Introduction of DiNovA Medical

DiNovA Medical is a company providing professional operation service to biomedical technology industry. With headquarter in Shanghai and R & D center in the United States, DiNovA Medical is committed to explore more effective treatments for major diseases which seriously threaten people’s health, but lack of effective treatment. There is a top international medical consultant team formed by the famous doctors and industry experts from mainland China and overseas in DiNovA Medical. The rich experience of the consultant team and the combination of different innovative models (original innovation, integrated innovation and imitative innovation) enable us to promote the localization and industrialization of global innovative medical technology in China.

With the support of professional venture capital fund, DiNovA Medical utilizes the capital, resources and professional experience to incubate the early innovative biomedical technology projects in China and speed up the growth and industrialization of them. At the same time, we work with the venture capital fund to introduce top medical technology projects from overseas, and localize the relevant technology through the imitative innovation. At this stage, we focus on the innovative technologies on diagnosis and treatment of cardiovascular diseases, tumor, diabetes, etc.

DiNovA Medical adopts the management and operation modes of corporatization, we set up a company for each project. In addition to the plant which is up to GMP standard, the equipment and facilities, and the property services, we also provide a series of professional value-added services, including technical consultation, legal consultation, market research, patent service, animal lab, clinical trials, product registration of medical device, platform of industrialization and marketing, etc.

Building incubators and accelerators with the sharing of resources and services, DiNovA Medical will form an open, integrated and sustainably developing ecosystem for the innovation of biomedical industry. It helps reach the new academic and industry peaks of biomedical technology in China and stimulate the collaborative development of relevant industries and thus boost the academic status and global influence of medical and scientific research institutions and make a contribution to the development of biomedical technology industry in China.

Below is a brief introduction of some projects managed by DiNovA Medical:
Worsening environment such as air pollution of smog and unhealthy lifestyle like smoking have driven accelerating increase of respiratory diseases. According to the statistics from the National Cancer Research and Control Office, the Ministry of Health, the incidence of lung cancer increases by 26.9% every year. There will be 1 million people with lung cancer in China by 2025 in case of no efficient control measures, and China will become the country with most lung cancer patients.

Current diagnosis and treatment for respiratory disease have a lot of limitations such as delayed diagnosis and large trauma. The five-year survival rate of lung cancer patients is as low as 15% in the United States. It is even lower in China. The patients and doctors are in great needs of diagnostic and therapeutic innovations for respiratory diseases.

Broncus Medical was founded in 1998. Its first technology, Bronchial Thermoplasty to treat asthma, was acquired by Boston Scientific at 440 million US dollars. Broncus has invested more than 150 million US dollars in product research and development and got more than 80 patents around the world. Its second generation core technology, virtual bronchoscopy navigation, was acquired by a Chinese venture capital group led by DiNova in 2012 and Broncus China was founded in the same year. Broncus now has a top international management and research team. It focuses on early diagnosis and treatment of respiratory diseases. Current research projects include minimum-invasive biopsy, navigation system, lung lesion marker for surgery and interventional therapy tools and accessories for lung nodules.

Broncus China’s minimum-invasive and accurate lung cancer treatment project was awarded “the Best Growth Potential Project” in Shanghai Innovation and Entrepreneurship Competition 2015. In the Shanghai Innovation and Entrepreneurship Exhibition, Mr. Yang Xiong, deputy mayor of Shanghai, visited Broncus’ booth and gave Shanghai government’s support to Broncus projects. And Broncus’ joint research project with Shanghai Chest Hospital on early diagnosis and treatment of lung cancer has won the support of RMB 600,000 from Shanghai Science and Technology Commission’s innovation fund. Now Broncus China, as a leader in China market, has established a sales network covering whole China with Beijing, Shanghai and Guangzhou as key markets and a strong tram of sales and distributors. And its products have been sold all over the world. The mission of Broncus is to conquer lung cancer by revolutionizing diagnosis and treatment of lung cancer.
Heart failure is a complex clinical syndrome with ventricular ejection and filling function impairment, and it is the last stage of various cardiac diseases. 17% to 45% heart failure patients die within 1 year after diagnosis, and most patients die within 5 years. There are 18 million people suffering from heart failure in China, and the morbidity is 1.3%. About 500,000 people are newly found with heart failure every year.

Although the current treatments (drug therapy, auxiliary equipment and heart transplantation) can improve the survival rate and quality of life of patients with heart failure, there are still many difficulties. Many patients still suffer from recurrent attacks after optimal drug therapy; and cardiac resynchronization therapy (CRT) is not suitable for all patients with heart failure and the clinical efficacy on some patients with CRT implanted is poor. Heart transplantation is the ultimate solution, but with inadequate source of donor organs. Patients desperately need new treatment technology and products of heart failure due to the limitation and poor efficacy of current treatment.

Algisyl is a new disposable and implantable medical device with the indication to reduce the symptoms of heart failure and improve cardiac structure and function and quality of life of patients by means of implantation of Algisyl in left ventricular myocardium. Algisyl is formed by a natural polysaccharide polymer gel, this biological material has a good biocompatibility and excellent dynamic performance.

The first clinical trial of Algisyl was launched in Germany in February 2009. Algisyl gained CE mark approval and could be applied to clinical treatment in 2014. China carried out Asia’s first case of Algisyl clinical surgery in April 2015. The 2-year follow-up data of the FIM clinical trial was published in the International Journal of Cardiology in June 2015 and the 1-year follow-up data of AUGMENT-HF was published in the European Journal of Heart Failure in November 2015.

LoneStar Heart got the financing support from CardioPolymers, Inc. and DiNovA Venture Capital, etc. LoneStar will further develop the Asian market and the new generation of Algisyl, and provide a better treatment to more patients with heart failure.
Mitral and tricuspid valve are the gateways connecting the left and right atrium and ventricle, ensure the blood flow from atriums towards ventricle. When the mitral and tricuspid valve have functional disorder, the blood would flow back to atrium partly, which is called functional regurgitation. This phenomenon will aggravate the load of atriums and ventricular dilatation, and then seriously affect the health and quality of life of patients. In America, less than 1% of patients with functional regurgitations can be treated by surgery.

Mitralign can cinch the annulus of the mitral and/or tricuspid valve by transcatheter means. It will eliminate regurgitation effectively by reducing the size of the valve orifice to coapt the valve leaflets and initiate remodeling. As the operation avoids the damage of atrioventricular node, arrhythmia seldom occurs. It helps retain other further therapeutic options for patients. The treatment of tricuspid valve, with the leading technology, is the only minimally interventional operation in the world.

Mitralign Inc., located in Massachusetts, the United States, has been working on R&D of the interventional therapy products of functional regurgitation for a long time. Its innovative treatment brings hope to patients suffering from severe regurgitation. While the Mitral product is being assessed for CE approval in major medical centers in Europe, the first successful case of tricuspid valve repair was published in JACC in January 2015.

The first stage of animal test on Mitralign has been completed, the second stage and follow-up clinical trial will be carried out soon. The launch of Mitralign will greatly enhance the proportion of patients under surgical treatment. The team of Mitralign consists of professionals in R&D, manufacturing, clinical and sales field, their innovative concept has brought a brand new treatment to the interventional cardiology specialists and their patients. Mitralign saves the life of patients with regurgitant valvular heart disease.
The stenosis or occlusive disease of coronary and peripheral arteries are usually the primary cause of myocardial infarction, pain of extremities and limb ischemic necrosis. When we treat this disease by interventional operation, the balloon dilatation is always accompanied by embolic debris.

Angioslide is a balloon catheter with dual functions: it not only helps the dilatation of a stenotic artery, but also captures and removes the embolic material at the same time by an on-site suction effect. Angioslide can effectively reduce the incidence of distal embolization caused by embolic debris and some resulting problems such as microcirculatory dysfunction, abnormal myocardial infarction and myonecrosis.

Angioslide, founded in 2005, is a medical device company devoted to supplying excellent and innovative interventional products for surgeons. The series of peripheral catheter balloon is the only interventional product with peripheral vascular embolic suction and removal functions approved by FDA. Quick embolic removal, affordability and easy operation are 3 major advantages of Proteus. The first successful interventional case of below-the-knee procedure was completed in US on 11 July 2012.

PROTEUS™ is also the first product with both FDA and CE approval in the stenosis area. According to the studies carried in major medical centers in Europe, the dual functions of Proteus has a complete combination with PTA balloon.

The team of Angioslide is very creative and has a keen insight of medical market, leading the innovation of industry technology to explore the best treatments. We aim at enhancing the efficacy of embolic capture balloon, and becoming the pioneer in the treatment of vessel stenosis.
Venus A transcatheter aortic valve

With an increasingly obvious tendency of aging population in China, more and more patients suffer from degenerative disease of valve. Foreign studies showed that about 2% ~ 7% of the elderly aged over 65 experienced valvular heart disease to different degrees. Among them, the symptoms of patients with aortic stenosis include chest congestion, shortness of breath, angina and even sudden death, etc. Some patients cannot be treated by thoracic surgery. However, drug therapy or simple balloon dilatation have poor efficacy with relatively high mortality rate.

Transcatheter Aortic Valve Implantation (TAVI, or TAVR), with little trauma and low risk, brings new hope to such elderly patients with aortic stenosis, especially to those who cannot receive thoracic surgery. TAVI becomes a new treatment option for the above patients with aortic valvular disease.

Venus A transcatheter aortic valve, manufactured by VENUS MEDTECH, is a kind of self-expandable valve device. Compared with the same kind of product made in Europe and US, it is furnished with more reasonable design, more user-friendly, and more suitable for Chinese patients.

The clinical trial of Venus A was held by Prof. Gao Runlin, the academician of the Chinese Academy of Engineering from Fuwai Hospital, CAMS & PUMC; the one-year clinical follow-up has been completed and showed a mortality rate of 6.3%, which was superior to the foreign product of the same kind. As an excellent representative of national brand, Venus A had live clinical surgery broadcast in China Interventional Therapeutics (CIT), China Heart Congress (CHC), CSI Conference in Frankfurt, Germany, Vietnam CSI-AP Conference, PCR-CIT China Chengdu Valves, etc., and made a lot of voice. In particular, when the Venus A Procedure by the heart team of Fuwai Hospital was transmitted at the 26th TCT Conference in Washington, US on September 13, 2014, it brought the valve industry in China to a new height.

Venus P transcatheter pulmonary valve

In China, RVOT transvalvular repair is generally performed during surgical correction to patients with outflow tract of right ventricle (RVOT) such as tetralogy of fallot (TOF) and pulmonary stenosis, which may cause expansion of pulmonary aortic valve ring, poor involution of valve leaflet, and lead to obvious pulmonary regurgitation. For patients with severe pulmonary
regurgitation, complicated with moderate to severe right ventricular dysfunction or expansion, it is reasonable to perform transcatheter pulmonary valve replacement.

Venus P transcatheter pulmonary valve manufactured by VENUS MEDTECH is a kind of self-expandable valve device. The bilateral flared design makes it unnecessary to pre-implant a stent for fixation during the surgery, the inner diameter of applicable valve ring is 16-32mm. It is the only choice for patients with primary pulmonary artery and right ventricular outflow tract obstruction all over the world.

The clinical study inclusion of Venus P was basically completed in China, the principal investigator (PI) of this study is Prof. Ge Junbo, academician of Chinese Academy of Sciences from Zhongshan Hospital, Fudan University. In addition, VENUS MEDTECH plans to start patient inclusion of CE Mark study in Europe by end 2015, the principal investigator (PI) of this study is Prof. Shakeel Qureshi of Evelina London Children’s Hospital in England.

The clinical trial of Venus P is not only carried out in China, but also all over the world; which has benefitted the patients in England, Vietnam, Thailand, India, Indonesia etc.

Introduction of VENUS MEDTECH

In 2009, VENUS MEDTECH was set up and based in Hangzhou National High-tech Industrial Development Zone. Later, Venus A transcatheter aortic valve and Venus P transcatheter pulmonary valve were included into the catalogue of CFDA “Special Approval Process of Innovative Medical Device (Green Channel)”.

As a patent-intensive enterprise, VENUS MEDTECH has applied for 28 patent families and 37 patents (invention/novel model) in China. Among them, 15 invention patents and 10 novel models were granted.

After the clinical study of Venus A transcatheter aortic valve has completed one-year follow-up and the clinical study of Venus P transcatheter pulmonary valve has basically completed inclusion, it is planned to formally carry out the clinical study of Venus P in Europe in 2015.

VENUS MEDTECH has won many awards during the stage of entrepreneurship, including First Prize of Biomedical Industry Enterprise group in the 3rd China’s innovation entrepreneurship competition, etc.