SAPH2021

THE 14TH ANNUAL CONFERENCE OF THE SAUDI ASSOCIATION FOR PULMONARY HYPERTENSION

18-20 FEBRUARY 2021 | VIRTUAL

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janssen
PHARMACEUTICAL COMPANIES
OF Johnson & Johnson

At Janssen, we never stop working toward a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, and you can count on us to keep working tirelessly to make that future a reality for patients everywhere, by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart.

We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Arterial Hypertension.

SILVER SPONSOR

Bayer is a Life Science company with a more than 150-year history and core competencies in the areas of health care and agriculture. With our innovative products, we are contributing to finding solutions to some of the major challenges of our time.

An analysis by well-known branding agency Interbrand in 2015 valued the Bayer brand at €6.3 billion.

A growing and aging world population requires an adequate supply of food and improved medical care.

With our innovative products, we are contributing to finding solutions to some of the major challenges of our time. With life expectancy continuing to rise, we improve quality of life for a growing population by focusing our research and development activities on preventing, alleviating and treating diseases. We are also making an important contribution to providing a reliable supply of high-quality food, feed and plant-based raw materials.

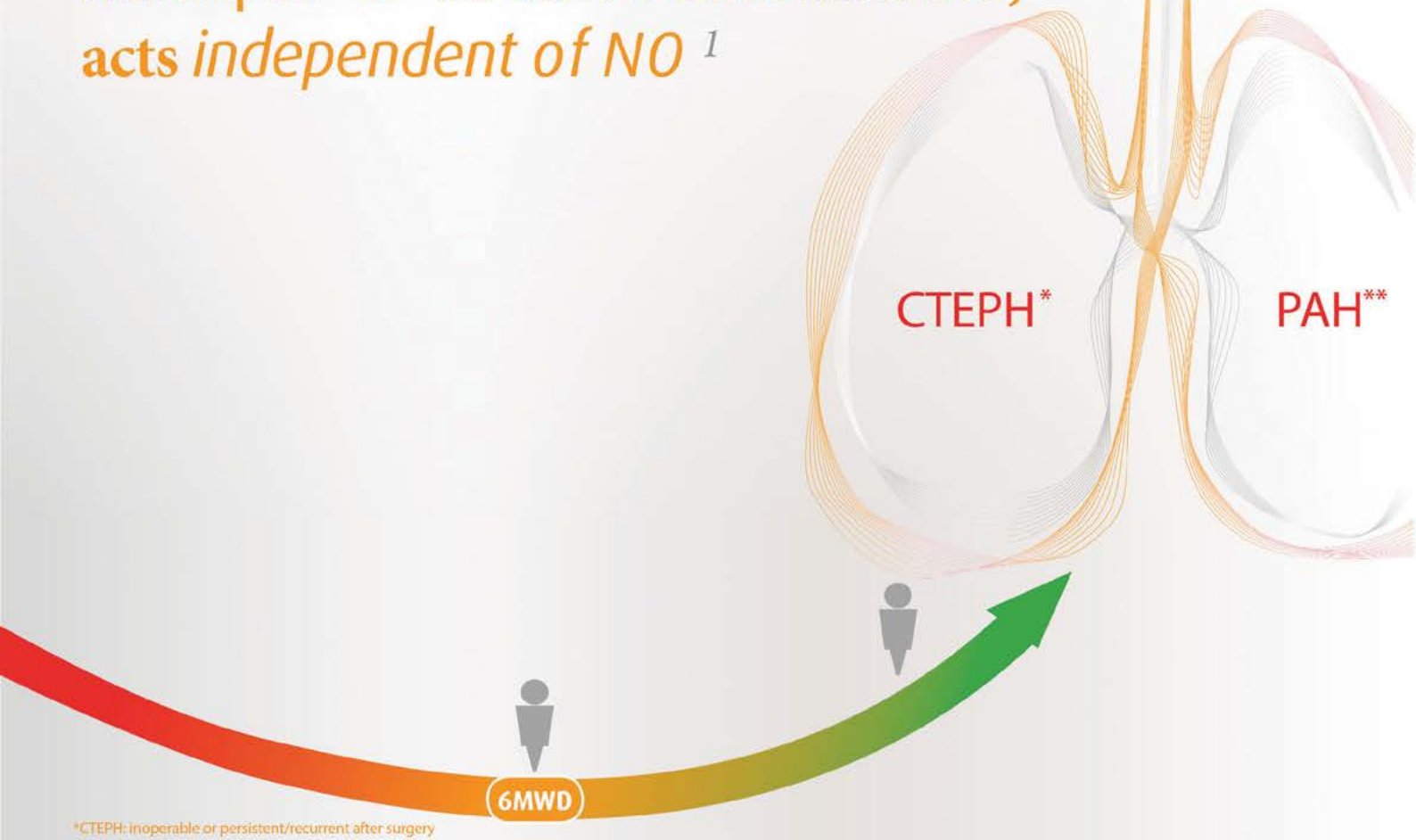
Our goal is to create value for our customers, stockholders and employees, while also strengthening the company's earning power. We are committed to operating sustainably and addressing our social and ethical responsibilities. Employees with a passion for innovation enjoy excellent development opportunities at Bayer. All this goes to make up our purpose:

Science for a **better life**

Adempas®
riociguat

The only approved Treatment in both
Pulmonary Arterial Hypertension and Chronic Thromboembolic Pulmonary Hypertension***

Adempas® 1st in class sGC stimulator, acts *independent of NO* [1]



*CTEPH: inoperable or persistent/recurrent after surgery
**PAH: in monotherapy or in combination with ERA
***Till now Oct. 2016.

References:
1-Ghofrani HA et al. Future Cardiol 66-155: 6; 2010.

Abbreviated Package Leaflet: Product Name: Adempas 0.5 mg, Adempas 1 mg, Adempas 1.5 mg, Adempas 2 mg, Adempas 2.5 mg. Composition: The active substance is riociguat. Each tablet contains 0.5 mg, 1 mg, 1.5 mg, 2 mg or 2.5 mg riociguat. The other ingredients are Tablet core: cellulose microcrystalline, crospovidone, hypromellose, lactose monohydrate, magnesium stearate and sodium laurilsulfate (see end of section 2 for further information on lactose). Film-coat*: hydroxypropylcellulose, hypromellose, propylene glycol and titanium dioxide (E 171).*1 mg, 1.5 mg, 2 mg and 2.5 mg tablets also have: ferric oxide yellow (E 172). *2 mg and 2.5 mg tablets also have: ferric oxide red (E 172). Indications: Adempas contains the active substance riociguat. Riociguat is a type of medicine called a guanylate cyclase (sGC)-stimulator. It works by widening the pulmonary arteries (the blood vessels that connect the heart to the lungs), making it easier for the heart to pump blood through the lungs. Adempas can be used to treat adults with certain forms of pulmonary hypertension, a condition in which these blood vessels become narrowed, making it harder for the heart to pump blood through them and leading to high blood pressure in the vessels. Because the heart must work harder than normal, people with pulmonary hypertension feel tired, dizzy and short of breath. By widening the narrowed arteries, Adempas leads to an improvement in your ability to carry out physical activity. Adempas is used in either of two types of pulmonary hypertension: chronic thromboembolic pulmonary hypertension (CTEPH). In CTEPH, the blood vessels of the lung are blocked or narrowed with blood clots. Adempas can be used for patients with CTEPH who cannot be operated on, or after surgery for patients in whom increased blood pressure in the lungs remains or returns. certain types of pulmonary arterial hypertension (PAH). In PAH, the wall of the blood vessels of the lungs are thickened and the vessels become narrowed. Adempas is only prescribed for certain forms of PAH, i.e. idiopathic PAH (the cause of PAH is unknown), heritable PAH and PAH caused by connective tissue disease. Your doctor will check this. Adempas can be taken alone or together with certain other medicines used to treat PAH. **Contraindications:** The patient should not take Adempas: if the patient is taking certain medicines called PDE-5 inhibitors (e.g. sildenafil, tadalafil, vardenafil). These are medicines used for the treatment of high blood pressure in the arteries of the lungs (PAH) or erectile dysfunction. If the patient has severe liver problems (severe hepatic impairment, Child Pugh C). If the patient is allergic to riociguat or any of the other ingredients of this medicine. If the patient is pregnant. If the patient is taking nitrates or nitric oxide donors in any form, such as amyl nitrite ("recreational drugs"); medicines often used to treat high blood pressure, chest pain or heart disease. If the patient has low blood pressure (systolic blood pressure less than 95 mmHg) before starting first treatment with this medicine. If any of these applies to the patient, the patient should talk to the doctor first and do not take Adempas. **Warnings and precautions:** The patient should talk to the doctor or pharmacist before taking Adempas if: the patient has recently experienced serious bleeding from the lung, or if the patient has undergone treatment to stop coughing up blood (bronchial arterial embolisation). The patient is taking blood-thinning medicines (anticoagulants) since this may cause bleeding from the lungs. The doctor will regularly monitor the patient. If the patient feel short of breath during treatment with this medicine, this can be caused by a build-up of fluid in the lungs. The patient should talk to the doctor if this happens. If the patient has problems with the heart or circulation. If the patient is older than 65 years. If the patient kidneys do not work properly (creatinine clearance < 30 ml/min) or if If the patient is on dialysis as the use of this medicine is not recommended. If the patient has moderate liver problems (hepatic impairment, Child Pugh B). If the patient has start or stop smoking during treatment with this medicine, because this may influence the level of riociguat in the blood. If the patient will receive Adempas only for special types of pulmonary arterial hypertension (PAH). There is no experience in the use of Adempas in other types of PAH. Use of Adempas in other types of PAH is therefore not recommended. The doctor will check if Adempas is suitable for the patient. Children and adolescents: The use of Adempas in children and adolescents (under 18 years of age) should be avoided. **Interactions:** The patient should tell the doctor or pharmacist if the patient is taking, have recently taken or might take any other medicines, in particular, medicines used for: high blood pressure or heart disease (such as nitrates and amyl nitrite) in any form, as the patient must not take those medicines together with Adempas. high blood pressure in the lung vessels (the pulmonary arteries), as if the patient must not take certain medicines (sildenafil and tadalafil) together with Adempas. Other medications for high blood pressure in the lung vessels (PAH), such as bosentan and iloprost, can be used with Adempas, but if the patient should still tell the doctor. erectile dysfunction (such as sildenafil, tadalafil, vardenafil), as if the patient must not take those medicines together with Adempas. fungal infections (such as ketoconazole, itraconazole). HIV infection (such as ritonavir). epilepsy (e.g. phenytoin, carbamazepine, phenobarbitone). depression (St. John's Wort). preventing rejection of transplanted organs (ciclosporin). joint and muscular pain (niflumic acid). cancer (such as erlotinib, gefitinib). stomach disease or heartburn (antacids such as aluminium hydroxide/magnesium hydroxide). These antacid medicines should be taken at least two hours before or one hour after taking Adempas. nausea, vomiting (feeling or being sick) (such as granisetron). Smoking. If If the patient smoke, it is recommended that If the patient stop, as smoking may reduce the effectiveness of these tablets. The patient should tell the doctor If the patient smoke or if the patient stop smoking during treatment. Pregnancy and breast-feeding. Pregnancy: The patient should not take Adempas during pregnancy. if there is a chance that the patient could become pregnant, the patient should use reliable forms of contraception while the patient is taking these tablets. The patient is also advised to take monthly pregnancy tests. If the patient is pregnant, the patient think that may be pregnant or are planning to have a baby, the patient should ask the doctor or pharmacist for advice before taking this medicine. Breast-Feeding: If the patient is breast-feeding or planning to breast-feed, the patient should ask the doctor or pharmacist for advice before taking this medicine because it might harm the baby. The doctor will decide with the patient if the patient should stop breast-feeding or stop treatment with Adempas. Driving and using machines: Adempas has moderate influence on the ability to drive and use machines. It may cause side effects such as dizziness. The patient should be aware of the side effects of this medicine before driving or using machines. Adempas contains lactose If the patient has been told by a doctor that the patient has an intolerance to some sugars, the patient should tell the treating doctor before taking these tablets. **Administration:** The patient should always take this medicine exactly as the doctor has told the patient. The patient should check with the doctor or pharmacist if the patient is not sure. Treatment should only be started and monitored by a doctor experienced in the treatment of CTEPH or PAH. During the first weeks of treatment the doctor will need to measure the blood pressure at regular intervals. Adempas is available in different strengths and by checking the blood pressure regularly at the beginning of the treatment, the doctor will ensure that the patient is taking the appropriate dose. Dose The recommended starting dose is a 1-mg tablet taken 3 times a day for 2 weeks. The tablets should be taken 3 times a day, approximately 6 to 8 hours apart. They can generally be taken with or without food. However, if the patient is prone to having low blood pressure (hypotension), the patient should not switch from taking Adempas with food to taking Adempas without food because it may affect how the patient react to this medicine. The doctor will increase the dose every 2 weeks to a maximum of 2.5 mg 3 times a day (maximum daily dose of 7.5 mg) unless the patient experience any side effects or very low blood pressure. In this case, the doctor will prescribe to the patient Adempas at the highest dose the patient is comfortable on. For some patients lower doses three times a day might be sufficient, the optimal dose will be selected by the doctor. Special considerations for patients with kidney or liver problems. the patient should tell the doctor if the patient has kidney or liver problems. the patient dose may need to be adjusted. If the patient has severe liver problems (Child Pugh C), the patient should not take Adempas. 65 years or older: If the patient is 65 years or older the doctor will take extra care in adjusting the dose of Adempas, because the patient may be at greater risk of low blood pressure. Special considerations for patients who smoke: The patient should tell the doctor if the patient start or stop smoking during treatment with this medicine. The dose of the patient may be adjusted. If the patient has taken more Adempas than the patient should. If the patient has taken more tablets than the patient should and experience any side effects, The patient should contact the doctor. If the patient blood pressure drops (which can make the patient to feel dizzy) then the patient may need immediate medical attention. If the patient forget to take Adempas. The patient should not take a double dose to make up for a forgotten dose. If the patient miss a dose, the patient should continue with the next dose as planned. If the patient stop taking Adempas: The patient should not stop taking this medicine without talking to the doctor first, because this medicine prevents the progression of the disease. If the patient treatment has to be stopped for 3 days or more, the patient should tell the doctor before restarting the treatment. If the patient have any further questions on the use of this medicine, the patient should ask the doctor or pharmacist. **Side effects:** Like all medicines, this medicine can cause side effects although not everybody gets them. The most serious side effects are: coughing up blood (common side effect). acute bleeding from the lungs may result in coughing up blood (uncommon side effect). If this happens, the patient should contact the doctor immediately as the patient may need urgent medical treatment. Overall list of possible side effects: headache, dizziness, indigestion, swelling of limbs, diarrhea, feeling or being sick, inflammation in the digestive system, reduction of red blood cells (anaemia) seen as pale skin, weakness or breathlessness. awareness of an irregular, hard, or rapid heartbeat, feeling dizzy or faint when standing up (caused by low blood pressure), coughing up blood, nose bleed, difficulty breathing through your nose. pain in the stomach, intestine or abdomen. Heartburn, difficulty in swallowing. Constipation. Bloating. acute bleeding from the lungs. The patient should contact the doctor immediately as the patient may need urgent medical treatment. Reporting of side effects. If the patient get any side effects, the patient should talk to the doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, the patient can help provide more information on the safety of this medicine. To report any side effect(s). National Pharmacovigilance and Drug Safety Center (NPC). Fax: + 966 – 11 – 205 – 7662. Call NPC at +966 - 11 - 2038222, Ext.: 2317 – 2356 – 2353 - 2354 - 2334 - 2340. Toll – free: 8002490000. E – mail: npc.drug@sfda.gov.sa. Website: www.sfda.gov.sa/npc. For other countries, please refer to the health authorities in your country. **Date of the information: March, 2014.** Detailed information on this medicine is available on the European Medicines Agency website: http://www.ema.europa.eu.

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AOP ORPHAN

FOCUS ON RARE DISEASES

We at AOP Orphan are European pioneers in the field of Orphan Diseases. We research, develop, produce, and distribute innovative solutions for Rare Diseases worldwide since 1996. AOP Orphan has acquired excellent expertise and developed a solid market presence thanks to its long-term experience. The fact that the company is privately owned ensures long-term commitment, high quality and continuity.

AOP Orphan is also the sole provider of key therapies for a number of highly specialized indications. AOP Orphan experts work closely with leading health care professionals on an international level. This enables them to respond quickly to new findings as well as to push both research and development projects forward. In the course of doing so, AOP Orphan can call upon a global network of qualified partners and, with the help of these strategic alliances, is able to compete with top pharmaceutical companies.

Our motivation at AOP Orphan is to help patients who suffer from rare diseases. We achieve this cooperating with stakeholders of the Middle East health care system. Partnerships within pharmaceutical and health care industry are crucial for finding and providing solutions for patients, especially in the treatment of orphan diseases.

AOP ORPHAN
FOCUS ON RARE DISEASES

Therapy divisions

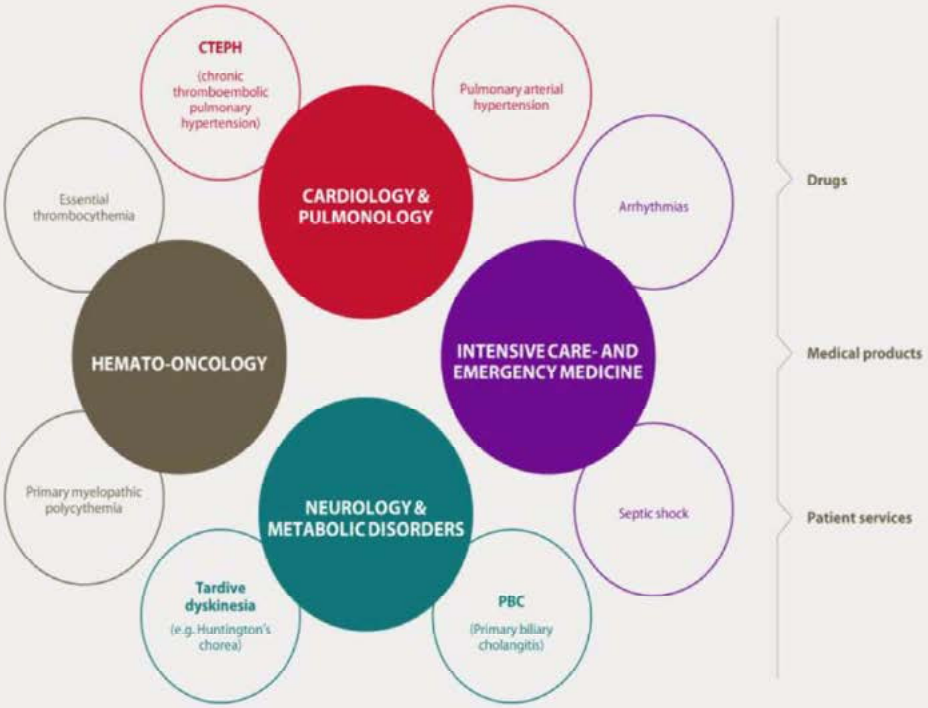
AOP ORPHAN IS THE EUROPEAN PIONEER IN THE FIELD OF RARE AND COMPLEX DISEASES

By taking over the European health care companies Amomed and SciPharm, AOP Orphan is continuing its consistent growth trajectory towards being a pan-European health care group with a focus on special diseases requiring a complex management.

AOP Orphan has been working in the field of rare and complex diseases for 25 years and places the problems and needs of the affected patients, their families and the doctors and care professionals performing treatment at the heart of its work.

The AOP Orphan Group's portfolio contains over 30 drugs as well as patient services and medical products in four indication areas: hemato-oncology, cardiology & pulmonology, neurology & metabolic disorders, and intensive care medicine. AOP Orphan brings the entire development and lifecycle of products under one roof: research & development, registration and marketing and supply.

There is a whole range of new products for existing and new indications in various phases of study and registration, including chronic myeloid leukemia (CML), septic shock, pulmonary arterial hypertension (PAH) or Huntington's chorea.



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Founded in 1983, Pharmascience Inc. is the largest pharmaceutical employer in Québec with over 1,500 employees proudly headquartered in Montréal. With product distribution in over 60 countries. Ranked 56th among Canada's top 100 Research & Development (R&D) investors with over $43 million invested in 2017, Pharmascience Inc. is the third-largest manufacturer of over-the-counter generic drugs in the country.

Pharmascience Inc. is a leading manufacturer and marketer of prescription generic, over-the-counter, and behind the-counter products as well as FDA-approved Canadian-made injectables. The company commercializes nearly 300 product families in 20 different dosage forms for over 2,000 products. In Canada alone, more than 45 million prescriptions a year are filled with Pharmascience products. In 2018, Forbes magazine ranked Pharmascience Inc. among its list of top 300 employers. Pharmascience Inc.

has strong long-standing philanthropic ties with its communities, both locally and internationally. For more than 20 years, Pharmascience has been working through Health Partners International of Canada (HPIC) as a partner of choice to increase access to medicine. Pharmascience's donations of essential medicine total close to $70 million.

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