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Verastem Oncology's Announcement Regarding Avutometinib (FDA Acceptance and Priority Review of New Drug Application for Avutometinib (in Combination with Defactinib) for the Treatment of Recurrent KRAS Mutant Low-Grade Serous Ovarian Cancer)

TOKYO, January 6, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Verastem Oncology issued a press release on December 30, 2024 that the U.S. Food and Drug Administration (FDA) has accepted for review the New Drug Application (NDA) under the accelerated approval pathway for avutometinib, an oral RAF/MEK clamp, in combination with defactinib, an oral FAK inhibitor, for the treatment of adult patients with recurrent low-grade serous ovarian cancer (LGSOC), who received at least one prior systemic therapy and have a KRAS mutation. The NDA has been granted Priority Review with a Prescription Drug User Fee Act (PDUFA) action date of June 30, 2025. In addition, the FDA has stated that it is not currently planning to hold an advisory committee meeting to discuss the application. Avutometinib was created by Chugai, and its clinical development is being conducted by Verastem Oncology.

Please refer to the link below for details of the Verastem Oncology's press release:
Verastem Oncology Announces FDA Acceptance and Priority Review of New Drug Application for Avutometinib in Combination with Defactinib for the Treatment of Recurrent KRAS Mutant Low-Grade Serous Ovarian Cancer
https://investor.verastem.com/news-releases/news-release-details/verastem-oncology-announces-fda-acceptance-and-priority-review/

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