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Corporate Communications

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Ono Enters into License Agreement with Bial

Ono Pharmaceutical Co., Ltd. (Osaka, Japan, President and Representative Director: Gyo Sagara) announced today that the company has obtained the right to exclusively develop and commercialize BIA 9-1067 (development code) (generic name: Opicapone) in Japan, which is a long acting COMT (Catechol-O-Methyl Transferase) inhibitor originated by and currently being developed outside Japan by Bial (Porto, Portugal, CEO: António Portela) for the treatment of symptom reemergence due to levodopa “wearing-off” in Parkinson’s disease (PD).

Under the License Agreement, Ono will pay Bial an upfront fee and development and sales milestones based on the development stage and sales performance of Opicapone.

Opicapone is an adjunct therapy to levodopa preparations (levodopa/carbidopa or levodopa/benserazide) in PD patients.

It is well established that levodopa preparations offer the most effective symptomatic treatment of PD. As the disease progresses, PD patients develop “wearing off” phenomenon, where the duration of the effect of levodopa is shortened. To address this “wearing off” phenomenon, adjunctive therapy to levodopa preparations is used to help maintain or boost the effects of levodopa. COMT inhibitors have been widely used to prolong the duration of levodopa effect.

The existing COMT inhibitor in Japan requires multiple administration per day due to its short duration of action and is concomitantly administered with each levodopa preparation.

Phase 3 clinical studies of Opicapone by BIAL are currently ongoing and in clinical studies so far it has demonstrated an increase in the systemic exposure to levodopa

and showed a long-lasting effect on COMT inhibition from once daily dosing. Opicapone is expected to improve a dosing convenience, compared to the existing COMT inhibitor in Japan.

Ono will continue to make great efforts to offer a new drug which truly contributes to patients wellbeing and fulfills unmet medical needs.

<References>

About Parkinson's disease

Parkinson's disease (PD) is a well defined neurological disorder with a clear loss of dopaminergic generating neurons in the substantia nigra region of the mid-brain. The classical features of PD are resting tremor, rigidity, disturbances of movement and postural instability.

About wearing-off

"Wearing-off" is a phenomenon in which the beneficial effect of levodopa disappears several hours after treatment due to shortening of the duration of action of levodopa. "On-time" is defined as the period in which levodopa is effective and "off-time" is defined as the period in which levodopa is ineffective and both "on-time" and "off-time" are observed repeatedly in a day. When wearing-off appears, PD patients have a restriction of time for daily living activities.

About Bial

Bial is a research based, privately owned Portuguese pharmaceutical group. Bial was founded in 1924 and has an international presence in over 50 countries. Research and development is focused on the central nervous system, cardiovascular system and allergic immunotherapy and Bial currently has several other innovative programs under development, which it expects to bring to the market within the next years.