NATIONAL MEDICAL PRODUCTS NEWSLETTER

Headline
NMPA becomes the applicant for PIC/S

In late September 2023, the National Medical Products Administration (NMPA) submitted formal application to the Pharmaceutical Inspection Co-operation Scheme (PIC/S). On Nov 8, 2023, PIC/S sent a letter to NMPA confirming the applicant status. Following this confirmation, NMPA will strengthen communication and cooperation with the PIC/S, promote itself to become a full member of PIC/S, and take this opportunity to continuously improve the country’s drug inspection system and standards, to constantly enhance its drug inspection quality management system and to steadily promote the development of its inspectors’ team, so as to modernize the national drug regulation in China.

(Dom 9, 2023)

Drugs

Deucravacitinib Tablets approved for marketing by China NMPA

Recently, the category 1 innovative product Deucravacitinib Tablets (trade name: Sotyaktu) of Bristol Myers Squibb is approved for marketing by China NMPA. This drug is indicated for adults with moderate-to-severe plaque psoriasis through systemic treatment or phototherapy.

Deucravacitinib is a tyrosine kinase 2 (TYK2) inhibitor. The marketing of this drug will provide new treatment options for patients with moderate-to-severe plaque psoriasis.

(Oct 19, 2023)

Ritlecitinib Tosylate Capsules approved for marketing

Recently, the Category 1 innovative drug Ritlecitinib Tosylate Capsules (trade name: LITFULO®) of Pfizer Inc. is approved for marketing through priority review and approval procedures by China NMPA. This drug is indicated for treating severe alopecia areata for adults and adolescents 12 years old and older.

Ritlecitinib is a kinase inhibitor, which can irreversibly inhibit Janus kinase 3 (JAK3) and the tyrosine kinase (TEC) family. The marketing of this drug provides new treatment options for patients with severe alopecia areata.

(Oct 19, 2023)
Tongluo Mingmu Capsules approved for marketing by China NMPA

Recently, the Category 1.1 innovative traditional Chinese medicine Tongluo Mingmu Capsules of Shijiazhuang Yiling Pharmaceutical Co., Ltd. is approved for marketing by China NMPA. This drug has undergone a randomized, double-blind, double-simulated, parallel-controlled multicenter clinical trial of calcium dobesilate capsules. The results of clinical trial study showed that after 12 weeks of treatment, the spot and patch hemorrhage of moderate nonproliferative diabetic retinopathy in the test group was superior to that in the control group. The drug can remove blood stasis and dredge collaterals, replenish qi and nourish yin, stop bleeding and brighten eyes. It is indicated for the symptoms related to blood stasis and obstruction of collaterals in moderate nonproliferative retinopathy caused by type 2 diabetes, and spot and patch hemorrhage of fundus and dryness of eyes caused by deficiency of both qi and yin. The marketing of this drug provides new treatment options for patients with the above-mentioned symptoms.

(Oct 19, 2023)

Children's Zibei Xuanfei Syrup approved for marketing

Recently, the Category 1.1 innovative traditional Chinese medicine Children's Zibei Xuanfei Syrup of Jianmin Pharmaceutical Group Co., Ltd. is approved for marketing by China NMPA. This drug has undergone a randomized, double-blind, parallel-controlled multi-center clinical trial. The results of clinical trial study showed statistical difference to the placebo control group. This drug is to disperse wind-heat, promote lung health, and relieve cough for children with acute trachea-bronchitis with wind-hea invading lung syndrome, with coughing, sweating, throat pain, thirst, thin and yellow tongue coating, and floating and rapid pulse. The marketing of this drug provides new treatment options for relieving cough for children with acute trachea-bronchitis.

(Oct 19, 2023)

Aponermin for Injection approved for marketing by China NMPA

Recently, the Aponermin for Injection (Chinese trade name: 沙艾特) of Wuhan HITECK biopharmaceutical Co., Ltd. is approved by China NMPA. This drug, plus thalidomide and dexamethasone, is indicated for the treatment of adult patients with relapsed or refractory Multiple Myeloma after two or more systemic therapies. The Aponermin for Injection is a Circularly Permuted TRAIL, which can bind and activate death receptor 4 (DR4)/death receptor 5 (DR5) on the surface of tumor cells, triggering intracellular Caspase reactions through exogenous cell apoptosis pathways, thereby exerting anti-tumor effects. The marketing of the drug will provide new treatment options for patients.

(Nov 2, 2023)

国立药品局批准中药创新药通络明目胶囊上市

近日，国家药品监督管理局批准了石家庄以岭药业股份有限公司申报的中药1.1类创新药通络明目胶囊上市。

该药物开展了随机、双盲、平行对照的多中心临床试验。临床试验结果显示，治疗12周后，中医非增殖性糖尿病视网膜病变的点片状出血试验组优于对照组。该药物用于治疗风热犯肺、干咳无痰、用于小儿急性支气管炎发热咳嗽的咳痰热，咳嗽，口干，咽喉痛，口渴，舌苔薄黄，脉浮数。该产品的上市为急性支气管炎的咳嗽患儿提供了又一种治疗选择。

(2023-10-19)

国家药监局批准中药创新药小儿紫贝宣肺糖浆上市

近日，国家药品监督管理局批准了健民药业集团股份有限公司申报的中药1.1类创新药小儿紫贝宣肺糖浆上市。

该药物开展了随机、双盲、平行对照的多中心临床试验。临床试验结果显示与安慰剂对照组间比较有统计学差异。该药物具有清热解毒作用，用于急性支气管炎的咳嗽痰热，咳嗽，口干，咽喉痛，口渴，舌苔薄黄，脉浮数。该药物的上市为急性支气管炎的咳嗽患儿提供了又一种治疗选择。

(2023-10-19)

国家药监局批准注射用埃普奈明上市

近日，国家药品监督管理局批准武汉海特生物制药股份有限公司申报的注射用埃普奈明（商品名，沙艾特）上市。该药品联合沙利度胺和地塞米松用于既往接受过至少2种系统性治疗方案的复发或难治性多发性骨髓瘤成人患者。

注射用埃普奈明为重组人肿瘤坏死因子相关凋亡诱导配体，可结合并激活肿瘤细胞表面的死亡受体4(DR4)和死亡受体5(DR5)。通过外源性细胞凋亡途径触发细胞内Caspase级联反应，从而发挥抗肿瘤作用。该品种的上市为患者提供了更多的治疗选择。

(2023-11-02)
Glofitamab Injection approved with conditions for marketing

Recently, the Glofitamab Injection (trade name: 高罗华/Columvi) of Roche Pharma (Schweiz) AG is approved with conditions by China NMPA. This drug is indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, after two or more lines of systemic therapy. Glofitamab is a bispecific antibody that binds to CD20 expressed on the surface of B cells and to CD3 in the T-cell receptor complex expressed on the surface of T cells, and mediates the formation of an immunological synapses with subsequent T-cell activation and proliferation, secretion of cytokines and release of cytoltyc proteins that results in the lysis of CD20-expressing B cells. The marketing of this drug provides a new treatment option for adult patients with relapsed or refractory diffuse large B-cell lymphoma.

Nov 8, 2023

Xianglei Tangzu Cream approved with conditions for marketing

Recently, the natural products Category 1.1 innovative drug Xianglei Tangzu Cream (Fespxion Cream) of Oneness Biotech Co., Ltd. was approved for marketing with conditions by China NMPA. This drug is used for treating Wagner grade 1 diabetic foot ulcer (DFU) with wound cross-sectional area less than 25cm² after debridement. The marketing of this drug provides a new treatment option for patients with Wagner grade 1 DFU.

Nov 14, 2023

Vebreltinib Enteric Capsules Approved with Conditions for Marketing

Recently, the Category 1 innovative drug Vebreltinib Enteric Capsules of Beijing Pearl Biotechnology Limited Liability Company was approved for marketing with conditions by China NMPA. This drug is indicated for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) patients with mesenchymal epithelial transition factor (MET) exon 14 mutation. Vebreltinib is a tyrosine kinase inhibitor of cell mesenchymal epithelial transition factor (c-MET) receptor that can inhibit the proliferation of tumor cells with high c-MET expression. The marketing of this drug provides a new treatment option for NSCLC patients with MET exon 14 mutation.

Nov 16, 2023

国家药监局附条件批准格非妥单抗注射液上市

近日，国家药品监督管理局通过优先审评审批程序附条件批准罗氏制药（中国）格非妥单抗注射液（商品名：高罗华/Columvi）上市。用于治疗既往接受过至少两线系统性治疗的复发难治性弥漫大B细胞淋巴癌成人患者。

格非妥单抗注射液是一种双特异性抗体，通过与B细胞表面的CD20和T细胞表面的CD3同时结合，介导免疫突触形成，随后引起T细胞活化与增殖、细胞因子分泌和细胞溶解蛋白释放，从而诱导表达CD20的B细胞溶解。

该产品的上市为复发难治性弥漫大B细胞淋巴癌成人患者提供了新的治疗选择。

2023-11-08

国家药监局附条件批准天然药物创新药香薯藤足膏上市

近日，国家药品监督管理局附条件批准了合生元中国有限公司申报的天然药物1.1类创新药香薯藤足膏上市，用于清创后创面面积小于25cm²的Wagner 1级糖尿病足局部伤口溃疡。该产品的上市为Wagner 1级糖尿病足患者提供了新的治疗选择。

2023-11-14

国家药监局附条件批准伯瑞替尼肠溶胶囊上市

近日，国家药品监督管理局附条件批准北京百济神州生物科技有限公司申报的1类创新药伯瑞替尼肠溶胶囊上市。该药适用于治疗具有间质-上皮转化因子（MET）外显子14跳跃的局部晚期或转移性非小细胞肺癌患者。

伯瑞替尼是一种细胞间质-上皮转化因子（c-MET）受体激酶选择性抑制剂，可抑制c-MET高表达肿瘤细胞的增殖。该产品的上市为MET外显子14跳跃非小细胞肺癌患者提供了新的治疗选择。

2023-11-16
Children's Chiqiao Qingre Syrup approved for marketing

Recently, the Category 2.2 modified new traditional Chinese medicine Children's Chiqiao Qingre Syrup of Jumpcan Pharmaceutical Group Co., Ltd. is approved for marketing by China NMPA. It is a pediatric drug with highly increased compliance after the modification of dosage form. This drug is to dispel wind and release the exterior, clear heat and promote stagnation, and is suitable for children with wind heat and cold stagnation syndrome. Indications include fever, cough, nasal congestion and runny nose, sore throat, anorexia and thirst, bloating in the epigastic region, constipation or sour and foul smelling stool, and deep-colored urine. The marketing of this drug provides new treatment choice for children with wind heat and cold stagnation syndrome.

(Nov 17, 2023)

Atilotrelvir Tablets/Ritonavir Tablets approved with conditions

Recently, the Category 1 innovative drug Atilotrelvir Tablets/Ritonavir Tablets (co-packaged) (Chinese trade name: 泰中核) of Fujian Guangsheng Zhongjin Biotechnology Co., Ltd. was approved with conditions by China NMPA through the emergency review and approval procedure in accordance with the relevant provisions of special review and approval prescribed in the Drug Administration Law. This is an oral small-molecule drug for the treatment of SARS-CoV-2(2019-nCoV) infection, indicated for treating adult patients with mild to moderate COVID-19 infection. The patients should use the drug by strictly following the package insert under doctors' guidance.
The MAH is asked by NMPA to complete relevant research works of the conditional requirements within a time limit, and submit the follow-up research results in time.

(Nov 24, 2023)

Dimdazile Capsules approved for marketing by China NMPA

Recently, the Category 1 innovative drug Dimdazile Capsules of Zhejiang Jingxin Pharmaceutical Co., Ltd. was approved for marketing by China NMPA. This drug is indicated for short-term treatment for insomnia patients.

Dimdazile is a benzodiazepine drug that is a partial positive allosteric modulator for γ-aminobutyric acid (GABAA) receptor. It exerts the effect of promoting sleep by partially activating GABAA receptors. The marketing of this drug provides a new treatment option for insomnia patients.

(Nov 29, 2023)
Recombinant Humanized Type III Collagen Solution Approved

Recently, the innovative product Recombinant Humanized Type III Collagen Solution for injection of Shanxi Jinbo Bio-pharmaceutical Co., Ltd. is approved by China NMPA. This product is a colorless or almost white liquid composed of recombinant humanized type III collagen and 0.9% physiological saline. It is applied for filling facial dermal tissue to correct dynamic wrinkles in the forehead (including eyebrow lines, forehead lines, and fishtail lines). The recombinant collagen biomaterial used in this product can be assembled into collagen fiber networks, which support cells and tissues in dermal collapse, and physically fills those areas. The immunogenicity risk of the product is controllable, as the substances will gradually be decomposed and absorbed by the collagenase after injection. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Aug 16, 2023)

Magnetic Resonance Imaging System approved for marketing

Recently, the innovative product Magnetic Resonance Imaging System of Wuhan VerImagin Medical Technology Co., Ltd is approved by China NMPA. This product is composed of magnets, an examination table, spectrometer, gradient power amplifier, RF power amplifier, xenon RF power amplifiers, power distribution system, physiological signal gating unit, etc., with independent intellectual property rights. This product adds xenon nuclear imaging function to the conventional magnetic resonance imaging system, which can enable non-invasive and radiation-free distribution of gas in the lungs. It is the first domestic magnetic resonance imaging system that can be used for pulmonary gas imaging. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Aug 16, 2023)

Cryoablation Equipment and Balloon Cryoablation Catheter Approved for Marketing

Recently, the innovative products Cryoablation Equipment and Balloon Cryoablation Catheter of Cryofocus Medtech (Shanghai) Co., Ltd. are approved by China NMPA. The Cryoablation Equipment consists of a freezing unit, a vacuum system, a cryogenic working fluid delivery circuit, and a control system. On the other hand, the Balloon Cryoablation Catheter consists of a device connection part, an operation control part, and a blood contact part. These two products are used in combination in medical institutions for the treatment of drug-refractory, recurrent, symptomatic, and paroxysmal atrial fibrillation. During the treatment, the Cryoablation Equipment delivers nitrogen gas to the inner lumen of the balloon after it is cooled by a heat exchanger, enabling the balloon to make contact with the tissue at a low temperature. Additionally, it dynamically adjusts the pressure and flow of the freezing medium based on the temperature feedback from the catheter to maintain the surface temperature of medical devices used by patients.

(Aug 16, 2023)
the balloon within the specified range. Simultaneously, the vacuum pump of the equipment continuously extracts air from the outer pipeline of the catheter, achieving a high vacuum insulation state in the outer pipeline of the product, ensuring the safety of the non-ablation area and therefore improving the safety of the surgery. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Aug 24, 2023)

Proton Therapy System Approved for Marketing

Recently, the innovative product Proton Therapy System of Varian Medical Systems Inc. is approved by China NMPA. This product is composed of proton accelerator subsystem and treatment subsystem. The proton accelerator subsystem consists of 3 major components: main proton accelerator system, energy selection system and beam transport system. The treatment subsystem contains 3 treatment room, including a 360-degree rotating beam treatment system and Treatment Planning System. The product provides radiation therapy with proton beams for the treatment of solid malignant tumors for all organs and several benign tumors, with specific indications to be determined by clinicians according to the actual situation. This product is the first approved proton therapy system with superconducting cyclotron and 360-degree rotating gantry. With these technologies, this product is compact in structure with multi-angle treatment function. It can effectively shorten the treatment time for patients while ensuring effectiveness. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Nov 1, 2023)

Single Photon Emission and X-ray Computed Tomography Imaging System Approved for Marketing

Recently, the innovative product Single Photon Emission and X-ray Computed Tomography Imaging System of Beijing Novel Medical Equipment Ltd. is approved by China NMPA. This product consists of a single photon emission computed tomography (SPECT) host (including two SPECT detectors), CT host frame, examination bed, PDU server, acquisition client workstation, SPECT acquisition server workstation, CT acquisition reconstruction workstation, image processing workstation, patient positioning monitor, SPECT collimator, etc. This product is clinically used for imaging examination and evaluation of tumors, cardiovascular system, urinary system, and neurological diseases, and its SPECT part can also enable imaging separately. As the first domestic multi-angle, dual-probe, and general-purpose SPECT/CT all-in-one machine, this product not only fills the domestic gap, but also is on par with international advanced standards in various performance indicators. Its clinical application can further improve the diagnostic ability of tumors, ischemic heart disease, and kidney diseases in China, conducive to save clinical resources and reduce medical costs. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Nov 8, 2023)
Additive Manufacturing Matching Knee Prosthesis Approved for Marketing

Recently, the innovative product Additive Manufacturing Matching Knee Prosthesis of Nation Biotechnology (Beijing) Co., Ltd. is approved by China NMPA. This product consists of a femoral condylar prosthesis, a tibial tray prosthesis, and a meniscus prosthesis. The femoral condylar prosthesis and tibial tray prosthesis is constructed from cobalt-chromium-molybdenum powder by laser additive manufacturing, while the meniscus prosthesis is constructed from ultra-high molecular weight polyethylene. Notably, this product adopts a personalized design of total knee prosthesis, featuring a bionic design of the joint surface that allows for the reconstruction of normal patellofemoral joint movement. With its application in knee prosthesis replacement, in combination with bone cement, this product is tailored for patients with osteoarthritis and those in special needs. Moreover, it is capable of achieving satisfactory coverage on each osteotomy plane, effectively solving the problems of mismatch and over-coverage. The marketing of this product will provide a new treatment option for patients. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients. (Nov 17, 2023)

Disposable Intracardiac Ultrasound Diagnostic Catheter Approved for Marketing

Recently, the innovative product Disposable Intracardiac Ultrasound Diagnostic Catheter of Jiangsu Tängan Technology Co., Ltd. is approved by China NMPA. This product consists of a catheter, an operating handle, and a connector. In conjunction with the color ultrasound diagnostic instrument manufactured by the company, it enables medical institutions to perform ultrasound imaging of the heart and the great vessels, as well as intracardiac anatomical structures. By harnessing high-frequency ultrasound, this catheter provides two-dimensional imaging and three-dimensional modeling of the heart, enabling accurate, rapid, and efficient ultrasound surgery. It also offers real-time, precise anatomical images and simultaneous monitoring of hemodynamic changes, enhancing the visualization of cardiac tissue characteristics and fine structures and real-time monitoring. This allows for the prompt detection of surgery-related complications, thus maximizing surgical safety. The marketing of this product is conducive to reducing the cost of clinical treatment and ultimately bringing benefits to more patients. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients. (Nov 29, 2023)

Transcatheter Mitral Valve Repair System approved for marketing

Recently, the innovative product Transcatheter Mitral Valve Repair System of Hangzhou Valgen MedTech Co., Ltd. is approved by China NMPA. This product consists of two components including a guide sheath and a mitral valve clamping system. Among them, the mitral valve clamping system includes a mitral valve clamp and a delivery system. The elastic center sealing network structure of the mitral valve clamping system provides a strong sealing effect, ensures the successful operation of the procedure, and protects the heart from injury. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients. (Nov 17, 2023)
valve clamp can increase the sealing performance, reduce residual leaflets at the center, and reduce the clamping force of the valve leaflets; At the same time, the mitral valve clamp also has functions such as individual capture of valve leaflets and repeated positioning capture, which can improve operational accuracy and reduce the risk of mitral valve clamp detachment and valve leaflet perforation.

This product is suitable for patients with degenerative mitral regurgitation (MR≥3+) who have been assessed by the cardiac team as having a high risk of surgical intervention and have a suitable anatomical structure of the mitral valve. The launch of this product will provide more options for clinical treatment. The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Nov 30, 2023)

Gelatin Polycapro lactone Layered Gingival Repair Membrane approved for marketing

Recently, the innovative product Gelatin Polycapro lactone Layered Gingival Repair Membrane of Neo Modulus (Suzhou) Medical Sci-Tech Co., Ltd. is approved by China NMPA. This product is a white film with a fiber layer structure. It is a three-layer composite film made of gelatin and polycapro lactone through electrospinning technology. The upper and lower layers are gelatin, and the middle layer is polycapro lactone, without distinguishing between the front and back sides. Among them, the gelatin fiber layer comes into contact with the wound surface, assisting in the widening of keratinized gingiva; The polycapro lactone fiber layer increases the mechanical strength of the composite film, making it easy to operate and remove without direct contact with human tissues.

This product is suitable for widening the keratinized gingiva and deepening the vestibular sulcus in the oral cavity. The appropriate model can be selected based on the expected repair area of the applicable area. The marketing of the product will provide new treatment options for patients.

The NMPA will strengthen the post-marketing surveillance of the product to protect the safety of medical devices used by patients.

(Nov 30, 2023)

Notes:

- All the Chinese information in the Newsletter is from newspapers and the Internet. All English articles are translated from the Chinese version. In case of any discrepancy, the Chinese version shall prevail.
- For e-paper of the Newsletter, please visit http://www.ccfdie.org
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