ONO PHARMACEUTICAL CO.,LTD.

August 8, 2019

ONO Submits an Application of ONOACT® for Intravenous Infusion 50mg・150mg, a Short-Acting Selective β_1 Blocker for Additional Indication of Tachyarrhythmia Associated with Sepsis for a Partial Change in Approved Items of Manufacturing and Marketing Approval in Japan

Ono Pharmaceutical Co., Ltd. (Osaka, Japan; President, Representative Director, Gyo Sagara; "ONO") announced today that it submitted an application of ONOACT® for Intravenous Infusion 50mg・150mg (generic name: landiolol hydrochloride) ("ONOACT"), a short-acting selective β1 blocker for additional indication of tachyarrhythmia (atrial fibrillation, atrial flutter and sinus tachycardia) associated with sepsis for a partial change in the approved items of the manufacturing and marketing approval in Japan.

This application is based on the result of a multi-center, randomized, open-label, parallel-group, late Phase Ⅱ/Ⅲ study (ONO-1101-32), conducted in Japan, in patients with tachyarrhythmia (atrial fibrillation, atrial flutter and sinus tachycardia) associated with sepsis.

Sepsis is defined as a condition that causes severe organ dysfunction due to infection. It is known that sympathetic hyperactivity promotes the organ dysfunction. Tachyarrhythmia may develop in sepsis patients as a result of sympathetic hyperactivity and increases in inflammatory cytokines.

ONOACT, discovered and developed internally by ONO, is a short-acting selective β_1 blocker which relaxes the tension of sympathetic nervous by selectively blocking β_1 receptor existing mostly in the heart. It is expected that ONOACT can contribute to patients for the therapy of tachyarrhythmia associated with sepsis.

ONO launched ONOACT for emergency treatment of intra-operative tachyarrhythmia (atrial fibrillation, atrial flutter and sinus tachycardia) in September 2002. Then, it was approved for additional indication of emergency treatment of post-operative tachyarrhythmia (atrial fibrillation, atrial flutter and sinus tachycardia) occurring under the monitoring of circulatory dynamics in October 2006, for treatment of tachyarrhythmia (atrial fibrillation and atrial flutter) in deteriorated cardiac function in November 2013 and for treatment of refractory and urgent fatal arrhythmia (ventricular fibrillation and hemodynamically unstable ventricular tachycardia) in March 2019.

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