YONDELIS® (trabectedin)
YONDELIS – Coronavirus Disease 2019 (COVID-19)

SUMMARY

- No data evaluating the use of YONDELIS in patients with active infections, including novel coronavirus disease 2019 (COVID-19), have been published. In addition, no published data were identified regarding the use of a COVID-19 vaccine in patients receiving YONDELIS. For more information on the use of vaccines and treatments for COVID-19, please contact the product manufacturers directly.

COVID-19 Prophylaxis or Infection in Patients Receiving YONDELIS

- If a patient is suspected to have been exposed to COVID-19, but is asymptomatic, providers should follow local and institutional guidelines to weigh risk vs benefit of the individual patient's treatment with YONDELIS based on the nature and status of the patient's underlying cancer, comorbidities, concomitant medications, and the potential risks associated with COVID-19 infection.
- For prophylaxis, or if a patient has a confirmed COVID-19 infection, physicians should consider the risk vs benefit of continuing YONDELIS based on the nature and status of the patient's underlying cancer, comorbidities, and the potential risks associated with the COVID-19 infection. Providers should refer to product labeling for additional information, including pharmacokinetics, safety, dosage & administration, dose modifications, monitoring, and drug-drug interactions for other medications used concomitantly in the prevention or management of COVID-19 infection.

Select COVID-19 Resources for Providers Treating Patients with Cancer

Please note: this is not a complete list of publicly available resources pertaining to this topic.

- The Centers for Disease Control and Prevention (CDC) provides clinical care considerations for clinicians caring for patients with confirmed infection and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1] Additionally, the National Institutes of Health (NIH) provides considerations and guidance for specific populations, including patients with cancer, and notes these patients may be at increased risk for severe illness.[2]
    - Interventions should be based on patient presentation and the clinical judgment of the treating physician. For the latest information from the CDC, visit: COVID-19.
- The American Cancer Society (ACS) and the American Society of Clinical Oncology (ASCO) recognize that cancer patients and cancer survivors often have weakened immune systems, increasing their risk for serious illness from infections such as the coronavirus. ASCO recommends that oncologists and health care teams should discuss with their patients how best to protect against infections, such as coronavirus.[3,4]
- ASCO advises oncologists to use the best available evidence in caring for patients who may be exposed to or infected with the coronavirus, referring to the following as general sources of information: Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), U.S. Food and Drug Administration (FDA), and U.S. CDC.[5] ASCO has also developed resources related to caring for patients with cancer in the context of the coronavirus pandemic for clinicians and the cancer care delivery team,[6] visit: ASCO Coronavirus Resources.
- Additional cancer organizations, including the National Comprehensive Cancer Network (NCCN) and the European Society for Medical Oncology (ESMO), have published resources for healthcare professionals, visit: NCCN COVID-19 Resources and ESMO COVID-19 and Cancer.
- For the latest global information and guidance from the World Health Organization (WHO) regarding the current outbreak of coronavirus (COVID-19), including daily updates, visit: Coronavirus Disease (COVID-19) Pandemic.

CLINICAL DATA

Phase 3 SAR-3007 Study

Demetri et al (2015)[7] conducted a phase 3, randomized, multicenter, registration study that evaluated the efficacy and safety of YONDELIS vs dacarbazine in patients with unresectable, locally advanced or metastatic liposarcoma (LPS) or leiomyosarcoma (LMS) previously treated with at least either a combination of an anthracycline and ifosfamide or an anthracycline plus ≥1 additional cytotoxic chemotherapy regimen (N=518). Patients were excluded from the study if they had an ongoing active infection.

The safety analysis included 340 patients treated with YONDELIS and 155 patients treated with dacarbazine.[7,8] Adverse events of clinical interest included neutropenia and infection, including sepsis and septic shock.[9] Most common adverse events occurring at a frequency of ≥20% included neutropenia.[7]

The incidence of neutropenia is shown in the Table below.

Neutropenia in Phase 3 SAR-3007 Study[7a]

	YONDELIS (n=340)			Dacarbazine (n=155)		
	All Grades, n (%)	Grade 3, n (%)	Grade 4, n (%)	All Grades, n (%)	Grade 3, n (%)	Grade 4, n (%)
Neutropenia	165 (49)	70 (21)	56 (16)	45 (29)	17 (11)	15 (10)
[a]Most common adverse events occurred with ≥20% frequency.						

The most common hematological toxicity seen in either treatment group was neutropenia with grade 3-4 decrease in neutrophil counts reported in 40.4% and 24.7% of patients in the YONDELIS and dacarbazine groups, respectively. Febrile neutropenia occurred in 5.0% and 1.9% of patients treated with YONDELIS and dacarbazine, respectively, and sepsis and septic shock in the neutropenic setting occurred in 2.1% of patients in the YONDELIS group.[9]

The most commonly reported infections, regardless of relationship to neutropenia, in either treatment group, were urinary tract infections (8.2% in the YONDELIS group and 5.2% in the dacarbazine group) and upper respiratory tract infection (4.7% in the YONDELIS group and 5.8% in the dacarbazine group).[9]

Infections reported as drug-related treatment-emergent adverse event (all grades) occurred in 2.9% of patients treated with YONDELIS and 1.3% of patients treated with dacarbazine as described in the Table below.[9]

Infections Reported as Drug-Related Treatment-Emergent Adverse Events in Phase 3 SAR-3007 Study[9]

	YONDELIS (n=340)			Dacarbazine (n=155)		
	All Grades, %	Grade 3, %	Grade 4, %	All Grades, %	Grade 3, %	Grade 4, %
Infections and infestations	10 (2.9%)	8 (2.4%)	1 (0.3%)	2 (1.3%)	1 (0.6%)	1 (0.6%)
Pneumonia	3 (0.9%)	2 (0.6%)	0	0	0	0
Lung infection	2 (0.6%)	2 (0.6%)	0	0	0	0
Urinary tract infection	2 (0.6%)	2 (0.6%)	0	0	0	0
Catheter site infection	1 (0.3%)	1 (0.3%)	0	0	0	0
Cellulitis	1 (0.3%)	1 (0.3%)	0	0	0	0
Sepsis	1 (0.3%)	0	1 (0.3%)	0	0	0

	YONDELIS (n=340)			Dacarbazine (n=155)		
Vaginal infection	1 (0.3%)	0	0	0	0	0
Wound abscess	1 (0.3%)	1 (0.3%)	0	0	0	0
Osteomyelitis	0	0	0	1 (0.6%)	1 (0.6%)	0
Peritonitis	0	0	0	1 (0.6%)	0	1 (0.6%)

Treatment-related deaths were reported in the YONDELIS group (n=7; 2.1%), and included: sepsis/septic shock (n=3), rhabdomyolysis/sepsis (n=1), renal failure (n=1), renal failure/cardiac arrest (n=1), or multiorgan failure (n=1).[7]

Efficacy and safety analyses were not performed separately for patients with a concurrent infection in the SAR-3007 study.

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) pertaining to this topic was conducted on 13 August 2024.

REFERENCES

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