## Executive Summary

The Clinical Pharmacology review of NDA 206229 (DARRTS, January 30, 2015) stated that NDA 206229 was acceptable provided that an agreement is reached between the sponsor and the Division regarding the language in the package insert labeling. The final agreement on clinical pharmacology sections was reached on Feb 23, 2015 and there are no pending issues from the Office of Clinical Pharmacology. The highlights of the prescribing information and Clinical Pharmacology relevant sections of the final agreed upon package insert labeling are included in Section 2 of this addendum.

### 1.1 Recommendation

The Division of Clinical Pharmacology-3, Office of Clinical Pharmacology finds the NDA 206229 acceptable.

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### References

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/s/

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02/24/2015

MYONG JIN KIM  
02/24/2015