CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213801Orig1s000

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

IND 069416

MEETING PRELIMINARY COMMENTS

Astellas Pharma Global Development, Inc.
Attention: Kristine Skjolaas, Ph.D.
Associate Director, Regulatory Affairs
1 Astellas Way
Northbrook, IL 60062

Dear Dr. Skjolaas:[1]

Please refer to your investigational new drug application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for YM178 (mirabegron) tablets and oral suspension.

We also refer to your August 15, 2019, correspondence, received August 15, 2019, requesting a meeting to discuss your planned new drug application, specifically, the overall clinical development program, the pediatric data package to fulfill PREA requirements as well as the terms of the Written Request, and your submission plans for the pediatric and adult populations.

Our preliminary responses to your meeting questions are enclosed.

You should provide, to me, a hardcopy or electronic version of any materials (i.e., slides or handouts) to be presented and/or discussed at the meeting.

In accordance with 21 CFR 10.65(e) and FDA policy, you may not electronically record the discussion at this meeting. The official record of this meeting will be the FDA-generated minutes.

[1]We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions, please call me at 301-796-0875.

Sincerely,

{See appended electronic signature page}

Nenita Crisostomo
Regulatory Health Project Manager
Division of Bone, Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE:

- Preliminary Meeting Comments

FOOD AND DRUG ADMINISTRATION
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PRELIMINARY MEETING COMMENTS

Meeting Type: B
Meeting Category: Pre-NDA

Meeting Date and Time: November 14, 2019, at 1:00 PM – 2:00 PM, Eastern
Meeting Location: 10903 New Hampshire Avenue
White Oak Building 22, Conference Room: 1315
Silver Spring, Maryland 20903

Application Number: IND 069416
Product Name: YM178 (mirabegron) tablets and oral suspension

Indication: Treatment of neurogenic detrusor overactivity in pediatric patients

Sponsor Name: Astellas Pharma Global Development, Inc.

Introduction:

This material consists of our preliminary responses to your questions and any additional comments in preparation for the discussion at the meeting scheduled for November 14, 2019, at 1:00 PM – 2:00 PM, in 10903 New Hampshire Avenue, Silver Spring, Maryland 20903 between Astellas Pharma Global Development, Inc. and the Division of Bone, Reproductive and Urologic Products. We are sharing this material to promote a collaborative and successful discussion at the meeting. The meeting minutes will reflect agreements, important issues, and any action items discussed during the meeting and may not be identical to these preliminary comments following substantive discussion at the meeting. If you determine that discussion is needed for only some of the original questions, you have the option of reducing the agenda and/or changing the format of the meeting (e.g., from face to face to teleconference). Contact me, the Regulatory Project Manager (RPM), if there are any major changes to your development plan, the purpose of the meeting, or the questions based on our preliminary responses, as we may not be prepared to discuss or reach agreement on such changes at the meeting.

1.0 BACKGROUND

Myrbetriq (mirabegron), 25mg and 50mg tablets, were approved for marketing in June 2012 for treatment of overactive bladder (OAB) in adults. As required under the Pediatric Research Equity Act (PREA), postmarketing studies were conducted for the treatment of neurogenic detrusor overactivity (NDO) in pediatric patients aged 3 years

to < 18 years of age. Also, a Written Request (WR) for pediatric studies was issued on March 18, 2016.

Astellas has developed mirabegron extended-release granules which, when reconstituted in water, result in an oral suspension of 8 mg/mL. The suspension is intended for administration to pediatric patients with NDO below a specified cutoff weight and to patients above that cutoff weight who cannot swallow tablets.

Astellas requested this meeting to discuss the 1) pediatric package intended to fulfill PREA and WR, 2) submission plans for sNDA 202611 for mirabegron tablets and NDA 213801 for mirabegron granules for oral suspension for the treatment of pediatric NDO patients, and 3) (b) (4)

The Meeting Information Package was received on September 24, 2019.

2.0 DISCUSSION

2.1. Regulatory

Question 1 (Phase 3 Study 178-CL-206A): Does the Agency agree that the pediatric clinical development program as already conducted for mirabegron is sufficient to support the submission of an efficacy and safety supplement and new NDA for the proposed indication for mirabegron tablets and granules for treatment of NDO in pediatric patients aged 3 to < 18 years?

FDA Response:
A determination as to whether your program is sufficient to support the filing of a supplemental NDA and a new NDA for mirabegron tablets and granules for oral suspension, respectively, for the treatment of NDO in pediatric patients cannot be made prior to our preliminary review of the submissions. However, in general, your development program appears reasonable.

Question 2 (Compliance with Written Request): Does the Agency agree that the pediatric clinical development program as already conducted for mirabegron is consistent with the requirements under PREA and is sufficient to support a Request for Pediatric Exclusivity for mirabegron?

FDA Response:
A determination as to whether your pediatric clinical development program meets the PREA requirements and the terms of the WR cannot be made prior to our review of the submissions and presentation of the data before FDA's Pediatric Exclusivity Board. However, your pediatric development program appears to be sufficient to provide information to determine whether the PREA and Written Request requirements have been met.

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