

Press Release

Astellas Announces Decision to Discontinue ASP8273 Treatment and Close Randomization for Clinical Study Protocol 8273-CL-0302

- Decision follows recommendation of Independent Data Monitoring Committee -

Tokyo, May 11, 2017 - Astellas Pharma Inc. (TSE: 4503, President and CEO: Yoshihiko Hatanaka, “Astellas”) announced today the discontinuation of ASP8273 treatment arm in the the late-stage SOLAR trial evaluating the efficacy and safety of ASP8273 versus erlotinib/ gefitinib for the 1st line treatment metastatic or advanced unresectable non-small cell lung cancer (NSCLC) harboring sensitizing epidermal growth factor receptor (EGFR) mutation. Following a recommendation by the trial's Independent Data Monitoring Committee (IDMC), Astellas is voluntarily closing study randomization and is informing investigators that ASP8273 treatment must be discontinued. Astellas is also planning to terminate future development programs for ASP8273 in NSCLC following its governance process.

“We are disappointed to be discontinuing the ASP8273 program and want to thank the patients and physicians involved in the program for their commitment to seeking new treatments for patients with non-small cell lung cancer,” said Steven Benner, M.D., senior vice president and global therapeutic area head, oncology development, Astellas.

No new patients are being enrolled in ASP8273 trials and all patients currently receiving ASP8273 are encouraged to speak with their physician about their treatment.

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About Astellas

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. We focus on Urology, Oncology, Immunology, Nephrology and Neuroscience as prioritized therapeutic areas while advancing new therapeutic areas and discovery research leveraging new technologies/modalities. We are also creating new value by combining internal capabilities and external expertise in the medical/healthcare business. Astellas is on the forefront of healthcare change to turn innovative science into value for patients. For more information, please visit our website at www.astellas.com/en.

Cautionary Notes

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi) infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

Contacts for inquiries or additional information:

Astellas Pharma Inc.
Corporate Communications
TEL: +81-3-3244-3201 FAX: +81-3-5201-7473