Patient ID SYN183 - Oncology Clinic Note (Early IO Response)

Clinic: River City Oncology Specialists
Visit Date: 23-NOV-2023
Provider: Vivian Wells, MD

REASON FOR VISIT: Follow-up visit, Assessment prior to Cycle 3 Pembrolizumab for Stage IV KRAS G12C mutated Lung Adenocarcinoma with high PD-L1 expression.

SUBJECTIVE: Mr. Daniels presents today appearing remarkably well and reporting significant clinical improvement since starting Pembrolizumab two cycles ago (last infusion 03-NOV-2023). His presenting symptoms of right-sided pleuritic chest pain and shortness of breath (related to pleural effusion) have **completely resolved**. He required one therapeutic thoracentesis (1.2L removed) just before starting Cycle 1 but has had no recurrence of effusion symptoms. Energy levels are "vastly improved," back to near baseline (ECOG 0). Appetite excellent, weight up 4 lbs since starting therapy. He emphatically denies any symptoms suggestive of immune-related adverse events (irAEs): no cough, no new SOB, no rash or itching, no diarrhea or abdominal pain/blood in stool, no jaundice or RUQ pain, no symptoms of thyroid dysfunction (no fatigue, temp intolerance, palpitations), no unusual muscle aches or weakness, no headache or vision changes. He is extremely pleased with his response and tolerance so far.

Patient: Daniels, Charles Patrick
DOB: 10-DEC-1971

ONCOLOGIC HISTORY:

- **Diagnosis:** Stage IV Lung Adenocarcinoma, Aug 31, 2023 (Age 51). Presented w/ R pleuritic chest pain, SOB.
- **Staging:** CT Chest showed extensive R pleural thickening/nodularity and moderate malignant pleural effusion. No definite primary lung mass or other distant metastases identified. Brain MRI negative.
- **Pathology (Pleural Biopsy via Thoracoscopy, 09/05/2023):** Metastatic Adenocarcinoma.
    - **Histology:** Predominantly **papillary architecture** with complex branching fibrovascular cores lined by cuboidal to columnar malignant cells. Cells show moderate nuclear pleomorphism, vesicular chromatin, and distinct nucleoli. Focal hobnail features noted. Psammoma bodies were rare. Tumor infiltrating lymphocytes (TILs) present, estimated at 15%.
    - **IHC:** Tumor cells strongly positive for TTF-1, CK7; Weakly positive for Napsin-A; Negative for P40, Calretinin, WT-1. Consistent with lung adenocarcinoma.
- **Molecular/PD-L1 (NGS on pleural tissue):** Identified **KRAS G12C mutation**. Other drivers negative. PD-L1 IHC (22C3): **TPS 75%, CPS 80, IC Score 3/+**. TMB 11 mut/Mb. MSS.
- **1L Rx:** Based on high PD-L1, started **Pembrolizumab 200 mg IV q3 weeks** on Sept 22, 2023. Today is assessment prior to Cycle 3.

PAST MEDICAL HISTORY: None significant. Non-smoker.

CURRENT MEDICATIONS: Pembrolizumab only (oncology-related). Takes OTC multivitamin.

OBJECTIVE:

- *Vitals:* T 36.6 C, BP 126/70 mmHg, HR 68 bpm, RR 14 /min, SpO2 99% on Room Air.
- *Weight:* 84 kg (Up 2 kg from C1D1). BMI 27.1 kg/m ^{2}.
- *ECOG Performance Status:* 0
- *General Appearance:* Vigorous, healthy-appearing male in NAD. Excellent energy.
- *HEENT:* Normal. Oral mucosa clear. Thyroid normal. No LAD.
- *Lungs:* Clear to auscultation bilaterally. Resonant throughout. No dullness suggesting effusion.
- *Cardiovascular:* Regular rate and rhythm. Normal S1/S2. No murmurs. No edema.
- *Abdomen:* Soft, non-tender, non-distended. Normal bowel sounds.
- *Skin:* Clear, no rashes or suspicious lesions.
- *Neurologic:* Alert and oriented x4. Cranial nerves intact. Strength 5/5. Non-focal.

LABORATORY DATA (Today, Pre-Infusion):

- CBC: WBC 6.8 k/uL (Neut 4.2 k/uL), Hgb 14.2 g/dL, Hct 42.8%, Plt 275 k/uL (All WNL).
- CMP: Na 141, K 4.0, Cl 104 , CO2 27, BUN 15, Cr 0.9 mg/dL, Glucose 92, Ca 9.6. AST 20 U/L, ALT 24 U/L, Alk Phos 70 U/L, Total Bili 0.6 mg/dL (LFTs WNL). Albumin 4.2 g/dL.
- TSH: 2.1 mIU/L (WNL). Cortisol AM (baseline screen): 15 mcg/dL (Normal).

ASSESSMENT:

1. **Stage IV KRAS G12C / PD-L1 High Lung Adenocarcinoma:** Patient demonstrating an excellent early clinical response to first-line Pembrolizumab monotherapy after two cycles, with complete resolution of presenting symptoms (pleuritic pain, dyspnea). Awaiting first radiographic assessment.
2. **Pembrolizumab Tolerability:** Outstanding tolerance to date, with no clinical or laboratory signs of immune-related adverse events (irAEs).
3. **KRAS G12C Mutation:** Noted, potential future target if resistance develops to immunotherapy.

PLAN:

1. **Administer Pembrolizumab 200 mg IV over 30 minutes today (Cycle 3, Day 1).** Patient agreeable and fit for treatment.
2. **Continue Pembrolizumab q3 week schedule.**
3. **Ongoing irAE Monitoring:** Continue close clinical monitoring at each visit. Reviewed irAE symptom checklist again with patient, reinforcing importance of reporting *any* new symptoms (rash, diarrhea >3x/day, abdominal pain, bloody stool, cough/SOB, jaundice, excessive fatigue/weakness, headache/vision changes, etc.)

promptly. Continue periodic lab monitoring (CMP including LFTs, TSH) q2-3 cycles currently.

4. **First Restaging Scans:** Schedule **CT Chest/Abdomen/Pelvis w/ contrast** to be performed after this cycle (Cycle 3), approximately 9 weeks after treatment initiation. Will review results at next visit. Brain MRI surveillance to start after first systemic restaging (baseline was negative).
5. **Follow-up:** Return in 3 weeks for Cycle 4 assessment and infusion. Patient provided with clinic contact numbers for urgent issues.

_____ M.D.
Vivian Wells, MD (Electronically Signed)