

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

210259Orig1s000

MULTI-DISCIPLINE REVIEW

Summary Review

Office Director

Cross Discipline Team Leader Review

Clinical Review

Non-Clinical Review

Statistical Review

Clinical Pharmacology Review

NDA/BLA Multi-disciplinary Review and Evaluation

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| Application Type | NDA, 505(b)(1) |
| Application Number(s) | 210259 |
| Priority or Standard | Priority |
| Submit Date(s) | June 13, 2017 |
| Received Date(s) | June 13, 2017 |
| PDUFA Goal Date | February 13, 2018 (expedited date of October 31, 2017) |
| Division/Office | CDER/OHOP/DHP |
| Review Completion Date | October 26, 2017 |
| Established Name | Acalabrutinib |
| (Proposed) Trade Name | CALQUENCE |
| Pharmacologic Class | Kinase inhibitor |
| Code name | ACP-196 |
| Applicant | Acerta Pharma B.V. |
| Formulation(s) | hard shell capsule |
| Dosing Regimen | 100 mg orally approximately every 12 hours |
| Applicant Proposed Indication(s)/Population(s) | Treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy |
| Recommendation on Regulatory Action | Accelerated Approval |
| Recommended Indication(s)/Population(s) (if applicable) | Treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. |

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