For Immediate Release

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China Approves Drug Marketing Authorization Holder Pilot Plan, Green Lights Pharmaceutical Contract Manufacturing Sector

ALBUQUERQUE, N.M., USA (June 20, 2016) - China's State Council issued an effective notice dated May 26, 2016, formally authorizing a trial plan for a new Drug Marketing Authorization Holder (MAH) System for ten provinces: Beijing, Tianjin, Hebei, Shanghai, Jiangsu, Zhejiang, Fujian, Shandong, Guangdong, and Sichuan. Pharmaceutical research institutions and individual researchers in these provinces can submit application for clinical trials or Marketing Authorization registration. Applicants obtaining marketing authorizations and approval documents can become MAHs and take legal responsibility for clinical trials, production and marketing, something previously not allowed.

According to PaizaBio's Chief Commercialization Officer David Deere, who oversees the company's aesptic fill/finish operations in China, this is significant as it approves the use of contract manufacturing organizations (CMOs) to produce drugs in China. Per the State Council's announcement, MAHs without manufacturing capabilities for production must contract with a CMO with qualification to produce approved drugs. MAHs with manufacturing capabilities can use their own facility to produce drugs or may contract production with qualified CMOs. MAHs or applicants can submit additional information, alternate MAH, and change CMO during and after the approval process.

The announcement is a clarification of policy reforms announced by China's Food and Drug Administration (cFDA) in late 2015 designed to accelerate the regulatory review of new drugs and expand options for manufacturing approved drugs. The new policies, which went into effect December 1, 2015, represent major changes in China's drug development and commercialization policies and address accelerating the high-volume backlog of drugs awaiting review and approval by the cFDA and fostering domestic clinical drug development and manufacturing to international technical and quality standards. Chinese and Western pharmaceutical companies are impacted.

Drugs qualified for MAH trials include:

- Therapeutic biologics class 1 - biologics that have not been marketed outside or inside China.
- Therapeutic biologics class 7 - biologics that have been marketed outside China but not inside China
- Biosimilars
- Traditional Chinese Medicine (TCM) and natural drug classes 1-6
- Chemical drug class 1- 4 (Current drug registration classification system)
    - Class 1 – Drugs that have not been marketed outside or inside China
    - Class 2 – Drugs whose administration route changed and have not been marketed outside or inside China
    - Class 3 - Drugs that have been marketed outside of China, but not inside China
    - Class 4 - Drug substance and its preparation that change acid radical and base of the marketed salts drugs without changing its pharmacological effect
- Chemical Drug Class 5 - Drug preparations that change the formulation of marketed drugs without changing administration route (In MAH Pilot it is limited to target-oriented, slow release and controlled release formulations).
- Chemical drug classes after new chemical registration classification system is enforced *(date to be determined)*.
    - Class 1 - Innovative drugs that contain new chemical entities with clinical value and have never been marketed anywhere in the world.
    - Class 2 - Improved and new forms of drugs based on known chemical entities (such as improved chemical structure, new administration route, and new indication) that have apparent clinical advantages and have never been marketed anywhere in the world.

- Approved generic drugs that have quality and efficacy consistency to original drugs. Including chemical drugs class 3 – 4 after the new chemical registration classification.
    - Domestic drugs (i) referencing originator drugs that are marketed outside of China, not in China yet, and (ii) consistent with the originator drugs in quality and efficacy.
    - Domestic drugs (i) referencing originator drugs that are already marketed in China, and (ii) consistent with the originator drugs in quality and efficacy

Drugs approved before this plan include those having the quality and efficacy consistency to the original drugs and drugs from manufacturing companies that have the approval documents relocate or emerge with other companies. The MAH Trial period takes effect on this date of plan issuance until November 4, 2018 at which time participants approval documents will remain valid for the full approval period as issued.

About PaizaBio
PaizaBio is a New Mexico-based contract manufacturing organization (CMO) and marketing agent that provides Western pharmaceutical companies with high-level support and quick entry into the rapidly growing Chinese aseptic drug market. Operating under the vision of *"In China, For China, To Western Standards*," PaizaBio is committed to quality, integrity and an innovative approach to products and services, including Asia's first dedicated "Sterile University" training program. Visit www.PaizaBio.com

Source: Chinese FDA: http://www.gov.cn/zhengce/content/2016-06/06/content_5079954.htm