

24.07.2019

Local Manufacture of an Orphan Medicine Enables NANOLEK to Cut Costs

On July 24, 2019 RUSNANO Management Company and the Russian biopharmaceutical company NANOLEK held a special press tour with the support of the Organisational Committee of the Prioritet 2019 National Award for import substitution and technology transfer.

In the press conference which was held as part of the event, experts discussed the subject of Pharmacoeconomics and import substitution in relation to an orphan medicine and a new Russian inactivated polio vaccine, both produced by NANOLEK, a RUSNANO portfolio company. The treatment of rare (or “orphan”) diseases is a very specific area of medicine, as it is closely linked to state spending and to data on the disease’s incidence.

In January 2018 NANOLEK, as part of an international partnership with the South Korean company Green Cross, registered Idursulfasum beta (trade name, HUNTERAZA®) an original medicine to treat Hunter syndrome (or Mucopolysaccharidosis Type II), an orphan genetic condition, which on January 1, 2019 was added to the list of high-cost nosologies financed from the state budget.

Experts consider that the Russian production of this medicine, in the NANOLEK biopharmaceutical complex in Kirov Region, will help to reduce pressure on the federal budget (treatment using Idursulfasum beta is more than 20% cheaper than enzyme replacement therapy, the approach currently used) and will ensure that Russian patients have uninterrupted access to the medicine they need. So far the first stage of localising manufacture in Russia has been completed, and it is planned that the staged transfer of technology and the full localisation of the medicine’s production will be completed by 2020. The use of this medicine rather than the alternative therapy will save the state budget RUB 7.3 mln a year for each patient. The saving over a five-year period will be RUB 36.9 mln. Once the transition to treatment using HUNTERAZA® is complete, the savings to the state budget will amount to RUB 796.8 mln over 5 years.

Another important subject was discussed in the press conference—specific issues relating to the production of a vaccine for the National Vaccination Calendar (NVC), including a possible partnership with Russian scientific institutes. Representatives of NANOLEK recalled that, as part of the programme to develop the production of fully-Russian medicines, and with the support of Veronica Skvortsova, the Russian Health Minister, the Russian



biopharmaceutical company NANOLEK and the M. P. Chumakov Federal Scientific Centre for Research and Development in the field of Immunobiological Medicines, a Federal State Budgetary Foundation, had signed an agreement on the creation of Invak, a small Investment Company, which will carry out the full-cycle production of vaccines to immunise Russian citizens in accordance with the NVC. The first stage of the Invak project will be the production of an inactivated polio vaccine (IPV) based on Sabin strains using a technology developed by the M. P. Chumakov Research Centre.

Russia will thus have its first fully domestically produced inactivated polio vaccine. In order to increase production capacity, additional facilities are to be constructed as part of the development of the Kirov Region Biotechnology Cluster, of which NANOLEK is one of the co-founders. The project will also help with the implementation of the plans for the development of the Biopolis centre.

Invak will invest more than RUB 3 bln in the industrial production of the inactivated polio vaccine. The production of finished medicines is to start in 2020, and the vaccine will be released for use in 2023. The planned production capacity will be enough to fully meet the state's needs for inactivated polio vaccine, both for the purposes of the Russian NVC and to supply to the other EAEU countries, as well as other foreign markets as part of joint programmes with UNICEF and the WHO. By 2025 the vaccine's export potential is expected to be in excess of 20 mln doses.

“The policy of substituting imports is aimed at supporting domestic producers, but also to ensure the country's independence from external factors. There are several ways in which this could be done, including the transfer of technologies through cooperation with foreign partners, and joint projects with Russian research centres and production facilities located in Russia. Putting measures like that into effect can help make government spending more efficient and also enable the transparent monitoring of original, Russian-made medicines to ensure their quality and effectiveness,” said **Maxim Stetsyuk**, Managing Director of NANOLEK in the press conference.

***NANOLEK** is a modern and rapidly growing Russian biopharmaceutical company with its own high-quality full-cycle production lines that meet GMP standards. It specialises in the domestic production of innovative medicines developed by itself or by foreign partners that it has recruited, with a focus on preventative medicine and the treatment of illnesses of significant social concern. The company is now one of Russia's leading producers of paediatric vaccines.*

NANOLEK's diversified product portfolio covers a number of clinical categories, including vaccines and HIV and oncology drugs. The company has unrivalled experience in the transfer of



technologies through partnerships with leading world pharmaceutical companies (Merck, Sanofi, Novartis, Egis, Aspen, Celltrion, Riemser and others).

RUSNANO has been an investor in NANOLEK since the company was founded in 2011.

For more information about the company, visit www.nanolek.ru

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The Prioritet National Award for Import Substitution and Technology Transfer has been granted each year for the past five years. The goal of the competition is to participate in the dynamic development of the country's economy, to promote the status of Russian producers and to increase demand for Russian goods and technologies. Experts from various sectors of the economy present success stories and highlight competitive advantages, and evaluate and provide support to Russian producers that focus on substituting imports with domestic production, localising manufacturing processes, and exporting their products.

In 2019 there were 23 nominations for the Prioritet award, covering the main sectors of the Russian economy, including machine building, agriculture, the defence industry, metallurgy, pharmaceuticals, electronics, chemical production, light industry, and tourism. In the first stage of the competition 85 companies from 24 regions in Russia applied to take part, each of them a regional leader in its sector and an investor in the development of innovative products and in the service sector

For details about the award, visit www.prioritetaward.ru

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RUSNANO Joint-Stock Company was founded in March 2011 through reorganization of state corporation Russian Corporation of Nanotechnologies. JSC RUSNANO contributes to implementation of the state policy on the development of the nanotechnology industry by investing directly and through investment funds of nanotechnology in financially effective high-technology projects providing the development of new production facilities in the Russian Federation. Its primary investment focus is in electronics, optoelectronics and telecommunications, healthcare and biotechnology, metallurgy and metalwork, energy, mechanical engineering and instrument making, construction and industrial materials, chemicals and petrochemicals. 100 percent of RUSNANO's shares are state owned. Thanks to RUSNANO's investments, there are currently 103 factories and R&D Centers opened in 37 regions in Russia. JSC RUSNANO has profit for the last 5 years.

Management of assets of RUSNANO JSC is carried out by Limited Liability Company established in December 2013, RUSNANO Management Company. Anatoly Chubais is the Chairman of its Executive Board.

Work to establish nanotechnology infrastructure and carry out educational programs is fulfilled by RUSNANO's **Fund for Infrastructure and Educational Programs**, which was also established during the reorganization of the Russian Corporation of Nanotechnologies.

Further details: en.rusnano.com

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