

Exhibit B

CDER Statement to Healthcare Professionals: Restricted Availability of Thyrogen

[XX-XX-2010] Healthcare professionals should be aware that the supply of Thyrogen (recombinant thyroid stimulating hormone [TSH]), a drug used in the treatment and follow-up diagnosis of thyroid cancer, will be temporarily limited.

On May __, 2010, the U.S. Food and Drug Administration (FDA) and Genzyme entered into a legal settlement (consent decree) that is designed to permit Genzyme to produce, for the United States market, enough Thyrogen to meet the needs of patients for whom FDA considers the drug to be medically necessary. Accordingly, the consent decree restricts Genzyme's U.S. distribution of Thyrogen to customers (meaning entities that purchase Thyrogen kits directly from Genzyme, such as distributors and wholesalers) who sign a Certificate of Procedures Related to Medical Necessity. This Certificate notes the customer's agreement to distribute the product with this Dear Healthcare Provider Letter, which describes the patients for whom FDA considers Thyrogen to be medically necessary. This restriction will remain in place until Genzyme corrects manufacturing issues at their Allston Landing facility, where the fill/finish manufacturing operations for Thyrogen are performed, or transfers fill/finish manufacturing operations for Thyrogen to other manufacturing facilities operating in compliance with FDA regulations.

The FDA has developed a set of criteria to help healthcare professionals identify patients for whom Thyrogen is considered medically necessary. The following are criteria which should be met for Thyrogen to be considered medically necessary for a patient with thyroid cancer.

1. Patients undergoing initial radioiodine ablation of thyroid tissue remnants, post-thyroidectomy, deemed to be at significantly increased risk of side-effects/complications from undergoing thyroid hormone withdrawal.*
2. Follow-up testing of patients considered high risk for thyroid cancer recurrence and who have unmeasurable basal thyroglobulin (Tg) levels and are deemed to be at significantly increased risk of side-effects/complications from undergoing thyroid hormone withdrawal.* The American Thyroid Association's 2009 Guidelines provide a three-level stratification for assessment of risk of thyroid cancer recurrence and identify as "high-risk" those patients who have 1) macroscopic tumor invasion, 2) incomplete tumor resection, 3) distant metastases, and possibly 4) thyroglobulinemia out of proportion to what is seen on the post-treatment scan.

Initial rhTSH stimulation testing in patients not considered high risk for thyroid cancer recurrence may also be considered appropriate if such patients are at risk of side-effects/complications from prolonged hypothyroidism due to thyroid hormone withdrawal.

*Patients deemed to be at significantly increased risk of side-effects/complications from undergoing thyroid hormone withdrawal for purposes of the two criteria above are:

- Patients with history of stroke, transient ischemic attack, or underlying heart disease, especially heart failure that may be exacerbated by hypothyroidism (NYHA class III or IV)².
- Patients with renal failure (National Kidney Foundation stage ≥ 3)³ in whom prolonged hypothyroidism will affect clearance of radioactive iodine.
- Patients with a history of or active psychiatric disorders (e.g., depression) that will be exacerbated by hypothyroidism.
- Patients whose overall performance status may be severely compromised during hypothyroidism (e.g., ECOG performance status ≥ 2)⁴.
- Patients on medications with a narrow therapeutic index (e.g., digoxin, lithium, warfarin) for which clearance of medications may be impaired by hypothyroidism.
- Patients with hypopituitarism or who have previously been unable to mount an adequate increase in endogenous thyroid stimulating levels (TSH) levels.
- Patients > 65 years of age regardless of the presence or absence of other concurrent medical conditions.

Generally, pediatric patients are not considered to be within the medically necessary category as they are more likely to tolerate a short period of hypothyroidism and can often mount an adequate elevation of endogenous TSH within two weeks of levothyroxine withdrawal.