PARNELL

07 February 2018

Parnell
7015 College Boulevard
Level 6
Overland Park, KS 66211
USA
Office: [redacted]
Fax:
parnell.com

European Medicines Agency
Veterinary MA Procedures
30 Churchill Place
Canary Wharf
London
E14 5EU
United Kingdom

Subject: Withdrawal of Marketing Authorisation Application for ZYDAX 100, 100 mg/mL, Solution for Injection, for Dogs: EMEA/V/C/0004375

Dear Sirs,

I would like to inform you that, at this point of time, Parnell Technologies (UK) Ltd. has taken the decision to withdraw the application for Marketing Authorisation of ZYDAX 100, glucuronoxylan sulfate sodium (GXS), 100 mg/mL, Solution for Injection, for Dogs, which was intended to be used for the treatment of lameness, pain and mobility impairment of osteoarthritis (non-infectious arthrosis) and related musculoskeletal disorders in dogs.

This withdrawal is based on the following:

> Parnell has decided, for commercial reasons, not to conduct - at this time - the additional elaborate and complex registration studies necessary for the completion of the marketing authorization for the current indication, due to the limitations of study endpoints for short-term assessment of clinical signs of osteoarthritis when applied to a compound with long-term disease-modifying actions.

We reserve the right to make further submissions at a future date in this or other therapeutic indication(s)/target species, if applicable.

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

Yours faithfully,

[redacted]
Vice-President, Regulatory

On Behalf Of: Parnell Technologies (UK) Ltd.
WHITTINGHAM RIDDELL LLP
Belmont House
Shrewsbury Business Park
Shrewsbury
Shropshire SY2 6LG
UK