### SUMMARY OF RECOMMENDATIONS

**Monitoring Patients Receiving KYNAMRO®**

<table>
<thead>
<tr>
<th>TIMING</th>
<th>RECOMMENDATION</th>
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<tr>
<td>Prior to initiating treatment</td>
<td>- Measure transaminases (ALT, AST), alkaline phosphatase, and total bilirubin</td>
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| During the first year of treatment | - Instruct patients to report symptoms of possible liver problems  
                                    - Conduct liver-related tests monthly (ALT and AST, at minimum) |
| After the first year of treatment | - Instruct patients to report symptoms of possible liver problems  
                                    - Conduct liver-related tests at least every 3 months (ALT and AST, at a minimum) |

**If liver enzyme elevations are observed:**

- If elevations in ALT or AST levels $\geq$3X and <5X ULN are observed, confirm elevation with a repeat measurement within 1 week. If confirmed, withhold dosing, obtain additional liver-related tests if not already measured (such as total bilirubin, alkaline phosphatase, and INR) and investigate to identify the probable cause.
- If elevations in ALT or AST levels $\geq$5X ULN are observed, withhold dosing, obtain additional liver-related tests if not already measured (such as total bilirubin, alkaline phosphatase, and INR) and investigate to identify the probable cause.
- If resuming KYNAMRO after transaminases resolve to <3X ULN, consider monitoring liver-related laboratory tests more frequently.

For patients with:

- Persistent or clinically significant elevations in transaminases
- Transaminase elevations accompanied by clinical symptoms of liver injury, increases in bilirubin $\geq$2X ULN, or active liver disease
- Clinically significant liver toxicity

Discontinue treatment with KYNAMRO and investigate to identify the probable cause.

*Please see the Prescribing Information for more information.*

Report all suspected adverse events associated with KYNAMRO. Please contact Genzyme at 1-800-745-4447 or the FDA at 1-800-FDA-1088 (332-1088) or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).