Press Release

U.S. FDA Grants Fast Track Designation to Astellas for the Development of ASP1128 for Patients at Risk for Acute Kidney Injury

TOKYO, October 28, 2019 – Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas") today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for the development of ASP1128 for patients at increased risk of developing moderate to severe acute kidney injury (AKI) after coronary artery bypass and/or valve (CABG/V) surgery. The Fast Track designation is intended to facilitate the development, and expedite the FDA review, of drugs to treat serious and life-threatening conditions so that, if approved, the compounds can reach the market more expeditiously.

ASP1128 is an investigational compound that is a potent and highly selective PPARδ modulator. ASP1128 is believed to have protective effects on kidney cells that are under cellular stress following CABG/V surgery by promoting fatty acid oxidation in the mitochondria. Further, ASP1128 may have the potential to reduce systemic and local inflammatory responses and oxidative stress. The 1128-CL-0201 proof of concept Phase 2 study is ongoing. The study design is a randomized, double-blind, placebo controlled study enrolling approximately 220 patients across the United States.

"Following the acquisition of Mitobridge, Inc. in 2018, Astellas is now at the forefront of developing mitochondrial-directed therapeutics. Today's announcement is an exciting advancement in an entirely new therapeutic modality and approach with the potential to treat patients with AKI, an area of high unmet need," said Salim Mujais, M.D., Senior Vice President and Therapeutic Area Head, Medical Specialties, Astellas. "Astellas recognizes the serious burden of AKI on patients and we are pleased that the FDA also acknowledges this unmet need and has granted the Fast Track Designation for ASP1128."

Mike Patane, Ph.D., President of Mitobridge, an Astellas Company located at Astellas's site in Cambridge, MA, commented, "Mitochondrial dysfunction is now recognized as an important driver in various diseases with high unmet medical need. For the past six years, our team has focused on this research, first as a biotech

joint venture with Astellas and now as an integrated global Biopharma. At Astellas, mitochondrial biology is one of our Primary Focus, and this biology platform drives our commitment to bring new biological concepts into the clinic for rapid proof of concept. Developing ASP1128 in AKI is the lead example of this effort and our robust pipeline as this area continues to expand."

About ASP1128

ASP1128 is a selective modulator of PPARδ. The Investigational compound is a potentially first-in-class approach to treating AKI. Mitobridge, an Astellas Company. has generated pre-clinical data demonstrated that intervention with ASP1128 improved mitochondrial function, overall energy metabolism and performance of the kidney following an acute ischemia reperfusion injury. In AKI animal models, ASP1128 improved renal function, histopathology and injury biomarkers. Additional information about the trials and participating centers can be found at Clinicaltrials.gov (identifier: NCT03941483).

About AKI

AKI is a sudden loss of kidney function that often occurs in hospitalized patients as a result of cardiac and/or vascular surgery, trauma, infection, cardiac disease or being treated with nephrotoxic anti-cancer therapy. AKI occur in up to 30% of cardiac surgery patients. Dialysis is required in 2% to 6% of the cardiac surgery-associated AKI patients. Currently, there are no drug available for either preventing or treating AKI. The clinical manifestations are, in part, due to early-onset mitochondrial deficits that drive multiple pathophysiological events that lead to AKI and appear to be linked to the severity of AKI and progression to Chronic Kidney Disease (CKD).

About Mitobridge, an Astellas Company.

Mitobridge, located at Astellas' site in Cambridge, Mass., is dedicated to delivering therapeutics that improve mitochondrial function. Our team of experienced drug discovery and development scientists is leveraging their exceptional knowledge of mitochondria biology to develop a pipeline of innovative programs for the treatment of kidney, muscle and other diseases with high unmet medical need. Mitobridge was launched in October 2013 with funding from Astellas Pharma, Inc., MPM Capital and Longwood Ventures and a shared vision for the promise of mitochondrial-targeted therapeutics. In January of 2018, the Company was acquired by Astellas Pharma. For more information about the Company, please visit www.mitobridge.com. The Mitobridge site, now acting as one of Astellas' affiliates in Massachusetts, continues to advance innovative compounds to proof of clinical concept and works with global Astellas teams to advance mitochondrial and biology driven medicine.

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. For more information, please visit our website at: https://www.astellas.com/us/

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.

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