

2020 China National Reimbursement Drug Negotiation Results Unveiled

Lanreotide Acetate Slow-Release Injection (Pre-filled) Is Included into the National Reimbursement Drug List

And will Benefit more Chinese Patients with Acromegaly

- Lanreotide acetate sustained-release injection (pre-filled), which is used for treating acromegaly, is the first ready-to-use sustained-release preparation based on self-assembled nanotube technology¹. With simple injection process, the drug has been registered and launched in about 73 countries around the world²;
- Lanreotide acetate sustained-release injection (pre-filled) 120mg is the only SSA (somatostatin analogue) approved to extend the interval of administration. Studies showed that for patients with good control of biochemical indicators, the interval of administration could be extended from 28 days to 56 days³;
- That the lanreotide acetate slow-release injection (pre-filled) is included into the new version National Reimbursement Drug List through negotiation will accelerate the in-depth development of Ipsen in the rare disease field in China. Ipsen is committed to bring innovative, effective and convenient treatment for more patients.

Beijing, December 28, 2020 - Today, the National Healthcare Security Administration and the Ministry of Human Resources and Social Security of China jointly released *the National Reimbursement Drug List for Basic Health Care Insurance, Work-related Injury Insurance and Maternity Insurance (2020)*. Lanreotide acetate slow-release injection (pre-filled) produced by Ipsen was included into the *National Reimbursement Drug List*, and hence will benefit more Chinese patients.

Acromegaly is a chronic progressive endocrine disease with insidious onset. The patient may have a disease course of several years or even more than 10 years when he/she visits a doctor.⁴

Acromegaly is a rare disease with slow-release low incidence rate and diagnostic rate. More than 95% of the acromegaly cases are caused by GH secreting pituitary adenoma⁵.

1 Pouget E et al. J Am Chem Soc. 2010; 132:4230-41.

3 Orlewska E, Kos-Kudla B, Sowinski J, et al. Endokrynol Pol. 2015;66(2):142-8.

4 The Chinese Neurosurgical Society, CHINA PITUITARY ADENOMA SPECIALIST COUNCIL, Chinese Society of Endocrinology. Guidelines for the diagnosis and treatment of acromegaly in China (2013). Chinese Journal of Neurosurgery. 2013,29 (10): 975-979.

5 Burton T, Le Nestour E, Neary M, Ludlma WH. Incidence and prevalence of acromegaly in a large US health plan database. Pituitary. 2016;19:262-267.

The acromegaly and its relevant complications can seriously affect the quality and span of life in patients. The physical injuries caused by the disease can lead to a significant decline in the quality of life and a shortened span of life, psychological problems derived from facial deformation, sufferings from complications, not being able to work normally, or even a broken family; many patients can't receive standardized treatment due to economic reasons, which results in gradually worsening conditions. Complications are common in acromegaly patients, which increases the consumption of medical resources and the medical costs.

Today, the National Healthcare Security Administration and the Ministry of Human Resources and Social Security of China released *the National Reimbursement Drug List for Basic Medical Insurance, Work-related Injury Insurance and Maternity Insurance (2020)* and includes lanreotide acetate sustained-release injection (pre-filled) into the scope of medical insurance payouts. This will further benefit more acromegaly patients, reducing their drug burden and improving the accessibility of the drug, and therefore will be of great significance to prolong the survival and improve the quality of life of patients with rare diseases.

Acromegaly Is Difficult to Be Detected and Therefore Difficult to Get Diagnosed for Most Patients

Acromegaly can not only change people's appearance, but also have adverse effects on all organs of their bodies. Studies have shown that the mortality rate of acromegaly patients is 1.3-1.9 times that of people at the same age, and their average life expectancy will be reduced by nearly 10 years. Cardiovascular complications are one of the most common causes of death in patients with acromegaly.

As acromegaly shows different and confusing symptoms, many patients with such symptoms feel that they have worse look than before because of their aging. Many young patients suffer from diabetes and hypertension, which are hard to be associated with acromegaly. As a result, many patients had a disease course of more than 10 years when they are diagnosed.

Patients Have a Heavy Burden of Disease

Professor Wang Renzhi from Department of Neurosurgery, Peking Union Medical College Hospital said, "the risk of death in patients with acromegaly is two to three times that in normal people, and the disease even affects their life span. Hypertension, diabetes and cardiovascular disease are the main causes of life-span shortening in patients with acromegaly. At present, most such patients need surgical treatment, and patients with abnormal hormone levels at preoperative treatment and after surgery / radiotherapy need further drug treatment and lifelong follow-up."

The Comprehensive Social Survey of Chinese Patients with Acromegaly 2019, a branch of the *Comprehensive Social Survey of Chinese Patients with Rare Diseases 2019* initiated by China Alliance for Rare Disease and co-sponsored by Peking Union Medical College Hospital, showed

that the individual burden of such Chinese patients was heavy due to the generally high direct and indirect treatment costs; the drug affordability of acromegaly patients was poor, and the average medical expenditure at their own expense accounted for 35.1% of the annual family income, especially, the self-funded part of drug treatment cost accounted for more than half of the total cost, with a median of RMB 26,000 yuan / year.

Lanreotide Acetate Slow-Release Injection (Pre-filled) Is Included into the National Reimbursement Drug List

The lanreotide acetate sustained-release injection (pre-filled) newly included into the National Reimbursement Drug List is a technical reform and the first ready-to-use sustained-release preparation based on self-assembled nanotube technology⁶. At present, the drug has two specifications, 90mg and 120mg, launched in China. Study data showed that patients with good biochemical control could be given 120mg in an extended injection interval of once every 6 or 8 weeks⁷.

Professor Jin Zimeng from Department of Endocrinology, Peking Union Medical College Hospital said: "acromegaly, as a rare and insidious disease that seriously threatens people's health, requires the endeavor of both the clinicians and patients for a long-term treatment and follow-up. Surgical treatment is the first choice at present, with an overall cure rate of about 65%⁹. If there is no biochemical remission after the operation, the patient needs to receive comprehensive treatment including drugs and radiation, and the therapeutic regimen should be adjusted according to the situation of the patient. "

Alan Chen, general manager of Ipsen China, said: "Ipsen is committed to providing advanced treatments for Chinese patients living with rare diseases. We have a deep understanding of the unmet needs of acromegaly patients and hope to bring more new treatment options for both the clinicians and patients to help more patients improve their quality of life. We are very grateful to the National Healthcare Security Administration for its concern about the needs of patients with rare diseases. Lanreotide acetate sustained release injection (pre-filled)'s being successfully included in the *National Reimbursement Drug List* will greatly improve the accessibility of innovative drugs. In the future, Ipsen will actively cooperate with China and respond to the call of the country to reduce the disease burden of patients, and help Chinese patients achieve early diagnosis and early treatment. We hope that patients with rare diseases can have available medicine, afford the medicine, and use good medicine. "

6 Pouget E et al. J Am Chem Soc. 2010; 132:4230-41.

7 Orlewska E, Kos-Kudla B, Sowinski J, et al. Endokrynol Pol. 2015;66(2):142-8.

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