UPTRAVI (SELEXIPAG) HAS BEEN REGISTERED IN THE RUSSIAN FEDERATION FOR THE TREATMENT OF PULMONARY ARTERIAL HYPERTENSION IN ADULT PATIENTS

MOSCOW, August 9, 2019 – Actelion, the company included in Janssen pharmaceutical division of Johnson & Johnson Corporation, announced the registration in the Russian market of an innovative drug product Uptravi (selexipag) for the treatment of Pulmonary Arterial Hypertension (PAH) [1].

Uptravi is the first and the only worldwide approved Oral Selective IP Prostacyclin Receptor Agonist, which is indicated for long-term treatment of II-IV functional classes of PAH in adult patients, according to classification of the World Health Organization (WHO), in order to prevent the disease progression [2,3,4]. Uptravi is effective both in combination with endothelin receptor antagonists and phosphodiesterase type 5 inhibitors as well as in monotherapy. The efficacy of Uptravi is proved with respect to idiopathic and heritable PAH, as well as PAH associated with connective tissue diseases and PAH associated with compensated simple congenital heart disease [3].

The long-term efficacy and safety of Uptravi in PAH patients has been demonstrated in the GRIPHON study, the largest ever seen in patients with pulmonary hypertension. GRIPHON is a long-term, multicenter, randomized, placebo-controlled event driven phase III study conducted in parallel groups, which involved 1156 patients with PAH who were treated in 181 medical centers in 39 countries, including 91 patients from Russia. The composite primary endpoint in the study design was the time from the moment of randomization to the onset of disease progression (hospitalization for PAH, initiation of intravenous or subcutaneous administration of prostanoids, oxygen therapy, lung transplantation, and other) or death. Uptravi demonstrated a 40% risk reduction of the disease progression / death in all patients with PAH, regardless of the treatment line. According to study results, the use of Uptravi at an early stage of therapy reduces by 64% the risk of PAH progression and death in patients [5,6].

Irina Evgenievna Chazova, Academician of Russian Academy of Sciences, Professor, M.D. Director of the Institute of Clinical Cardiology named after A.L. Myasnikov, FSBI National Medical Research Center of Cardiology of the Ministry of Health care of Russia, comments: “Over the past decade, significant progress has been made in understanding the mechanisms of PAH progression, in developing approaches to the diagnosis and treatment of patients with this pathology. New therapy strategies focusing on long-term outcomes in patients change the paradigm of PAH treatment from short-term goals (symptomatic improvement in exercise tolerance) to long-term ones (slowing the progression of the disease and reducing mortality). Recent large-scale controlled clinical studies dictate the need for early combination therapy for PAH.” [8].

Pulmonary Arterial Hypertension (PAH) is an orphan (rare), progressive, life-threatening disease characterized by abnormally high blood pressure in the pulmonary arteries. Symptoms of PAH are nonspecific and can range from mild shortness of breath and fatigue during normal daily activities to symptoms of right ventricular dysfunction and severe exercise limitations [7].

Three main signaling pathways are involved in the development of PAH: endothelin pathway, nitric oxide pathway and prostacyclin pathway. Uptravi is the only oral medication that specifically targets the prostacyclin pathway and improves long-term outcomes in patients with PAH [4,8]. “We knew that the prostacyclin pathway could play a key role in the treatment of PAH. Up to the present moment, the possibilities of treatment aimed at the prostacyclin pathway have been extremely limited in our country. Now we have access to innovative oral therapy, the safety and efficacy of which is supported by the results of serious clinical studies, - says Sergey Nikolaevich Avdeev, Corresponding Member of Russian Academy of Sciences, M.D. Chief Pulmonologist of the Ministry of Healthcare of the Russian Federation. - With the advent of selexipag, significant clinical opportunities for combination therapy with drugs, that affect different mechanisms of the PAH development, open up. Selexipag provides brilliant long-term treatment results even in those patients who already receive basic PAH therapy with one or two drug products. Together with good tolerance, this makes Uptravi a treatment option that can really qualitatively change the approach to the treatment of many patients with PAH”.

“Our company has been a pioneer in the fight against pulmonary arterial hypertension and for a long time has been making a significant contribution to improving the quality of life of patients with this fatal disease. Our commitment to innovation in this area is confirmed by the registration of the innovative Uptravi drug product in Russia. We will make every effort to ensure that all patients, who need this drug for life, could get access to it and therefore live longer, maintaining high quality of life”, - said Katerina Pogodina, General Director of Johnson & Johnson LLC, Managing Director of Janssen Russia and CIS.

ABOUT JOHNSON & JOHNSON

At Johnson & Johnson, we believe that good health is a key to a happy life, the foundation for a prosperous society and progress development. That is why for more than 130 years our goal has been to maintain the well-being of people of all ages throughout the whole life. As one of the largest companies in the healthcare industry, we use our capabilities, market size and resources for the benefit of humanity. We strive to make healthcare more accessible, to create a society in which everyone everywhere can enjoy mental and physical health and beauty and everything is done for that. We use our enthusiasm, knowledge and innovative thinking to fundamentally change the trajectory of human health development.

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At Janssen, we are creating a future in which diseases will be a thing of the past. We are Johnson & Johnson pharmaceutical companies and we spare no effort to make this future a reality for patients around the world. We defeat disease with advanced science. We invent how to help those who need help. We heal hopelessness with human warmth.

We work in the areas of medicine in which we can bring the most benefits: cardiovascular diseases, immune-mediated diseases and

metabolic disorders, infectious diseases and vaccines, diseases of the central nervous system, oncology, pulmonary arterial hypertension.

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About Actelion

Actelion, the company located in the Swiss city of Allschwil, in the western suburbs of Basel, is an industry leader in the treatment of pulmonary hypertension, mainly pulmonary arterial hypertension. The company's product portfolio for the treatment of pulmonary arterial hypertension covers a range of diseases from II to IV functional class according to WHO classification, including drug products for oral, pulmonary and intravenous administration.

Over the past two decades, Actelion medications have helped to significantly improve the prognosis and quality of life in patients with pulmonary arterial hypertension.

Janssen has added pulmonary hypertension to its priority therapeutic areas to support and expand Actelion's leadership in this area.

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