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ASIA EDITION

Lynparza receives three new approvals for cancer treatment in Japan

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Approvals in Three Types of Cancer are based on the PAOLA-1, PROfound and POLO Phase 3 Trials

AstraZeneca and Merck, known as MSD outside the United States and Canada, have announced that LYNPARZA has been approved in Japan for the treatment of three types of advanced cancer: ovarian, prostate and pancreatic cancer.

The three approvals authorize LYNPARZA for use as maintenance treatment after first-line chemotherapy containing bevacizumab (genetical recombination) in patients with homologous recombination repair deficient (HRD) ovarian cancer; the treatment of patients with *BRCA* gene-mutated (*BRCA*m) castration-resistant prostate cancer with distant metastasis (mCRPC); and maintenance treatment after platinum-based chemotherapy for patients with *BRCA*m curatively unresectable pancreas cancer.

The concurrent approvals by the Japanese Ministry of Health, Labor, and Welfare are based on results from the PAOLA-1, PROfound and POLO Phase 3 trials, which each were published in *The New England Journal of Medicine*.

LYNPARZA, which is being jointly developed and commercialized by AstraZeneca and Merck, has a broad and advanced clinical trial development program, and AstraZeneca and Merck are working together to understand how it may affect multiple PARP-dependent tumors as a monotherapy and in combination across multiple cancer types.

LYNPARZA Approved as Maintenance Treatment After First-Line Chemotherapy Containing Bevacizumab (Genetical Recombination) in Patients with HRD-Positive Ovarian Cancer

The approval is based on a biomarker subgroup analysis of the PAOLA-1 Phase 3 trial which showed LYNPARZA, in combination with bevacizumab maintenance treatment, demonstrated a substantial progression-free survival (PFS) improvement versus bevacizumab alone for patients with HRD-positive advanced ovarian cancer.

LYNPARZA Approved for the Treatment of *BRCA*m Castration-Resistant Prostate Cancer with Distant Metastasis

The approval is based on a subgroup analysis of the PROfound Phase 3 trial which showed LYNPARZA demonstrated a

substantial improvement in radiographic progression-free survival (rPFS) and overall survival (OS) versus enzalutamide or abiraterone in men with *BRCA*1/2 mutations. LYNPARZA is the first and only PARP inhibitor approved in Japan in mCRPC.

LYNPARZA Approved as Maintenance Treatment After Platinum-Based Chemotherapy for Patients with *BRCA*m Curatively Unresectable Pancreas Cancer

The approval is based on the results of the POLO Phase 3 trial which showed LYNPARZA demonstrated a statistically significant and clinically meaningful improvement in PFS versus placebo in patients with g*BRCA*m metastatic pancreatic cancer. LYNPARZA is the first and only PARP inhibitor approved in Japan in this disease.