ZYTIGA® (abiraterone acetate)
Concomitant Use of ZYTIGA with Other Non-Janssen COVID-19 Vaccines

SUMMARY

- **Use with other non-Janssen COVID-19 Vaccines**
  - Data from a prospective observational study evaluating immunologic response to non-Janssen COVID-19 vaccines showed a similar immune response in a subset of patients with prostate cancer receiving androgen receptor-targeted agents (ARTAs; n=25), including those taking ZYTIGA plus prednisone (n=8), compared to a matched cohort of healthy subjects (n=100) at 22 days after first vaccination (D22) and at 50 days after first vaccination (D50). Results were not delineated between patients taking ZYTIGA plus prednisone and patients taking enzalutamide.[1]
  - ZYTIGA is coadministered with prednisone/prednisolone.[2-4] In the two phase 3 pivotal studies, COU-AA-301 and COU-AA-302, patients with metastatic castration-resistant prostate cancer (mCRPC) were randomized to receive ZYTIGA 1,000 mg plus prednisone 5 mg **twice** daily (BID) or placebo plus prednisone 5 mg BID.[2,3] In another phase 3 pivotal study, LATITUDE, patients with metastatic high-risk castration-sensitive prostate cancer (CSPC) were randomized to receive ZYTIGA 1,000 mg plus prednisone 5 mg **once** daily or placebos.[4]
  - Clinicians should use clinical judgement based on local/institutional guidelines, standards of care, and individual patient risk/benefit assessment when considering concomitant use of ZYTIGA and the other COVID-19 vaccine.
  - For additional information regarding the use of other non-Janssen COVID-19 vaccines, please refer to the vaccine manufacturer.
- **General Vaccination Information**
  - Cancer organizations, including the National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO), and the European Society for Medical Oncology (ESMO), have published healthcare professional resources related to COVID-19 vaccination and patients with cancer, visit: NCCN COVID-19 Resources, ASCO: COVID-19 Vaccines & Patients with Cancer, and ESMO Statements on Vaccination Against COVID-19 in People With Cancer.[5-7] Please note: This list is not all inclusive and is subject to change.
  - Refer to the Centers for Disease Control (CDC) and Prevention Advisory Committee on Immunization Practices (ACIP) COVID-19 Vaccine Recommendations, Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, and General Best Practice Guidelines for Altered Immunocompetence. For more information, including additional mRNA COVID-19 vaccine dose recommendations for patients with solid tumor malignancies receiving active treatment, visit: COVID-19 ACIP Vaccine Recommendations, Interim Clinical Considerations for Use of COVID-19 Vaccines in the United States, and General Best Practice Guidelines for Immunization, Altered Immunocompetence.[8-10]

CLINICAL DATA

A prospective observational study (NCT04743388) evaluated the immunologic response to vaccination against SARS-CoV-2 infection with the BNT162b2, AZD1222 or mRNA-1273 vaccines in patients with solid or hematological cancers compared to healthy subjects.

Liontos et al (2022)[1] reported the immunologic response to non-Janssen COVID-19 vaccines in a subset of patients with prostate cancer receiving ARTAs (n=25), including 8 patients taking ZYTIGA plus prednisone and 17 patients taking enzalutamide, compared to healthy control subjects (n=100) matched to the prostate cancer group for age and type of COVID-19 vaccine received. No patients or subjects had a known history of COVID-19. A total of 88% (22/25) of patients and 68% (68/100) of control subjects were vaccinated with BNT161b2 or mRNA-1273, while all others were vaccinated with AZD1222 (P=0.046).

Immunologic response, measured as level of neutralizing antibodies (NAb) against SARS-CoV-2 in blood samples, was recorded prior to vaccination on day 1 (D1), on D22, and on D50. No patients or control subjects had NAb titers ≥30% (positivity cut-off) at D1. A similar immune response was noted between patients and healthy subjects at D22 and D50 (Table: Immune Response After COVID-19 Vaccination). No significant difference in the median NAb titers for patients receiving ZYTIGA plus prednisone or enzalutamide was observed (*P*=0.872). On D50, median NAb titer in patients was 89% (IQR, 77-95%) for those vaccinated with either BNT162b2 or mRNA-1273 vaccine and 28% (IQR, 23-48%) for those vaccinated with AZD1222. Results were not delineated between patients taking ZYTIGA plus prednisone and patients taking enzalutamide.

Immune Response After COVID-19 Vaccination[1]

	Prostate Cancer Group (n=25)	Control Group (n=100)	*P*-value
Median NAb Inhibition Titer, % (IQR)			
D1	-	-	0.58
D22	37 (21-47)	31 (27-36)	0.26
D50	88 (62-95)	81 (44-94)	0.29
NAb Titer ≥30%[a], n (%)			
D22	13 (52)	43 (43)	0.41
D50	18 (90)	72 (82.7)	0.734
NAb Titer ≥50%[b], n (%)			
D22	4 (16)	19 (19)	0.729
D50	16 (80)	60 (68.9)	0.41

Abbreviations: D1, prior to vaccination on day 1; D22, 22 days after first vaccination; D50, 50 days after first vaccination; IQR, interquartile range; NAb, neutralizing antibody.
[a]NAb titer ≥50% is positivity cut-off.
[b]NAb titer ≥50% is clinically relevant viral inhibition.

After the first vaccination dose, 24% (n=6) of patients in the prostate cancer group experienced pain at injection site. Adverse events (AEs) reported by patients after the second dose were nausea (n=1), dizziness (n=1), and pain at injection site (n=2).[11] AE reports were not provided for control subjects.

LITERATURE SEARCH

A literature search of MEDLINE®, Embase®, BIOSIS Previews®, and Derwent Drug File (and/or other resources, including internal/external databases) was conducted on 20 May 2024.

REFERENCES

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