



FOR IMMEDIATE RELEASE

CONTACT:

Ajay Sharma
Frontage Labs, Inc
610.232.0100
asharma@frontagelab.com

Frontage Laboratories works with Beijing Second Pharmaceuticals to receive US ANDA Approval

(Exton, PA; May 3, 2011) – [Frontage Laboratories, Inc.](#) (“Frontage”), a leading provider of preclinical DMPK, drug development & Clinical Trial Materials manufacturing, Bioanalytical, Clinical and GMP / Regulatory Consulting services, congratulates its client, Beijing Second Pharmaceutical Co., Ltd. (“BSPC”), on its US FDA approval of ANDA 090752 for Amlodipine Besylate. BSPC is a China-based generic pharmaceutical company focused on manufacturing ophthalmic dosage forms and oral solid dosages targeted for cardiovascular therapies, utilizing their EU and US cGMP-compliant finished product and API facilities. The approval represents a milestone for the Chinese pharmaceutical industry, as BSPC will become the first Chinese-owned pharma firm to be able to launch an FDA-approved Oral Solid Dose product on the US market. The product will be marketed by a US-based distribution partner with harmonized vision for supplying generics in the US marketplace.

As part of the collaborative efforts between Frontage and BSPC, Frontage developed the generic-equivalent formulation and analytical methodologies, provided GMP training and facilities commissioning services, performed technical transfer and scale-up of the developed formulation process, assisted in the execution of the submission batch manufacturing, executed the bioequivalence study, and compiled the electronic ANDA application on behalf of BSPC.

Frontage received approval from the Division of Bioequivalence for its client on April 15th, confirming that the Amlodipine Besylate Tablets USP developed by Frontage for BSPC is bioequivalent and therapeutically equivalent to the reference listed drug Norvasc®, manufactured and marketed by Pfizer, Inc.

This approval adds to the already established track record of Frontage Laboratories as a leading product development CRO in the global marketplace.

Related Links

Frontage Laboratories website - <http://www.frontagelab.com>

Frontage Laboratories, Inc. is a dynamic contract research, development and manufacturing organization, offering a full range of pharmaceutical R&D services. As a rapidly expanding CRO in the US with a ten-year successful history of its high quality GXP services, Frontage has established an international standard in pharmaceutical product research, quality and management systems.

Beijing Second Pharmaceutical Co., Ltd., located at Beijing, China, a subsidiary of China Resources Beijing Pharmaceutical Group Co., Ltd. (the top 2 pharmaceutical group in China), is the first China based pharmaceutical company to get US FDA's marketing approval for its 1st ANDA in US market. Beijing Second Pharmaceutical Co., Ltd. will be the 1st China based pharmaceutical company to launch generic prescription drugs in US market. It is also the first group of China based pharmaceutical companies to get successful both EU GMP and US cGMP compliance site inspection in China pharmaceutical industry.

###