FOR IMMEDIATE RELEASE – CRANBURY, NEW JERSEY - December 14, 2018

On July 12, 2018, Prinston Pharmaceutical Inc. announced that one of its affiliated companies, Solco Healthcare, LLC, based in Cranbury, New Jersey, voluntarily recalled all lots of Valsartan Tablets, 40mg, 160mg, and 320mg; and Valsartan-Hydrochlorothiazide Tablets, 80mg/12.5g, 160mg/25mg, 320mg/12.5mg and 320mg/25mg, to the consumer level. This product recall was due to the detection of a trace amount of an unexpected impurity, N-nitrosodimethylamine (NDMA), in a drug ingredient made by the manufacturer, Zhejiang Huahai Pharmaceutical Co. Ltd., in which the ingredient was used in the manufacture of the subject lots.

Subsequently, as a result of an FDA inspection of the manufacturer's Linhai plant in China, the FDA issued certain observations regarding the plant's operations and processes, and the company responded to those observations in a detailed and lengthy submission to the FDA, which was supplemented after certain validation testing was completed of newly implemented manufacturing and testing processes and procedures. On November 29, 2018, the FDA, having reviewed these submissions, issued a warning letter to the company requesting that further corrective actions be implemented to ensure the investigation of quality-related complaints, and requiring the company to evaluate changes to its manufacturing processes to control the level of impurities in products made at the plant. The company is now in the process of implementing additional changes in its processes and procedures to respond to the FDA's warning letter, the completion of which are expected soon.

Regrettably, there have been reports in the media significantly misinterpreting and mischaracterizing the FDA's warning letter and disregarding all of the positive, proactive steps which the company has implemented and will continue to implement. For example, a press report characterized the FDA's warning letter as stating that the impurity found in Valsartan could have been discovered by the company two years prior to the recall. That is not correct. As a result of an inquiry received from a customer this year, the company investigated its Valsartan product to determine the nature of the impurity and devised a special test to isolate and identify it as NDMA. The company thereafter took quick action to notify regulatory agencies and customers, and immediately stopped production, quarantined inventory, and initiated the voluntary recall. Press reports also erroneously identify as Valsartan a customer-returned product identified by the FDA in its warning letter as Levetiracetam, a different product, and criticize the company's retesting and reprocessing of this product for resale notwithstanding its compliance with product release specifications.

Prinston Pharmaceutical, Solco Healthcare, Zhejiang Huahai, and their affiliated companies assure the public, drug prescribers and patients that they are taking every step to ensure that their products remain safe, therapeutically effective, and meet the highest standards. They and their dedicated employees are also cooperating fully with the FDA and regulatory agencies in other countries to address matters relating to the Valsartan recall.