additionally, some of the existing atherectomy devices only work with a dedicated guide wire – preventing the use of competing systems, some of which require a specific guide wire.

Currently there are four categories of atherectomy devices: directional, rotational, orbital, and laser. To the best knowledge of the company, the FDA clearance of the new indication following the trial and the submission of a 510(k), will make WIRION the only protection system cleared for use with all atherectomy devices in the US.

Asaf Alperovitz, CEO of Allium: "We are very pleased with the approval of the clinical trial for the use of WIRION® in peripheral arteries, and see this as a vote of confidence in our ability to provide good protection for PAD patients. We expect this trial to be successful, since its risk profile is lower relative to that of the successful clinical trial we performed in the carotid arteries (supplying blood to the brain).

In light of the above, the company is expected to begin recruiting patients in the coming months".

The WIRION® was approved last year by the FDA for the use in clinical indication of protection from embolisms in carotid arteries catheterization. It also has CE approval for use in Europe, and AMAR approval for use in Israel, in a wide range of indications for catheterization in the cardiovascular system – including in the carotid, coronary and peripheral arteries, with some 40 successful procedures performed in Europe on peripheral arteries, and over 500 in all types of blood vessels. The system was received with great enthusiasm by physicians, since it entails clear competitive advantages over other FDA-approved products from leading global companies.

About the WIRION® system:

WIRION® is a unique, patent-protected system of the filter type, protecting against blood clots and embolisms occurring in the course of catheterization aimed at unblocking of blood vessels. The system possess a unique locking mechanism, allowing the performing physician to use a guide wire of choice and to place the filter in the most appropriate location. The freedom of placing the filter anywhere on the guide wire simplifies the procedure, makes it safer and more effective – a great advantage over other solutions on the market.

The WIRION® system also includes a unique catheter for easy, quick and safe retrieval of the filter following the placement of the stent. Currently the company is not aware of any alternatives, existing or under development, that could offer competitive medical advantages comparable to those of WIRION®.

The WIRION® system is approved for marketing in the US under the clinical indication of protection against embolism during catheterization of carotid arteries. In Israel it is approved by AMAR and in Europe by CE for use in catheterization of all blood vessels.

The WIRION® system with its many unique properties, is the next generation of devices protecting against embolism. It can be used for a variety of medical indications, including: catheterization of carotid, peripheral and renal arteries, as well as in SVG.