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PHOTODYNAMIC THERAPY WITH APL-1702 FOR HIGH-GRADE SQUAMOUS INTRAEPITHELIAL LESIONS (HSIL): RESULTS FROM A RANDOMIZED PHASE 3 GLOBAL STUDY（YHGT-CEV-R1/APRICITY）

25 - Cervical neoplasia

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Background/Objectives: To evaluate the efficacy and safety of the investigational product APL-1702, which is an integrated combination of topical hexaminolevulinate (HAL) hydrochloride with photodynamic therapy (PDT), compared to placebo (PBO, PDT without HAL) in treatment of patients (pts) with cervical histologic HSIL.

Methods: The YHGT-CEV-R1/APRICITY study is a prospective, double blind, randomized, PBO controlled, multi-center global phase 3 study, which enrolled pts with cervical histologic HSIL from 8 countries (China, Hungary, Germany, Czech Republic, Slovakia, Poland and the Netherlands). Eligible pts were randomly (2:1) assigned to receive APL-1702 (5% HAL HCl ointment, PDT 125 J/cm2 over 4.6 hours) or PBO no more than twice in 6 months. The primary endpoint is response rate (RR], defined as normal histology or Low-grade squamous intraepithelial lesions (LSIL) histology and clearance of baseline HPV] at 6 months after first treatment. Secondary endpoints are proportion of HPV, HPV16, HPV16 and/or 18 positive patients with clearance of baseline HPV at 6 months after first treatment, and proportion of patients with histologic regression (LSIL or normal histology at 6 months after first treatment). All histologic samples were reviewed by an independent adjudication panel of three pathologists.

Results: Between Nov 10, 2020 and Jul 18, 2022, 402 eligible pts were randomized. Median age was 29.6 years (range 18.7-51.9). A total of 93.3% of pts were HPV positive, with 55.7% being HPV16+. The RR in the APL-1702 group nearly doubled that in the PBO group (41.1% vs. 21.7%, p = 0.0001). The clearance rate of high risk HPV16/18 was also significantly improved in the APL-1702 group (31.4% vs. 15.4%, p = 0.01). Treatment emergent adverse events (TEAEs) in the APL-1702 and PBO groups were 56.8% and 56.0%, respectively. The majority of TEAEs were mild, including vaginal discharge (10%), vaginal infection (9.3%), abdominal pain (6.5%), vaginal hemorrhage (5.5%). Treatment related AEs in the APL-1702 and PBO groups are 31.6% and 26.1%, respectively. The incidence of serious TEAEs was 1.5% in both groups.

Conclusions: Results from the APRICITY trial demonstrate robust efficacy and excellent safety of APL-1702 in cervical HSIL pts. This study provides evidence of an innovative, non-surgical treatment option for precancerous cervical lesions, and APL-1702 shows efficacy as early as 6 months after the first treatment.