

# Phase II study of weekly PM00104 (ZALYPSIS®) in patients with pretreated advanced/metastatic endometrial or cervical cancer.

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This open-label, two-arm, phase II clinical trial evaluated the antitumor activity and safety profile of PM00104 (Zalypsis®) administered as a 1-h, weekly, intravenous infusion (days 1, 8 and 15; every 4 weeks) at a dose of 2 mg/m<sup>2</sup> to patients with advanced and/or metastatic endometrial (EC) or cervical cancer (CC) after one previous line of systemic chemotherapy. Twelve patients (median age, 61.5 years) with pretreated EC received a median of 2 treatment cycles (range 1-5) and seven patients (median age, 38 years) with pretreated CC received 2 treatment cycles. None achieved objective tumor response. Median progression-free survival (PFS) was 1.8 months, and median overall survival (OS) was 5.5 months in EC (median follow-up = 20.1 months); median PFS was 1.5 months, and median OS was 5.6 months in CC (median follow-up = 17.1 months). The most common toxicities reported were mild to moderate asthenia, nausea, vomiting and diarrhea. Despite PM00104 showing mostly mild, predictable, manageable and reversible toxicity, protocol criteria for further recruitment were not met in EC, a futility analysis was done and recruitment was stopped; a low patient recruitment rate together with no evidence of activity in CC resulted in early study closure.

<b>Major Subject Heading(s)</b>	<b>Minor Subject Heading(s)</b>	<b>CAS Registry / EC Numbers</b>
	<ul style="list-style-type: none"><li>• <u>Adult</u></li><li>• <u>Aged</u></li><li>• <u>Antineoplastic Agents</u> [administration &amp; dosage] [adverse effects]</li><li>• <u>Disease-Free Survival</u></li><li>• <u>Endometrial Neoplasms</u> [drug therapy]</li><li>• <u>Female</u></li><li>• <u>Humans</u></li><li>• <u>Middle Aged</u></li><li>• <u>Tetrahydroisoquinolines</u> [administration &amp; dosage] [adverse effects]</li><li>• <u>Uterine Cervical Neoplasms</u> [drug therapy]</li></ul>	<ul style="list-style-type: none"><li>• <u>0 (Antineoplastic Agents)</u></li><li>• <u>0 (PM 00104)</u></li><li>• <u>0 (Tetrahydroisoquinolines)</u></li></ul>