

ALIZYME PLC

CETILISTAT PHASE III DEVELOPMENT PLAN

Opportunity for label for type 2 diabetes as well as for obesity

Cambridge UK, 6 March 2008: Alizyme plc ("Alizyme") (LSE: AZM) today announces that FDA has agreed the remaining two protocols for its Phase III development programme for cetilistat under the Special Protocol Assessment ("SPA") procedure and recommended that Alizyme open a separate diabetes IND.

Cetilistat

Cetilistat is Alizyme's metabolic product under development for the treatment of obesity and associated co-morbidities, including type 2 diabetes. It is a gastrointestinal lipase inhibitor that blocks fat digestion and absorption, leading to reduced energy intake, and thus weight loss.

Following successful end of Phase II discussions, FDA approved Alizyme's outline plan for the Phase III clinical development programme of cetilistat. This comprises three 12 month studies involving:

- (i) obese patients without co-morbidities and obese patients with treated or untreated co-morbidities (other than type 2 diabetes);
- (ii) obese patients without co-morbidities and obese patients with untreated co-morbidities (other than type 2 diabetes); and
- (iii) obese patients with treated type 2 diabetes and who may have treated or untreated other co-morbidities.

In April 2007, Alizyme announced that the protocol for the first study was agreed with FDA under the SPA procedure. The protocols for the second and third studies have now also been agreed with FDA under the SPA procedure. The second study will involve a direct comparison with Xenical[®], as well as placebo.

FDA issued draft guidance on the development of diabetes drugs at the end of February 2008. Under this guidance, it has acknowledged that improvement in HbA_{1c} has become the standard surrogate outcome measure for diabetes studies.

Evidence of the safety and efficacy of cetilistat has been established through extensive Phase I and Phase II studies. Furthermore, in Phase II studies, cetilistat was shown to cause statistically significant weight loss, compared to placebo and, in clinically obese diabetic patients, to cause statistically significant reductions in HbA_{1c}.

FDA has corresponded directly with Alizyme in relation to its planned Phase III programme and recommended that Alizyme open a separate diabetes IND for cetilistat, since it is not now requiring that a drug's effect on glycaemic control be independent of its effect on body weight in order for the drug to be considered for a stand alone diabetes indication. Although FDA has publicly stated that long-term safety studies lasting longer than one year may be required for some therapeutics in which substantial safety issues or questions arise, it has indicated that a 12 month study would be sufficient for a pivotal study with cetilistat for obese diabetics.

The Phase III development programme for cetilistat, which provides a clear route to registration as an obesity product, is now ready to commence following the conclusion of a commercial deal. There continues to be significant partnering and development interest in cetilistat; discussions are ongoing.

Commenting on the announcement, Chief Executive Officer, Tim McCarthy said:

"I am delighted with this news. Not only is the regulatory pathway for cetilistat as an obesity product firmly established with FDA, giving clarity to potential partners with respect to the route to market for cetilistat, but the opportunity to develop the market for cetilistat further by opening an IND for diabetes is of great commercial significance."

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Further information on Alizyme can be found on the Company's website: www.alizyme.com

Editor's Note

Alizyme plc

Alizyme is a speciality biopharmaceutical development company, focused on the therapeutic areas of metabolic disorders, gastrointestinal disorders and cancer supportive care. It is developing cetilistat for the treatment and management of obesity and related diseases, such as type 2 diabetes, renzapride for the treatment of irritable bowel syndrome ("IBS"), COLAL-PRED[®] for ulcerative colitis, and ATL-104 for mucositis, a side effect of cancer therapy.

Special Protocol Assessment (SPA)

In conjunction with the reauthorisation of the Prescription Drug User Fee Act of 1992 (PDUFA) in November 1997, FDA agreed to specific performance goals for special protocol assessment and agreement. These goals provide that, upon request, FDA will evaluate certain protocols (i.e. carcinogenicity protocols, stability protocols, and Phase III protocols for clinical trials that will form the primary basis of an efficacy claim) to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor (in this case Alizyme).

Once FDA and the sponsor concur, under the Special Protocol Assessment, the Agency documents agreement that the design and planned analysis of a study adequately address objectives in support of a regulatory submission.

As stated in the PDUFA goals for Special Protocol Assessment, having agreed to the design, execution, and analyses proposed in protocols reviewed under this process, the Agency will not later alter its perspective on the issues of design, execution, or analyses unless public health concerns unrecognized at the time of protocol assessment under this process are evident.

Cetilistat

Alizyme's metabolic product, cetilistat, is being developed for the treatment of obesity and associated co-morbidities (including type 2 diabetes). It is a gastrointestinal lipase inhibitor that blocks fat digestion and absorption, leading to reduced energy intake, and thus weight loss. It is distinct from most other anti-obesity agents as it does not act on the brain to reduce appetite, but acts peripherally. The compound remains in the gastrointestinal tract with no significant absorption into the body. It can, therefore, be expected to have a superior risk-benefit profile to centrally acting drugs. Accordingly, cetilistat is not subject to the safety concerns generally associated with centrally acting drugs.

Roche's Xenical[®] is an approved obesity product and is also a peripherally acting lipase inhibitor. However, in clinical trials, cetilistat has been demonstrated to be much better tolerated than Xenical[®] which has side effects that detrimentally affect patient compliance.