**Common Drug Review**

**Product:** Latuda  
**Generic Name:** lurasidone hydrochloride  
**Manufacturer:** Sunovion Pharmaceuticals Canada Inc.  
**Indication:** schizophrenia

<table>
<thead>
<tr>
<th>Phase</th>
<th>Target Time (Business Days)</th>
<th>Target Date</th>
<th>Actual CDR Date</th>
<th>Comments</th>
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<tr>
<td>1</td>
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<td>5</td>
<td>2012-Jul-10</td>
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<td>2</td>
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<td>5</td>
<td>2012-Jul-24</td>
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<td>3</td>
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<td>45</td>
<td>2012-Sep-25</td>
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<td>4</td>
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<td>7</td>
<td>2012-Oct-04</td>
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<td>5</td>
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<td>2012-Nov-21</td>
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<td>6</td>
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<td>5 to 7</td>
<td>2012-Nov-28</td>
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<td>7</td>
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<td>10</td>
<td>2012-Dec-12</td>
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<td>8 (a)</td>
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<td>2012-Dec-18</td>
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<td>8 (b)</td>
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<td>8 (c)</td>
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<td>25</td>
<td>2013-Jan-16</td>
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<td>9</td>
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<td>5</td>
<td>2013-Jan-23</td>
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</tbody>
</table>

1. **Date Submission Received:** 2012-Jul-03  
2. **Date NOC Issued:** 2012-Jun-13  
3. **Original Targeted CDEC Meeting:** 2012-Nov-21  
4. **Priority Review Granted:** Not Requested

**Phase Details:**

- **Phase 1:** Submission deemed complete
  - **Target Time:** 5 business days
  - **Target Date:** 2012-Jul-10
  - **Actual CDR Date:** 2012-Jul-10
  - **Comments:**
    - Pending submission notification posted on 2012-Jun-20
    - Patient input deadline 2012-Jul-24

- **Phase 2:** Patient group input submission received
  - **Target Time:** 5 business days
  - **Target Date:** 2012-Jul-24
  - **Actual CDR Date:** 2012-Jul-24
  - **Comments:** 
    - Patient group input submission received

- **Phase 3:** CADTH Reviewers’ Reports sent to Manufacturer
  - **Target Time:** 45 business days
  - **Target Date:** 2012-Sep-25
  - **Actual CDR Date:** 2012-Oct-02
  - **Comments:** 
    - New Target date: 2012-Oct-02

- **Phase 4:** Comments from Manufacturer on Reviewers’ Reports Received by CADTH
  - **Target Time:** 7 business days
  - **Target Date:** 2012-Oct-04
  - **Actual CDR Date:** 2012-Oct-12
  - **Comments:** 
    - New Target date: 2012-Oct-12

- **Phase 5:** CDEC Meeting
  - **Target Time:**
    - 5 to 7 business days
    - **Target Date:** 2012-Nov-28
  - **Actual CDR Date:** 2012-Nov-28

- **Phase 6:** CDEC Recommendation Sent to Drug Plans and Manufacturer
  - **Target Time:** 5 to 7 business days
  - **Target Date:** 2012-Nov-28

- **Phase 7:** Embargo Period
  - **Target Time:** 10 business days
  - **Target Date:** 2012-Dec-12
  - **Actual CDR Date:** 2012-Dec-18
  - **Comments:**
    - Request for extension to embargo period received from manufacturer on 2012-Dec-06
    - Extension to embargo period granted.

- **Phase 8(a):** Final Recommendation sent to Drug Plans and Manufacturer (No Requests for Clarification are made AND no Request for Reconsideration is made OR Request for Reconsideration is Resolved)
  - **Target Time:** 5 business days

- **Phase 8(b):** Clarification and Final Recommendation sent to Drug Plans and Manufacturer (Clarification Requested, no Request for Reconsideration made)
  - **Target Time:** 5 business days

- **Phase 8(c):** Placed on CDEC Agenda For Reconsideration (At Manufacturer’s request)
  - **Target Time:**
    - 25 depends on meeting dates
  - **Target Date:** 2013-Jan-16
  - **Actual CDR Date:** 2013-Jan-16

- **Phase 9:** Final Recommendation sent to Drug Plans and Manufacturer
  - **Target Time:** 5 business days
  - **Target Date:** 2013-Jan-23
  - **Actual CDR Date:** 2013-Jan-23
  - **Comments:** Notice of Final Recommendation issued

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**Notes:**

2. The target dates for this report are based on the CDEC meeting schedule, which is posted on www.cadth.ca.
3. The deadline for Patient Group Input is 15 business days after CADTH receives the Submission or up to 25 business days if advance notice of a Submission is received from the Manufacturer.
4. Target time is calculated, based on the date the Reviewers receive copies of the Manufacturer’s Submission. Target time does not include the time allocated for receipt of Manufacturer’s binders (5 business days) and time allocated for distribution of binders to reviewers (3 business days).
5. The Recommendation is held in confidence by all stakeholders and not acted upon until after CADTH has issued the notice of Final Recommendation.

This Submission Status Report reflects status as of Thursday noon.