

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**211192Orig1s000**

**MULTI-DISCIPLINE REVIEW**

**Summary Review**

**Office Director**

**Cross Discipline Team Leader Review**

**Clinical Review**

**Non-Clinical Review**

**Statistical Review**

**Clinical Pharmacology Review**

## NDA Multidisciplinary Review and Evaluation

<b>Application Number</b>	<b>NDA 211192</b>
<b>Application Type</b>	Original 351(a)
<b>Priority or Standard</b>	Priority Expedited
<b>Submit Date</b>	12/21/2017
<b>Received Date</b>	12/21/2017
<b>PDUFA Goal Date</b>	8/21/2018
<b>Division/Office</b>	DHP/OHOP
<b>Review Completion Date</b>	
<b>Applicant</b>	Agios Pharmaceuticals, Inc.
<b>Established Name</b>	Ivosidenib
<b>(Proposed) Trade Name</b>	Tibsovo
<b>Pharmacologic Class</b>	Isocitrate dehydrogenase-1 inhibitor
<b>Formulations</b>	Tablet (250 mg)
<b>Dosing Regimen</b>	500 mg taken orally once daily
<b>Applicant Proposed Indication/Population</b>	For the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.
<b>Recommendation on Regulatory Action</b>	Regular approval
<b>Recommended Indication/Population</b>	For the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test

## **NDA Multidisciplinary Review and Evaluation**

NDA 211192

Tibsovo (ivosidenib)

### **Addendum Clinical Pharmacology**

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In the Clinical Pharmacology section of the finalized review, the following appears under “Outstanding Issues”:

We have issued one PMR, as presented in the PMR/PMC Section above. There are no other outstanding issues.

It should be corrected to:

We hve issued two PMRs, as presented in the PMR/PMC Section above. There are no other outstanding issues.

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**This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.**

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/s/  
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WENCHI HSU  
07/20/2018

GENE M WILLIAMS  
07/20/2018

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<b>PDUFA Goal Date</b>	8/21/2018
<b>Division/Office</b>	DHP/OHOP
<b>Review Completion Date</b>	7/19/2018
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