medDay
PHARMACEUTICALS

Dr. Tomas Salmonson
Chair of Committee for Medicinal Products for Human Use
European Medicines Agency
30 Churchill Place
Canary Wharf
London E14 5EU
United Kingdom

Paris, 13 November 2017

Subject: Withdrawal of Qizenday (biotin), 100 mg, hard capsules EMEA/H/C/004153

Dear Dr. Salmonson

I would like to inform you that, at this point of time, Medday Pharmaceuticals has made the decision to withdraw the Marketing Authorisation application of Qizenday for the treatment of patients with progressive multiple sclerosis

This withdrawal is based on the CHMP consideration that the extent of clinical data collected in the single phase III study MS-SPI forming the basis of this application did not allow the Committee to conclude formally on a positive benefit/risk ratio.

Medday Pharmaceuticals considers that this withdrawal does not have any impact on the ongoing clinical trial SPI2 with MD1003/Qizenday nor on the compassionate use programs proposed in EU for this product.

Medday Pharmaceuticals reserves the right to re-apply for the same indication at a future date.

Medday Pharmaceuticals would like to sincerely thank the (Co)-Rapporteurs and all Assessors, the EMA Project Leader and Project Manager, as well as the PRAC and CHMP members for the time dedicated to reviewing this application and the valuable support and guidance provided during the procedure.

I agree for this letter to be published on the EMA website.

Yours sincerely,

[redacted]