China Medicinal Biotech Association Newsletter
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Policy News

CFDA notice on new chemical drug classification standard on registration price

2016.08.23

The notification for reform of chemical drug classification has reclassified the chemical drug, Afterward, CFDA publishes the new classification of registration standard of chemical drug. The main aspects are:

1. The registration price for chemical drug category 1 and 2 follows the new drug registration price. The registration price for chemical drug category 3 and 4 follows generic drug registration price. Domestic and overboard drug followed the two standards respectively.

2. The registration price for chemical drug category 5 follows the imported drug requires or does not requires clinical trials.

For more detailed information, please refer to Chinese version website of CFDA: http://www.sda.gov.cn/WS01/CL0087/164024.html
SOURCE: CFDA

CFDA notices on drug packing and excipient approval

2016.08.10

In order to simplify the drug approval procedure, CFDA publishes the notification that the approvals of the drug packaging and excipientbecome together with the drug approval from separate approval. The former application will still follower the former procedure. For detailed information, please refer to Chinese version website of CFDA:http://www.sda.gov.cn/WS01/CL0087/162540.html
SOURCE: CFDA

CFDA looks to resolve vaccine shortages

2016.07.18

The China Food and Drug Administration (CFDA) has called on its regional offices to take steps to resolve the country's vaccine supply shortage. The request comes at a

time when CFDA and the vaccine industry it regulates are adapting to the changes that were proposed in response to the scandal that recently engulfed the sector.

CFDA sees the implementation of the revised vaccine distribution and procurement regulations as a way to address the shortages. The regulator is encouraging staff at all levels of its organization to both adopt the aspects of regulations that are relevant to their jobs and encourage manufacturers and distributors to bring their practices in line with the new policies. Officials have created the new regulations to end the conditions that allowed organizations to supply improperly stored vaccines for years.

The enforcement of the new regulations is seen as preventing such illegal activities and supporting the supply of safe, effective vaccines. In its notice calling for staff to work toward this goal, CFDA also mentioned some other actions it wants its offices to take. Specifically, CFDA wants its staff to step up their supervision, inspection and product sampling activities. CFDA's ambitions for such work extend beyond the identification of noncompliant organizations. The regulator also sees the actions as an opportunity for regulators to work with the vaccine industry to raise standards.

CFDA wants its staff to actively help companies to solve the problems they identify. In doing so, the regulator thinks it can help the industry achieve sustained and stable output of vaccines. Specific areas in which CFDA wants to see its staff provide regulatory support include the construction of cold chain logistics networks. Such work will serve two purposes: The presence of a functioning cold chain could lead to the elimination of improperly stored vaccines from the supply chain, while also helping to ensure that logistics capacity constraints never restrict the availability of products.

The regulator also used the notice to address issues outside its traditional areas of focus. Officials are concerned the storage scandal has affected consumer confidence in the safety and efficacy of vaccines. As such, CFDA is encouraging its staff to work to raise awareness about the importance of vaccinations. The regulator is also urging manufacturers to do their part. CFDA wants companies to establish and stick to production schedules, even if temporary sales difficulties tempt them to cut or stop output.
SOURCE: Ruters

CFDA issues the Decision on Amending Good Supply Practice for Pharmaceutical Products

2016.07.22

In order to further strengthen the quality management of drug distribution, and ensure drug safety, the Decision on Amending Good Supply Practice for Pharmaceutical Products was adopted at the executive meeting of China Food and Drug

Administration (CFDA) on June 30, 2016, and shall go into effect as of the date of promulgation. CFDA issued the newly amended Good Supply Practice for Pharmaceutical Products on July 20, 2016.
For detail information, please visit the CFDA Chinese website: http://www.sda.gov.cn/WS01/CL0053/159780.html

Industrial News

First national gene bank opens

2016.09.23

National GeneBank, the country's first national gene bank, was officially put into use on Thursday. The complex is expected to offer strong support to the development of the genetics industry.

Located in Shenzhen, Guangdong province, the billion-dollar CNGB covers an area of 47,500 square meters with a unique design like terraced fields and has saved more than 10 million bio-samples with a data storage capacity of 20 petabytes for phase I. One petabyte is about 400 billion pages of word documents.

It is the world's fourth national-level gene bank. The other three are in the U.S., Europe and Japan.

Wang Jian, president of Shenzhen-based genetic sequencing firm BGI, said: "The CNGB's data will be open to society, providing strong support to the development of the genetics industry."

China's genetic sequencing market, one of the most important aspects of the industry, in 2016 has become the largest in the world with an annual growth rate of above 20 percent, according to research firm iResearch Consulting Group.

To further support the development of the industry, the National Development and Reform Commission in 2011 approved the establishment of CNGB and entrusted BGI-Research with its construction.

Mei Yonghong, former mayor of Jining in Shandong province who is now director of CNGB, said he believes the gene bank can link all elements of gene-related fields, from resources and scientific research to applications in different industries, such as precision medicine and agriculture.

At the opening ceremony, CNGB signed cooperation agreements with some international and local partners, such as Svalbard Global Seed Vault, German Cancer Research Center, Shenzhen Institute of Advanced Technology and Huawei Technologies, which provides data storage service for the bank.

Lyu Jiancheng, vice director of SIAT, said the CNGB will help them to write genes of 10 million phages (a kind of virus) so that they can make new reagents and develop new medicines.

The opening of the gene platform will also reduce costs in the genetic industry, thanks to home made equipment with high precision.

The world leading gene company Illumina has managed to practice individual genetic sequencing within the cost of below 1,000 in 2014, but Mei Yonghong said the aim of CNGB is 1,000 yuan.

BGI's new genetic sequencing equipment BGISEQ-500, which is expected to hit the market in October and the price is said to be one third of its counterparts.
CNGB owns 150 sets of the equipment now and the platform could satisfy the gene sequencing needs of 50,000 people.

Xu Xun, executive director of CNGB, disclosed the machine is completely manufactured in Shenzhen—an important reason for its low price, and more models of their genetic sequencing equipment will be released in November.
SOURCE: China Daily

Scientists identify small-molecule targeting of E3 ligase adaptor SPOP in kidney cancer

2016.09.21

In the cytoplasm of virtually all clear-cell renal cell carcinoma (ccRCC), speckle-type POZ protein (SPOP) is overexpressed and misallocated, which may induce proliferation and promote kidney tumorigenesis. In normal cells, however, SPOP is located in the nucleus and induces apoptosis. Scientists from Shanghai Institute of Materia Medica, Chinese Academy of Science show that a structure-based design and subsequent hit optimization yield small molecules that can inhibit the SPOP-substrate protein interaction and can suppress oncogenic SPOP-signaling pathways. These inhibitors kill human ccRCC cells that are dependent on oncogenic cytoplasmic SPOP. Notably, these inhibitors minimally affect the viability of other cells in which SPOP is not accumulated in the cytoplasm. The findings validate the SPOP-substrate protein interaction as an attractive target specific to ccRCC that may yield novel drug discovery efforts.
SOURCE: Cancer Cell

Progress on the research of histone deacetylase inhibitor for treating cancer

2016.09.21

Quiescent leukemia stem cells (LSCs) that are insensitive to BCR-ABL tyrosine kinase inhibitors confer resistance to imatinib in chronic myelogenous leukemia (CML). Identifying proteins to regulate survival and stemness of LSCs is urgently needed. Although histone deacetylase inhibitors (HDACis) can eliminate quiescent LSCs in CML, little is known about the underlying mechanism that HDACis kill LSCs. By fishing with a biotin-labeled probe, scientist from Guangzhou Institute of Biomedicine and Health, Chinese Academy of Sciences identifies that HDACi JSL-1 binds to the proteinγ -catenin. γ -Catenin expression is higher in LSCs from CML patients than normal hematopoietic stem cells. Silencing γ -catenin in human CML CD34+ bone-marrow (BM) cells sufficiently eliminates LSCs, which suggests that γ -catenin is required for survival of CML LSCs. Pharmacological inhibition ofγ -catenin thwartes survival and self-renewal of human CML CD34+ cells in vitro, and of murine LSCs in BCR-ABL – driven CML mice. γ -Catenin inhibition reduces long-term engraftment of human CML CD34+ cells in NOD.Cg-Prkdcscid II2rgtm1Sug/JicCrl (NOG) mice. Silencing γ -catenin by shRNA in human primary CD34+ cells does not alter β -catenin, implying a β -catenin-independent role of γ -catenin in survival and self-renewal of CML LSCs. Taken together, their findings validate that γ -catenin may be a novel therapeutic target of LSCs, and suppression of γ -catenin by HDACi may explain elimination of CML LSCs. The paper is published on the journal *Theranostics*.
(SOURCE:*Theranostics*)

Capita to play key role in healthcare development in China

2016.09.12

Capita Healthcare Decisions, in partnership with China's National Health and Development Research Centre (CNHDRC) and the International Decision Support Initiative (iDSI), has successfully won funding from the UK Government to support healthcare development in China.

The Prosperity Fund, a cross-government initiative managed by the Foreign and Commonwealth Office (FCO), is a £1.3 billion fund to promote the economic reform and development needed for growth in eligible partner countries over the next five years. Funding is being received by a number of providers. In China, the project has six objectives consistent with the Fund's global goal of promoting reform and growth – including a focus on healthcare.

The strategic partnership between Capita, CNHDRC and the iDSI (which is led by the National Institute for Health and Clinical Excellence (NICE) International), will enable extensive skill sharing and strategic guidance, allowing Chinese healthcare to achieve benefits and improvements in a number of areas.

As part of this, Capita will use its 16 years of experience to guide Chinese healthcare organisations on the use of clinical content. As well as its widely used and accredited specialist clinical teletriage algorithms, and patient focused web based clinical algorithms, Capita's internal clinical editorial team – supported by an extensive network of external experts – can create or update tailored clinical content to meet clients' requirements.

Insight will also be given on the capability to make this content digitally dynamic using Capita's Decision Management System (DMS) technology and Patient Relationship Management System, Salus, built on Microsoft Dynamics CRM.

This strategic relationship between three leading authorities in healthcare policy and healthcare technology, with particular strengths in emerging markets, will set the foundations for transformed healthcare delivery.

Dr Charles Young, chief medical officer at Capita Healthcare Decisions, said: "Our relationship with iDSI and CNHDRC is extremely exciting, both strategically and in a practical way. Working closely with these partners enables us to functionalise high level strategic guidance, and so enable healthcare providers to directly improve health outcomes globally."
(SOURCE: Pharma Asia)

Chinese doctors successfully implant a 15cm long 3D printed titanium vertebrae prosthetic

2016.09.01

A team of doctors from China's Shanghai Changzheng Hospital have successfully implanted a 15 centimeter long 3D printed titanium vertebrae prosthetic into a patient suffering from a serious case of cervical chordoma. The patient, 40-year-old Ms. Zhou from Hunan province, had been suffering from the debilitating disease for nearly 7 years and had just about given up on life until 3D printing presented an almost miraculous treatment option.

During the course of her disease, Ms. Zhou underwent a number of surgeries which proved ultimately unsuccessful, as the tumor located on her upper spinal cord and neck kept returning. The malignant tumor itself, which had grown to envelop the length of six vertebrae, was causing a number of problems, including severe

compression of the trachea and esophagus, which made breathing and eating two very difficult tasks for the patient.

As one can imagine, this made life very difficult for Ms. Zhou, but the patient, inspired by her family, was not ready to give up. After reaching out to a number of hospitals and clinics around China and finding that many of them could not help her because of the complexity of the disease and its treatment, the patient's case finally got picked up by a team from the Shanghai Changzheng Hospital.

The team, led by one Professor Xiao Jianru, investigated Ms. Zhou's condition and found a potential, though still risky solution as her condition was indeed complex. Specifically, after conducting a number of magnetic resonance examinations, the doctors found that Ms. Zhou's tumor had grown to be wrapped around her vertebrae section 3-7, her thoracic section 1, and on both sides of her carotid and vertebral arteries. Additionally, because one side of her vertebral arteries had already been blocked as a result of one of her first surgeries, the blockage of the remaining side caused by the tumor was becoming increasingly critical and presented a number of challenges for the doctors and their surgical plans.

For instance, if any additional damage was caused to the vertebral artery during the procedure, there could be a shortage of blood supply to the brain, which could even be fatal. Even in the case of a successful removal of the tumor from the vertebrae, traditional cervical vertebra plates and titanium meshes would not be sufficient for supporting and protecting the spinal cord, nerve roots, and other surrounding parts.

To meet these challenges, the team of doctors spent a long time discussing possible treatment options and finally settled on using an anatomically correct 1:1 3D printed cervical tumor model to use as a preoperative device. This 3D printed model allowed them to visualize and plan out their next steps, which also included the designing and manufacturing of a 3D printed plate integrated system.

As Professor Xiao Jianru explained, "We used 3D imaging and 3D printing technology based on the patient's CT and MRI imaging data and designed a spinal prosthesis which is similar to the shape and length of the patient's spinal section." After many mechanical and simulation tests, the team was able to 3D print a 6 vertebrae plate integrated system, which is being heralded as the world's first of its kind. The novel system was to be implanted in Ms. Zhou and act as a 15cm long support on her cervical and thoracic vertebra by completely replacing the defected 6 section of her spine.

The 3D printed implant was also designed to incorporate a sponge-like porous structure meant to promote the natural growth of bone cells and ultimately result in bone fusion in the patient for optimal recovery and strength.

Additionally, the implant system also has a three-point perspective fixed mode in addition to a pair of lateral vertebral screw fixation devices which adds additional biomechanical stability. According to the doctors, the implant's design overcomes the current artificial vertebral anti-pull and anti-rotation and helps to achieve all around better support and stability.

The surgery itself took a gruelling 12 hours, but resulted in a successful implantation of the 3D printed vertebrae. According to the doctors, the patient's symptoms have been improving since the surgery and no related complications have occurred. Since the surgery, Ms. Zhou has been discharged from the hospital and is now in the care of a rehabilitation hospital to continue her treatment.
SOURCE: 3ders.org

BeiGene to Start Clinical Trials of PARP Inhibitor in China

2016.08.23

BeiGene, a clinical-stage biopharmaceutical company focused on developing innovative molecularly-targeted and immuno-oncology drugs for the treatment of cancer, has received Clinical Trial Application (CTA) approval from the China Food and Drug Administration (CFDA) to conduct clinical trials in China with BGB-290, a highly potent and selective PARP inhibitor. China is the third territory in which BGB-290 has received approval to conduct clinical trials, in addition to Australia and the United States. Data from the Phase I proof-of-concept trial of BGB-290 were previously presented at the 2015 AACR-NCI-EORTC conference.

"The CTA approval for BGB-290 represents the third molecule from the BeiGene portfolio to receive regulatory clearance for initiation of clinical trials in China. We look forward to commencing the development of BGB-290 in China, in addition to continuing global development of BGB-290, both as a monotherapy and in combination with BGB-A317, our PD-1 antibody," said John V. Oyler, the founder, CEO and chairman.
SOURCE: Pharma Asia

China's 13th Five-Year Plan offers opportunities in biomedical engineering

2016.08.17

This year the National People's Congress, China's top legislature, approved a new five-year plan—a blueprint outlining key social and economic developmental initiatives, which it has been doing every five years since 1957. China's 13th five-year plan has as its key goals a move away from old heavy industry and

construction to a modern information-intensive infrastructure, bridging welfare gaps between rural and urban areas, developing green energy technology, and better distributing the fruits of economic growth.

Our question is what will this plan bring in the area of biomedical engineering? To answer that question, we've taken a closer look at the stated goals of the Chinese government, and its actions thus far through analysis of surveys and data.

CHALLENGES AND OPPORTUNITIES

Biomedical engineering (BME) and the medical device industry show a remarkable rise in China, perhaps as a result of previous five-year plans which have emphasized these areas. According to the data of 2015 China Blue Book of Development of Medical Device Industry, during the 12th five-year plan, China focused intently on nurturing medical companies and developing medical equipment, regarding it as an emerging industry. The number of medical equipment manufacturers climbed to 17,211 in 2015, up from 14,603 in 2011. Manufacturers include MINDRAY, SHINVA, LEPU Medical, and WEGO. Medical devices manufactured in China include sophisticated high-end medical equipment such as large X-ray machines, CTs, magnetic resonance imaging devices, color B-mode ultrasounds, intravascular stents, and artificial joints.

In 2011, the Ministry of Science and Technology published the Specific Plan of Medical Device Technology Industry, regarded as a seminal document for the medical device industry. Recently, related governmental departments, including the Chinese Food and Drug Administration, the National Health and Family Planning Commission of PRC, and the National Development and Reform Commission have introduced similar documents, regulations, and rules. They not only attach importance to the development of China's medical device industry from a strategic perspective but pledge strong support on policies, funding, human resources, and techniques. According to the National Bureau of Statistics, China has invested 489,782 billion yuan in the medical device industry in 2014, which is higher than any year before (data in 2015 has not been published yet).

Recently, Xi Jinping, general secretary of the Communist Party of China (CPC) Central Committee, has proposed the Four-Pronged Comprehensive Strategy. First is the idea of building a moderately prosperous society whose foundation is health care. Because health care is such a pressing need in China, these goals fit in well with societal needs.

According to statistics, there are nearly 260 million people in China who have a major disease. That, combined with the fact that the population is aging, (the number of people 60 years old or older has reached 202 million) creates a strong imperative to address health care. In addition, there are an estimated 80 million disabled people in China. China, therefore, is now facing an exceedingly severe problem. Generally,

China's health care is plagued by difficult and expensive medical treatment and uneven medical resources, which further stunts development of our country.

How can we address these issues? So far, the cruel reality is an uneven distribution of medical resources. Based on the National data report, during the period of the 12th five-year plan, China spent 7 to 8 billion dollars on importing medical equipment each year. We rely on the importation of high-tech medical equipment, which leads to a catastrophic expenditure. It is clear that the only solution is promoting the domestic medical equipment industry and modifying the uneven distribution of health care through technological and model innovation. Mainstream medical devices need to be made in China. At the same time, we need to force the entire health care industry to develop beyond just the medical device industry to the entire field of BME.

THE PLAN AND OBJECTIVES

The overall objective of the 13th five-year plan is to build a moderately prosperous society before 2020. As part of this objective, the goal has been set to deepen economic reform, allowing the market to play a decisive role in resource configuration. Once the 13th five-year plan ascertains the basic ideas, it will propose a series of criteria on economic and social development, including GDP, and offer a number of major projects. Admittedly, there is an almost decade-old gap between the current development status of the BME market in China and the international advanced level. However, fast economic growth has been accompanied by the rapid development of electronic technology, computer technology, and biomaterials science, as well as BME. The Chinese government is vigorously supporting the bio-industry whose rate of industrial output value is above 20% during these years: in the 11th five-year period, the output value of Chinese bio-industry jumped from 600 billion to 1.6 trillion yuan, while it develops into 4 trillion in the 12th five-year target.

The National Recommendation for the 13th five-year plan in Economy and Social Developmentindicates that we should persist in innovating and developing by focusing on improving quality and efficiency. The fifth point that the National Recommendation raises is that we should create intelligent manufacturing engineering by constructing new manufacturing systems, and facilitate the growth of industries, including a new generation of information and communication technology, high-end CNC machine tools and robotics, aerospace equipment, marine engineering equipment and high-tech ships, advanced rail transportation equipment, energy-saving and new energy vehicles, power equipment, agricultural equipment, new materials, bio-medicine and high-performance industrial and medical equipment.

To promote the capitalization and industrialization of these scientific and technological achievements, the Recommendation puts forward some new proposals, including promoting interdisciplinary collaborative innovation, and advancing the integration of technology and economy. Moreover, we hope to build and enhance the platform for technology and intellectual property transactions, along with innovative

financial models that would take us from experimental study to pilot production to final output.

THE MAIN TASKS OF INNOVATION

Obviously, innovation, the core of holistic national development, is the primary impetus to create improvement. Scientific and technological innovation play a leading role in overall innovation. The medical equipment industry, which is a strategic point to guide our national transformation and structural adjustment and an important national force in technological innovation, has the important contribution of stimulating domestic demand and improving the living standards of the population. And it can integrate multi-disciplinary subjects, driving the development of technological innovation and manufacturing. It brings numerous unprecedented opportunities. Five categories of medical devices need focus: digital diagnostic equipment; tissue repair and renewable materials; molecular diagnostic instruments and reagents; artificial organs and life-support equipment; and health monitoring equipment. In addition, high-end medical imaging products, combined with 3-D printing personalized treatment equipment, and medical biomaterials, especially renewable repair materials, are likely to become areas of focus during the 13th five-year plan period.

Digital medical equipment is not only the most important basic equipment in the health care and public health system, but also the core engine of development. It is strategic, catalytic, and crescive. To enhance the competitiveness of China’s digital medical equipment, promote its industrial development, and fully implement the tasks in the National Long-term Science and Technology Development Plan (2006-2020) and Made in China 2025, digital diagnostic equipment R&D has been taken as one of the key projects. According to the whole-chain deployment and the principles of integrative implementation, the Plan sets four tasks including the forefront of innovation and common technology, major equipment development, application solutions for research, and demonstration and evaluation. In 2016, there are 105 universities offering professional BME courses of undergraduate education in China, an increase of 6.06% over 2014 and 2015.

Although high-tech digital medical equipment is still a central concern of the 13th five-year plan, integration of diagnosis and treatment is an important trend for medical devices, especially for cancer treatment, image-guided radiotherapy, and image-guided minimally invasive therapy. Thus, they gain a lot of support from the 13th five-year plan. Radiotherapy systems and high-end imaging equipment were an important foundation of the 12th five-year plan and will be continually funded in this five-year plan.

The encouraging news showing in national data is as the number of patents, inventions, research, and projects in the medical device industrial grows, real income has grown accordingly. In addition, from 2016 onwards, the state has issued several

special programs such as accurate medical research, research on biomedical materials and repair of tissues and organs, prevention and research on major chronic non-communicable disease, and mobile health. These are likely to bring tangible results in the area of absorbable materials, especially bone screws and bone plates, the development of the in vitro diagnostic device industry, intelligent medicine, and so on.

If it is carried forth as it is laid out, there is no doubt that the introduction of the 13th five-year plan will have a substantial and profound impact on BME's development. This is a great opportunity to advance our independent research and development capabilities, as well as boost the presence of BME in China.
SOURCE: IEEE

Zhejiang Hisun Strikes Deal for China Rights to Celsion Immunotherapy

2016.08.16

Celsion has signed a long-term Technology Transfer, Manufacturing and Commercial Supply Agreement with Zhejiang Hisun Pharmaceutical Co. to pursue an expanded partnership for the technology transfer relating to the clinical and commercial manufacture and supply of GEN-1, Celsion's proprietary gene mediated, IL-12 immunotherapy, for the greater China territory, with the option to expand into other countries in the rest of the world after all necessary regulatory approvals are in effect. GEN-1 is currently being evaluated by Celsion in first line ovarian cancer patients.
SOURCE: Pharma Asia

China FDA Accepts NDA for Eisai's Anticancer Agent Halaven

2016.08.12

The China Food and Drug Administration (CFDA) has accepted for review a New Drug Application (NDA) submitted for Eisai's in-house developed anticancer agent eribulin mesylate ("eribulin", product name: Halaven) for use in the treatment of patients with locally advanced or metastatic breast cancer in China.

The NDA was based on Study 304, a multicenter, open-label, randomized, parallel group Phase III clinical study conducted in China to evaluate the efficacy and safety of eribulin and vinorelbine in 530 female subjects with locally recurrent or metastatic breast cancer, previously treated with at least two and a maximum of five prior chemotherapy regimens, including an anthracycline and a taxane. In this study, the primary objective was to assess progression-free survival (PFS) in both treatment groups. From the results for the study, eribulin demonstrated a statistically significant extension in PFS over the comparator treatment vinorelbine.

SOURCE:Pharma Asia

WuXi AppTec's STA subsidiary opens operations in San Diego

2016.08.08

WuXi AppTec (WuXi), a leading open-access R&D capability and technology platform company serving the global pharmaceutical, biotechnology and medical device industries, today announced that its small-molecule process development and manufacturing subsidiary, Shanghai SynTheAll Pharmaceutical Co., Ltd. (STA), is opening operations in San Diego, which provides Process R&D and API manufacturing services for early phase clinical studies.

"STA is a leading global Contract Development and Manufacturing Organization for innovative small molecule active pharmaceutical ingredients and advanced intermediates, from preclinical through commercial," said Dr. Minzhang Chen, CEO of STA. "Our new U.S. based presence with a highly experienced scientific and production team is another step towards better enabling our partners through added capacity, greater flexibility, and our customer-centric approach to drug development and manufacturing services."

"WuXi's open-access capability and technology platform strives to enable anyone and any company to discover and develop healthcare products more efficiently and cost effectively," said Dr. Ge Li, Chairman and CEO of WuXi AppTec. "This new facility further brings our comprehensive R&D services closer to our North American customers and partners in their efforts to improve patients' lives."

WuXi also has U.S. facilities in Cambridge (MA), Plainsboro (NJ), Philadelphia, Lansdale (PA), St. Paul (MN), Atlanta, and global presence in Germany, Iceland, Israel, South Korea, and Japan. Headquartered in Shanghai, WuXi has a global footprint of over 6.0 million square feet of R&D space across 26 sites around the world.
SOURCE: WuXi AppTec

Pei Xuetao team convert human gastric epithelial cells to multipotent endodermal progenitors using defined small molecules

2016.07.27

Endodermal stem/progenitor cells have diverse potential applications in research and regenerative medicine, so a readily available source could have widespread uses.

Pei Xuetao leads his team from Academy of Military Medical Sciences describing derivation of human induced endodermal progenitor cells (hiEndoPCs) from gastrointestinal epithelial cells using a cocktail of defined small molecules along with support from tissue-specific mesenchymal feeders. The hiEndoPCs show clonal expansion in culture and give rise to hepatocytes, pancreatic endocrine cells, and intestinal epithelial cells when treated with defined soluble molecules directing differentiation. The hiEndoPC-derived hepatocytes are able to rescue liver failure in Fah/Rag2/ mice after transplantation, and, unlike hESCs, transplanted hiEndoPCs do not give rise to teratomas. Since human gastric epithelial cells are readily available from donors of many ages, this conversion strategy can generate clonally expandable cell populations with a variety of potential applications, including personalized drug screening and therapeutic strategies for liver failure and diabetes.
SOURCE: Cell Stem Cell

Luye Pharma takes a milestone step forward proposed acquisition of Acino's TDS business

2016.07.26

25 July 2016, Luye Pharma Group Ltd. (2186.HK) (the "Company", and together with its subsidiaries, "Luye Pharma" or the "Group") announces its agreement to acquire the TDS business from Acino, through the purchase of the entire issued share capital of Acino AG and Acino Supply AG (the "Target Group") for €245,000,000 (the "Acquisition").

The Target Group is a Europe based global leader in advanced transdermal drug delivery systems ("TDS") and it is one of the largest independent TDS manufacturers in Europe. The TDS business includes the business of developing, producing and distributing therapeutic systems for drug release and related products, and providing related services, which in particular include the transdermal systems and implants.

The product portfolio of the Target Group is focused on more sophisticated and higher margin specialty patch categories such as CNS, pain and hormone spaces under several successfully commercialised and hard-to-make formulations such as Rivastigmine, Buprenorphine, Fentanyl and fertility control patch.

The Target Group has a stable cash flow and a relatively high level of net profit margin, which are primarily generated from developed markets. Possessing high quality factories with European Union Good Manufacturing Practice certificate and certification from the Food and Drug Administration of the United States, the Target Group has strong manufacturing and quality control capabilities. Luye Pharma also considers that, with clear product lines focusing on the specialty patch categories of central nervous system (CNS) and pain spaces, the products of the Target Group are

expected to create a synergistic effect with the Group's existing lines of business. Furthermore, the competition in the market of TDS and subcutaneous implants products (being one of the Target Group's products) is low and as such, Luye Pharma believes that there is substantial growth potential in the Target Group's present and pipeline products.

Luye Pharma believes that the Acquisition represents a valuable growth opportunity to acquire a well-established European specialized pharmaceutical platform and a leading business in niche markets, together with a strong revenue base supported by a diversified product portfolio as well as a promising pipeline of products. The Acquisition will be a significant step in the Group's international expansion strategy and will help the Group achieve various strategic goals.

"As we execute our international strategy, this transaction serves as an important milestone. With its innovative technology platform, focused product portfolio, loyal customer base and experienced leadership, this acquisition will significantly enhance Luye Pharma's international capabilities and accelerate its penetration into broader therapeutic areas and geographies", said Dr. Yehong Zhang, Luye Pharma (International) CEO.

"The divestment will allow us to focus on the growth in our key markets, and we believe that Luye's vision and strategy fits better with our R&D and manufacturing capabilities in our present TDS business. An R&D focused company like Luye will be able to leverage the high potential of our TDS operations in the best possible way also in the future", says Kalle Känd, CEO at Acino.
SOURCE: Luye Pharma

Chen Ze team make progress in intranasal administration of Chitosan against H7N9 virus infection

2016.07.20

Influenza virus evolves constantly in an unpredictable fashion, making it necessary to vaccinate people annually for effective prevention and control of influenza. In general, however, during the first wave of an influenza outbreak caused by a newly emerging virus strain, influenza morbidity and mortality have been observed to rise sharply due to the lack of a matching vaccine. This necessitates the exploration of novel intervention approaches, particularly those prophylactic or therapeutic agents that have a broad range of antiviral activities and are also proven to be non-toxic.

Chen Ze team from Shanghai Institute of Biological Products reported that stimulation of the innate immune system by intranasal administration of chitosan as a single agent was sufficient to completely protect BALB/c mice from lethal infection

by H7N9 virus, a newly emerged viral strain that is highly pathogenic to humans. Remarkably, animals could still be protected against lethal challenge by H7N9 (10× LD50), even ten days after the intranasal chitosan administration. The significantly enhanced infiltration of leukocytes in the bronchoalveolar lavage and elevated levels of proinflammatory cytokines in the bronchia/lung tissues revealed the potent activation of mucosal immune responses by intranasally delivered chitosan. We also observed that chitosan can protect mice from three other virus strains. The marked breadth and magnitude of protection against diverse viral strains makes chitosan an attractive candidate as a universal anti-influenza agent.
SOURCE: Scientific Report

China discoveries and characteriises a novel potent type II native and mutant BCR-ABL inhibitor for CML

2016.07.20

BCR gene fused ABL kinase is the critical driving force for the Philadelphia Chromosome positive (Ph+) Chronic Myeloid Leukemia (CML) and has been extensively explored as a drug target. With a structure-based drug design approach，scientists from Chinese Academy of Sciences and other institutes have discovered a novel inhibitor CHMFL-074, that potently inhibits both the native and a variety of clinically emerged mutants of BCR-ABL kinase. The X-ray crystal structure of CHMFL-074 in complex with ABL1 kinase (PDB ID: 5HU9) revealed a typical type II binding mode (DFG-out) but relatively rare hinge binding. Kinome wide selectivity profiling demonstrated that CHMFL-074 bore a high selectivity (S score(1) = 0.03) and potently inhibited ABL1 kinase (IC50: 24 nM) and PDGFR α/β (IC50: 71 nM and 88 nM). CHMFL-074 displayed strong anti-proliferative efficacy against BCR-ABL‐driven CML cell lines such as K562 (GI50: 56 nM), MEG-01 (GI50: 18 nM) and KU812 (GI50: 57 nM). CHMFL-074 arrested cell cycle into the G0/G1 phase and induced apoptosis in the Ph+ CML cell lines. In addition, it potently inhibited the CML patient primary cell’s proliferation but did not affect the normal bone marrow cells. In the CML cell K562 inoculated xenograft mouse model, oral administration of 100 mg/kg/d of CHMFL-074 achieved a tumor growth inhibition (TGI) of 65% without exhibiting apparent toxicity. As a potential drug candidate for fighting CML, CHMFL-074 is under extensive preclinical safety evaluation now.
SOURCE: Oncotarget

China approves use of GSK vaccine Cervarix for cervical cancer

2016.07.12

Drugmaker GlaxoSmithKline Plc said on Monday the China Food and Drug Administration (CFDA) has approved its human papillomavirus (HPV) vaccine, Cervarix, for use in the country to help women fight cervical cancer.
GSK's China unit said in a statement Cervarix will be the first HPV vaccine licensed for use in the country and is expected to be launched there in early 2017.

Cervical cancer is the second most common cancer in women aged between 15 to 44 years in China, with an estimated 130,000 new cases each year, it said. China accounts for more than 28 percent of the world's cervical cancer cases, while a new case is detected every minute on average worldwide, GSK said.

The launch will give girls and women aged 9-25 years access to a preventive vaccine against cervical cancer, it said.

A CFDA spokeswoman said it has granted approval for GSK's application for an import registration of the vaccine.

GSK has had a rough ride in China. It has struggled to rebuild sales after being fined nearly $500 million in 2014 for bribing doctors in the country. In May, Chinese health authorities sharply cut the prices of three drugs, including GSK's hepatitis B drug Viread.

The company said it will work with the Chinese authorities to ensure that people in the mainland have increased access to vaccines.

"To achieve this we are ready to explore an innovative pricing approach to support the inclusion of Cervarix into public cervical cancer immunisation programmes," Hervé Gisserot, senior vice president of pharmaceuticals and vaccines, GSK China/Hong Kong, said in a statement. It did not elaborate.
SOURCE:RAPS

CMBA News

CMBA solicits public opinion on the Draft Guidelines for Preparation of Immune Cell Product

2016.09.19

In order to standardize the domestic immune cell product preparation, strengthen the quality management, and promote the industrial self-discipline, CMBA organized the specific experts of immune cell research and manufacture drafting the Guidelines for Preparation of Immune Cell Product in recent one year. Right now, CMBA is soliciting the opinion from members and related companies in China.

Notice about CMBA carrying out calf blood product raw material quality management self-discipline

2016.08.31

On the executive member meeting of the 5th council, the attendees passed the discussion that CMBA carries out the industrial self-discipline work for the quality control of calf blood product raw material. Two documents, the self-discipline guideline for the quality control of calf blood product raw material and the self-discipline principle of for the quality control of calf blood product raw material are published that the members of CMBA may follow.

The 8th National Biotherapy Convention takes place in Anhui

2016.08.17

August 12th, 2016, The 8thNational Biotherapy Convention takes place in Bantang Biotechnology Experimental Zone of Hefei Chaohu Economy & Technology Developmental zone, Anhui province. It is organized by CMBA and co-organized bythe Professional Committee of ClinicalApplication, CMBA, Sinobioway Group Co., Ltd. and Sinohepo Biomedical Tech Co., Ltd.

Well-known biotherapy experts attend the opening ceremony such as Wu Zuze, the Academician of Chinese Academy of Sciences,Hao Xishan, Academician of Chinese Academy of Engineering, Yang Xiaomin, the president of Sinobioway Group Co., Ltd.

and the vice president of CMBA, Wang Aihua, the director of Chaohu Economy & Technology Developmental zone. There are totally more than 300 experts, professors, medical practitioner and researchers within the field join the event.

The opening ceremony is hosted by Wu Zhaohui, the general-secretary of CMBA. Mr. Hao Xishan gives the remarks to welcome and appreciation to the participants. Mr. Wu Zuze and Mr. Hao Xishan give keynote speaking concerning regenerative medicine and tumor precision medicine. Song Xiaotong, the chief scientist of Sinobioway cellular therapy and Zhai Zhimin from Anhui Medical University give keynote speaking about CAR-T technology and CD19-CAR-T cell technology. The listeners give high grade about the speeches.

Besides that, In the afternoon of August 11th, sub-forum of immune cell is held; In the evening, the seminar themed "The opportunity and challenge of Chinese cellular therapy industry" is held.

Currently, there is not clear guideline for cell therapy. In order to promote the self regulatory development of the industry, CMBA surveyed the members and received the clear requirement from the enterprises. Beyond that, CMBA lead the experts and companies to make the Self Regulatory Guideline of Quality Control of Stem Cell Preparation and the Self Regulatory Guideline of Quality Control of Cell Preparation.

The convention takes 3 days and includes 30 lectures. The participants have hilarious discussion. It have a positive influence to the development of cellular therapy industry.

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