KAMADA
High Quality Pharmaceuticals

London, 21 June 2017

Tomas Salmonson

CHMP Chairman

European Medicines Agency

30 Churchill Place

Canary Wharf

London E14 5EU

United Kingdom

Withdrawal of Infinia (Alpha-1-Antitrypsin), 80 mg, nebuliser solution – EMEA/H/C/003934

Dear Dr. Salmonson,

I would like to inform you that, at this point of time, Kamada BioPharma Limited ("Kamada") has taken the decision to withdraw the Marketing Authorisation Application (MAA) of Infinia (Alpha-1-Antitrypsin), 80 mg, nebuliser solution, which was intended to be used for the treatment and maintenance therapy of adult patients with congenital deficiency of alpha-1 antitrypsin and lung disease with clinical evidence of emphysema and airway obstruction (FEV_1/SVC < 70%).

Although all manufacturing and non-clinical questions from the CHMP have been solved, Kamada does not have enough time at this stage of the procedure to collect the requested information to answer the remaining clinical questions from the CHMP. Consequently, Kamada withdraws its MAA immediately while reserving the right to make further submissions at a future date in this or other therapeutic indication(s).

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

Yours sincerely,

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