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Pfizer, Astellas announce results from Ph 3 ARCHES trial in men with mHSPC

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Pfizer Inc. and Astellas Pharma Inc. have announced the results from the Phase 3 ARCHES trial in men with metastatic hormone-sensitive prostate cancer (mHSPC). Prostate cancer is considered metastatic once the cancer has spread outside of the prostate gland to other parts of the body. Men are considered hormone (or castration) sensitive if their disease still responds to medical or surgical treatment to lower testosterone levels.

The results show that XTANDI (enzalutamide) plus androgen deprivation therapy (ADT) met the primary endpoint by significantly reducing the risk of radiographic progression or death by 61% versus ADT alone (n=1,150; HR=0.39 [95% CI: 0.30-0.50]; p<0.0001). These data will be presented in an oral session at the 2019 Genitourinary Cancers Symposium in San Francisco.

“The ARCHES trial demonstrated that XTANDI plus standard hormonal therapy delayed disease progression, and if approved, has the potential to be an important treatment option for men with prostate cancer that has spread but has not yet become hormone resistant,” said Andrew Armstrong, M.D., Professor of Medicine, Surgery, Pharmacology and Cancer Biology, and Director of Research in the Duke Cancer Institute’s Center for Prostate and Urologic Cancers.

Median time to a radiographic progression-free survival (rPFS) event was not reached in the XTANDI plus ADT arm, while median time to an rPFS event in the ADT alone arm was 19.4 months. Significant improvements in rPFS were also observed in all prespecified subgroups including disease volume, pattern of disease localization at baseline, geographic region, and prior docetaxel use (HRs=0.24-0.53). Secondary endpoints reported in the abstract showed that XTANDI plus ADT reduced the risk of PSA progression (HR=0.19 [95% CI: 0.13-0.26]; p<0.0001) and reduced the risk of starting a new antineoplastic therapy (HR=0.28 [95% CI: 0.20-0.40]; p<0.0001) compared to ADT alone. Undetectable PSA and objective response rates were also higher in men treated with XTANDI plus ADT versus ADT alone (68.1% versus 17.6%; p<0.0001 and 83.1% versus 63.7%; p<0.0001, respectively). Treatment with XTANDI plus ADT did not significantly reduce the risk of deterioration in urinary symptoms compared to ADT alone. At the time of the analysis, overall survival (OS) data were not mature.

Adverse events (AEs) in the ARCHES clinical trial were generally consistent with those reported in enzalutamide clinical trials in patients with castration-resistant prostate cancer (CRPC). Grade 3 or 4 AEs were reported in 23.6 percent of men receiving XTANDI plus ADT versus 24.7 percent of men receiving ADT alone. Common AEs (occurring in at least 5 percent of patients) that were reported more often in patients treated with XTANDI plus ADT versus those treated with ADT alone

included hot flush, fatigue, arthralgia, hypertension, nausea, musculoskeletal pain, diarrhea, asthenia and dizziness.

Based on the ARCHES results, the companies intend to discuss these data with global health authorities to potentially support a new indication for XTANDI in men with mHSPC. XTANDI is currently approved in the U.S. and Japan for the treatment of CRPC and in the EU for the treatment of metastatic and high-risk non-metastatic CRPC.

Seven additional abstracts evaluating XTANDI will also be presented at the 2019 Genitourinary Cancers Symposium.