SAMPLE CASE: HCV TREATMENT MANAGEMENT ADVISORY BOARD

Non-confidential material

Case 4 —Treatment Experienced Patient: Introduction and History

- 73-year-old African-American male
- Retired, former biology teacher
- CHC GT-1 infection diagnosed 12 years ago
- Liver biopsy in mid-2013 showed F2 fibrosis
- “Failed” telaprevir + PEG-IFN + RBV in late 2013
  - Completed treatment, but did not achieve SVR
- No biopsy since, but FibroSURE™ last month was 0.74
- BMI 28, describes moderate to occasionally severe daily fatigue
- Treated for alcohol addiction 3 years ago, denies current SU
- History of hypercholesterolemia, hypertension, GERD
  - Simvastatin 20 mg QD, lisinopril 40 mg QD, omeprazole 20 mg QD
  - Takes OTC antacids (aluminum hydroxide) “when needed”

Case 4: History, Laboratory Tests

- What else from this patient's history might you want to know?
- What laboratory tests would you request for this patient?

Case 4: Laboratory Findings

- Albumin 3.9 mg/dL
- Total Bilirubin 0.8 mg/dL
- AST 47 U/L
- ALT 80 U/L
- Prothrombin WNL (11 seconds)
- HCV GT 1b
- Current HCV viral load 810,000 IU/mL

Case 4: Treatment and Counseling

- What is your first choice for treating this TE patient's HCV genotype 1b infection? Why?
- Assume that this patient has been approved for treatment with Vikiera Pak. Would you work toward approval of Harvoni?
- How might BMI (28 in this case) affect treatment recommendation?
- How would you communicate your treatment decisions with the patient?
- Before starting therapy, what (if any) medications adjustments might be needed?
  - How do concomitant use of statins, PPIs, and OTC antacids affect treatment decisions and topics you discuss with patients?
  - How would you discuss when to dose omeprazole?

Case 4: Monitoring and Follow-Up

- At what points during treatment would you monitor HCV viral load?
- For how long and at what time points after SVR would you request follow-up liver imaging?
- What else might you want to monitor during and after treatment for this patient? Why?

Case 4: Discussion (part 1)

- How might your treatment approach change if this patient was non-cirrhotic (F2-F3)?
- What are the main reasons for your recommendations?

Case 4: Discussion (part 2)

- How, if at all, might your treatment approach change if this patient also had type 2 diabetes mellitus with associated renal impairment (eGFR 39 mL/min/1.73m^2)?
  - What if the renal impairment was borderline severe (eGFR 31 mL/min^2)?

Case 4: Discussion (part 3)

- How, if at all, would your treatment approach change if this patient was also taking disopyramide for ventricular tachycardia?

- How might your approach change if this patient was taking digoxin for an arrhythmia, instead of disopyramide?

- Considering the case as a whole, what else might you want to know in order to evaluate, treat, counsel, and monitor this patient?