ADDITIONAL DISCLOSURE DATA FOR SWITZERLAND

Name of Sponsor/Company: Janssen Research & Development*

* Janssen Research & Development is a global organization that operates through different legal entities in various countries. Therefore, the legal entity acting as the sponsor for Janssen Research & Development studies may vary, such as, but not limited to Janssen Biotech, Inc.; Janssen Products, LP; Janssen Biologics, BV; Janssen-Cilag International NV; Janssen Pharmaceutica NV; Janssen, Inc; Janssen Sciences Ireland UC; or Janssen Research & Development, LLC. The term "sponsor" is used to represent these various legal entities as identified on the Sponsor List.

Date: 06 January 2022

Swiss marketing authorisation data

Swiss Marketing Authorisation number: 68114

Swiss Marketing Authorisation date: 16 November 2021

Name of the preparation: Ponvory – 2+3+4+5+6+7+8+9+10+20 mg – filmcoated tablets

Name of active pharmaceutical ingredient: Ponesimod (JNJ-67896153 / ACT-128800)

Clinical trial data

1. Clinical trial identification

Protocol No.: AC-058B301

Title of Study: Multicenter, Randomized, Double-Blind, Parallel group, Active-Controlled, Superiority Study to Compare the Efficacy and Safety of Ponesimod to Teriflunomide in Subjects with Relapsing Multiple Sclerosis

Study Name: OPTIMUM

EudraCT Number: 2012-000540-10

NCT No.: NCT02425644

2. Protocol change history

Protocol and Amendments:

Original Protocol, 06 January 2015

Amendment-1, 29 April 2015 – substantial

Amendment-2, 16 July 2015 – substantial

Amendment-3, 05 February 2016 – substantial

Amendment-4, 14 November 2016 – substantial

Amendment-5, 30 August 2017 – substantial

Amendment-6, 05 December 2018 – substantial

3. Clinical trial investigators and study centres

Principal Investigator*:* Xavier Montalban, MD, PhD

Study Centres: Subjects were screened at 171* centers in 28 countries: 16 centers in North America (Canada [4], United States [12]); 3 centers in Latin America (Mexico [3]); 91 centers in Europe (Bulgaria [8], Croatia [5], Czech Republic[9], Finland [2], France [5], Germany [5], Greece [3], Hungary [5], Italy [5], Latvia [3], Lithuania [3], Poland [12], Portugal [4], Romania [4], Serbia [5], Spain [6], Sweden [3], and United Kingdom [4]); 61 centers in rest of the world (Belarus [5], Bosnia and Herzegovina [1], Georgia [5], Israel [4], Russia [29], Turkey [1], and Ukraine [16]).

* Subjects were screened at 171 centers. However, during the study, one subject in Hungary was transferred from center 2901 to center 2910 (at which no subjects were screened). Therefore, the study was conducted at 172 centers.

4. Medication used

Test Product, Dose and Mode of Administration, Batch No.: Ponesimod was supplied as its free base in film-coated tablets at the doses of 2, 3, 4, 5, 6, 7, 8, 9, 10, and 20 milligrams (mg) for oral administration. The 20 mg tablet was over-encapsulated. One tablet of ponesimod was to be taken orally once daily. Ponesimod batch numbers were 4901, 4152, 4251, 4301, 4501, 4601, 4701, 4801, 4101,4401, 5902, 5153, 5252, 5403B, 7407, 7322, 7503, 7603, 7703, 7803, 7103, 5402

Reference Therapy, Dose and Mode of Administration, Batch No: Teriflunomide was supplied as the commercially available 14 mg film-coated Aubagio tablet. Teriflunomide tablets were over-encapsulated prior to administration in this study. One over-encapsulated tablet of teriflunomide was to be taken orally once daily. Teriflunomide batch numbers were E125847-0001E, E125847-0035E, E125847-0064E, E125847-0089E, E125847-0105E, E125847-0107E, E125847-0154E, E125847-0156E, E125847-0178E, E125847-0188E, E125847-0202E, E125847-0209E, E125847-0243E, E125847-0244E, E125847-0245E, E125847-0175E.

5. Study population

Number of participants – planned: 1100

Number of participants – analysed: 1133

6. Summary and conclusion

- The pivotal study OPTIMUM in relapsing multiple sclerosis met its primary objective and demonstrated a clinically meaningful, statistically significant, and robust effect of ponesimod 20 mg, which was superior to teriflunomide 14 mg in reducing the annualized relapse rate. The results of this study showed a statistically significant effect of ponesimod 20 mg on fatigue symptoms and combined unique active lesions, a reliable outcome measure of inflammatory MS disease activity, compared to teriflunomide 14 mg. The safety profile of ponesimod

appears to be consistent with previously observed safety findings with ponesimod, and the known safety profile of other S1P receptor modulators. The gradual uptitration starting at 2mg appears to successfully mitigate first-dose effects of ponesimod.

7. Results reporting

Date of Clinical Trial Report: 05 February 2020

Prepared by: Actelion Pharmaceuticals Ltd (a Janssen Pharmaceutical Company of Johnson & Johnson)

Publication(s) Reference(s): Kappos L, Fox RJ, Burcklen M, et al. Ponesimod Compared With Teriflunomide in Patients With Relapsing Multiple Sclerosis in the Active-Comparator Phase 3 OPTIMUM Study: A Randomized Clinical Trial. *JAMA Neurol.* 2021;78(5):558–567.

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