American Journal of Cardiovascular Drugs Features Article about HSCI's Innovative Ischemia Treatment

Moscow – February 01, 2017. PJSC HSCI – The Human Stem Cells Institute ("HSCI", MOEX: ISKJ), a leading Eastern European biotech company, today announced that in January 2017 the results of an international postmarketing surveillance study of Neovasculgen's safety and efficacy were published in American Journal of Cardiovascular Drugs (*doi:10.1007/s40256-016-0210-3: Results of an International Postmarketing Surveillance Study of pl-VEGF165 Safety and Efficacy in 210 Patients with Peripheral Arterial Disease*).

Neovasculgen® is a first-in-class gene therapy drug developed by HSCI and approved in 2011 for human use in Russia for treatment of atherosclerotic Peripheral Arterial Disease (PAD), including Critical Limb Ischemia (CLI). In 2012 Neovasculgen® went on sales in the Russian market and in late 2015 was included in the List of Vital and Essential Drugs (VED).

In addition to the Russian market, HSCI intends to make its innovative ischemia drug available on other markets as well. In 2016 the agreements with the US partners were signed for the development of the drug candidate based on IP linked to Neovasculgen® in the United States and Canada.

The postmarketing surveillance study, which results are presented in the research article published in Am J Cardiovacs Drugs, was undertaken to evaluate the safety (identification of uncommon side effects) and efficacy of gene therapy in patients in routine clinical practice. It total, 210 patients with stage II-III chronic limb ischemia (according to the Fontaine-Pokrovsky classification) in 33 healthcare facilities in Russia and the Ukraine were enrolled in the study which makes it one of the largest among the clinical trials of gene therapy drugs.

The study indicated that the use of pl-*VEGF165* in combination with standard pharmacological therapy significantly improves clinical signs of claudication in patients with chronic lower limb ischemia. The study results showed that the therapeutic effect was most prominent in patients with stage IIB and III disease. No angiogenic therapy-related adverse events or side effects were recorded.

Effective treatment of chronic lower limb ischemia is one of the most challenging issues confronting vascular surgeons. Current pharmacological therapies play an auxiliary role and cannot prevent disease progression, so new methods of treatment such as pl-*VEGF165* (a gene therapy drug Neovasculgen®) are obviously needed.

To read the whole article, please go to: www.springer.com

More about Neovasculgen®

Neovasculgen® is a first-in-class gene therapy drug whose mechanism - therapeutic angiogenesis - introduces a new approach to treating ischemia: the use of an evolutionarily programmed process of blood vessel creation and growth.

Developed by HSCI for the treatment of atherosclerotic Peripheral Arterial Disease (PAD), including Critical Limb Ischemia (CLI), Neovasculgen® contains the gene of the Vascular Endothelial Growth Factor (*VEGF 165*) embedded in a plasmid vector (carrier) and thus stimulates the growth of collateral blood vessels (angiogenesis).

Compared to standard therapies, Neovasculgen® promotes a long-term therapeutic effect and significantly improves patients' quality of life, first of all manifested in a substantial increase of Pain Free Walking Distance (Neovasculgen® has a long-term effect /up to 5 years – compared to 6-8 months for standard therapies/ and can be effectively applied at PAD, including CLI /Stages 2a-3 of low limb ischemia according to Fontaine-Pokrovsky/). By increasing the number of functioning capillaries in ischemic tissues and improving the blood supply, Neovasculgen® reduces the rate of amputation and mortality in patients with lower limb ischemia, especially in those who are inoperable for an occlusive PAD. In addition, the drug has a significant healthcare economic efficiency (cost-saving effect).

Russian government granted Neovasculgen® reimbursement approval and included it in the List of Vital and Essential Drugs (VED) [1] starting 2016.

[1] The Vital and Essential Drugs (VED) List is a register of pharmaceutical drugs approved by the Russian Government in order to provide state control over prices to increase availability of essential medicines to the people of Russia. The VED List mainly serves as the basis for drug purchases by hospitals and for recommended treatments of various diseases.

As Neovasculgen® is the first-in-class gene therapy product for treatment via stimulation of angiogenesis, HSCI plans to implement new clinical trial protocols in order to expand the range of indications for applying Neovasculgen®. To start with, HSCI aims to work in the therapy of Diabetic Foot Syndrome and IHD (Ischemic Heart Disease). In October 2016 HSCI received a permission to start clinical trials for Diabetic Foot Syndrome in Russia, while in September 2016 HSCI's subsidiary "NextGen" Co. Ltd. received a patent for gene-therapy method of Diabetic Foot Syndrome treatment.

In addition, R&D is in progress for the creation of gene-activated bone grafts based on Neovasculgen®.

Human Stem Cells Institute PJSC (HSCI, www.eng.hsci.ru**)** is a Russian public biotech company founded in 2003.

HSCI engages in drug discovery, R&D and marketing of innovative proprietary products and services in the field of regenerative medicine, bio-insurance, medical genetics including reproductive genetics, gene therapy and biopharmaceutics.

The Company aims to foster a new culture of medical care – developing new health care opportunities in such areas as personalized and preventive medicine.

HSCI owns the largest family cord blood stem cell bank in Russia – Gemabank®, as well as the reproductive cell and tissue bank Reprobank® (personal storage and donation).

The Company launched Neovasculgen®, the first-in-class gene therapy drug for treating Peripheral Arterial Disease, including Critical Limb Ischemia, and also introduced the innovative cell technology SPRS-therapy**,** which entails the use of autologous dermal fibroblasts to repair skin damage due to aging and other structural changes.

HSCI is implementing a socially significant Genetico® project for the development of its own medical center & testing lab to provide a range of genetic diagnostic and consulting services with the aim of early identification, prediction and prophylactic treatment of genetic disorders, including reproductive system diseases (e.g. PGD, NIPT, Oncogenetics, Bioinformatics)**.**

The Company actively promotes its products and services on the Russian market and intends to open new markets throughout the world.

HSCI is listed on the Innovation & Investment Market (iIM) of the Moscow Exchange (ticker: ISKJ). The Company conducted its IPO in December 2009, becoming the first Russian biotech company to go public.

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Certain statements in this press-release are forward-looking statements within the meaning of the U.S. federal securities laws and are intended to be covered by the safe harbors created thereby.

Those forward-looking statements include, but are not limited to:

- *management's assessment of the Company's future results, including revenue, net profit(loss), profit(loss) per share, dividends, investments, capital structure, margins and other operating and financial results;*
- *forecasts of the present value of future cash flows and related factors;*
- *the Company's plans, goals and tasks relating, among other things, to its products and services development;*
- *the Company's expectations with respect to improving its corporate governance practices;*
- *the Company's market position – as anticipated;*
- *economic outlook and industry trends;*
- *the Company's expectations as to the sector regulation and assessment of impact of regulatory initiatives on the Company's activity;*
- *assumptions and prerequisites under the statements.*

Such forward-looking statements are subject to risks, uncertainties and other factors, which could cause actual results to differ materially from those expressed or implied by these forward-looking statements.

These risks include the risk of changes in political, economic and social conditions in Russia as well as changes in global economic environment, the risks relating to changes in industry regulation and the Russian legislation, the risk of changes in the Company's operations and business prospects, the competition and other risks.

For a more detailed discussion of these and other factors, see the Company's Annual Report and other public filings.

Many of these factors are beyond the Company's ability to control or predict. Given these and other uncertainties, readers are cautioned not to place undue reliance on any of the forward-looking statements contained herein or otherwise. The Company does not undertake any obligation to release publicly any revisions to these forward-looking statements (which are made as of the date hereof) to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events, except as may be required under applicable laws.

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