News Release

Verastem Oncology's Announcement Regarding AVMAPKI (FDA Approval for AVMAPKI FAKZYNJA Combination Therapy as the First-Ever Treatment for Adult Patients with KRAS-Mutated Recurrent Low-Grade Serous Ovarian Cancer)

TOKYO, May 9, 2025 -- Chugai Pharmaceutical Co., Ltd. (TOKYO: 4519) announced that Verastem Oncology issued a press release on May 8, 2025 that the U.S. Food and Drug Administration (FDA) has approved for AVMAPKI™ FAKZYNJA™ CO-PACK (avutometinib capsules; defactinib tablets) for the treatment of adult patients with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC), who received prior systemic therapy. AVMAPKI FAKZYNJA CO-PACK is the first and only FDA-approved medicine for this disease. This indication is approved under accelerated approval based on the tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. AVMAPKI plus FAKZYNJA is only commercially available in the U.S. as an oral combination co-pack with the two prescription products, known as "AVMAPKI FAKZYNJA CO-PACK." AVMAPKI was created by Chugai, and its clinical development is being conducted by Verastem Oncology. AVMAPKI is the seventh globally approved product created by Chugai.

Please refer to the link below for details of the Verastem Oncology's press release:
FDA Approves the AVMAPKI™ FAKZYNJA™ Combination Therapy as the First-Ever Treatment for Adult Patients with KRAS-mutated Recurrent Low-Grade Serous Ovarian Cancer
https://investor.verastem.com/news-releases/news-release-details/fda-approves-avmapkitm-fakzynjatm-combination-therapy-first-ever

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