Press Release – Update on Valsartan API – A Statement from the Company

FOR IMMEDIATE RELEASE - CRANBURY, NEW JERSEY, August 21, 2018. Huahai US Inc., a subsidiary of Zhejiang Huahai Pharmaceutical Co. Ltd is issuing a statement. Recent articles in several print and on-line media have misrepresented information about the discovery of a trace amount of a genotoxic impurity in Valsartan, an active pharmaceutical ingredient (API) made by Zhejiang Huahai Pharmaceutical Ltd. (the Company). These articles have incorrectly suggested that the discovery and identification of this impurity occurred one year or more ago. Their authors speculate that FDA inspections of the Company's manufacturing facilities in 2016 and 2017 disclosed the presence of this impurity, when, in fact, both inspections were ultimately closed by the FDA with its issuance of Establishment Inspection Reports on January 17, 2017 and September 15, 2017, respectively, and without any finding of a genotoxic impurity in the Company's Valsartan API. In truth, and as described below in correct temporal sequence, the discovery of this impurity in the Company's API was made by the Company in June 2018 during a review of manufacturing and optimization processes. After further analyses and confirmations, regulatory authorities were notified promptly and recall actions were voluntarily initiated by the Company for the remaining API in the Company's and its customers' inventories.

In compliance with all product specifications and manufacturing processes approved by domestic and international regulatory agencies, the Company has manufactured and distributed its Valsartan API for many years in conformity with international cGMP requirements. In early June of this year, during a review of its manufacturing processes, the Company discovered an unexpected impurity in its Valsartan API which, after further testing and consultation with toxicology experts, was determined to be N-nitrosodimethylamine (NDMA), which is classified as a carcinogen with very limited evidence of human carcinogenicity. Out of an excess of caution, and contemporaneous with confirmatory technical evaluations, the Company on its own initiative isolated its storage of Valsartan API on hand, suspended its further release and manufacture, and notified the FDA and other regulatory agencies of these findings. Customers were subsequently notified as well and instructed to suspend the further use of the Company's Valsartan API. The Company's voluntary recall of its Valsartan API was then initiated, and periodic informational updates have been furnished to both regulatory agencies and customers in press releases and additional communications.

To protect human health, recalls at the consumer level are being undertaken by the Company and its affiliates, and these will continue under the close supervision of the FDA and regulatory agencies in all affected countries.