Essai Clinique

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Titre	A Single-Arm, Open-Label, Multicenter, Extended Treatment, Safety Study in Patients Treated With Talazoparib
Protocole ID	MDV3800-13
ClinicalTrials.gov ID	NCT02921919
Type(s) de cancer	Autre
Phase	Phase II
Type étude	Traitement
Médicament	Talazoparib
Institution	CIUSSS DU CENTRE-OUEST-DE-L'ILE-DE-MONTREAL HOPITAL GENERAL JUIF SIR MORTIMER B.DAVIS 3755 rue de la Côte Ste. Catherine, Montréal, QC, H3T 1E2
Ville	Montréal
Investigateur principal	Dr Cristiano Ferrario
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Statut	Fermé
But étude	This is a single-arm, open-label, extended treatment, safety study in patients treated with talazoparib in qualifying studies.
Critères d'éligibilité	• Eastern Cooperative Oncology Group (ECOG) performance status ≤ 2. • Female patients of childbearing potential must have a negative pregnancy test before the first dose of talazoparib and must agree to use a highly effective birth control method from the time of the first dose of talazoparib through 45 days after the last dose. • Male patients must use a condom when having sex with a pregnant woman or with a woman of childbearing potential from the time of the first dose of talazoparib through 105 days after the last dose. Contraception should be considered for a nonpregnant female partner of childbearing potential. • Female patients may not be breastfeeding at the first dose of talazoparib and must not breastfeed during study participation through 45 days after the last dose of talazoparib.
Critères d'exclusion	• Permanently discontinued from any Medivation sponsored study with talazoparib alone or in combination with another agent. • Received an antineoplastic therapy or investigational agent after treatment with talazoparib in the originating protocol. • Has a clinically significant cardiovascular, dermatologic, endocrine, gastrointestinal, hematologic, infectious, metabolic, neurologic, psychologic, or pulmonary disorder or any other condition, including excessive alcohol or drug abuse, or secondary malignancy, that may interfere with study participation in the opinion of the investigator. • Diagnosis of myelodysplastic syndrome (MDS).